



A brief history of
tuberculosis control
in India



World Health
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Abbreviations and glossary

ACSM

advocacy, communication and social mobilization

ART

antiretroviral therapy

ARTI

annual risk of TB infection

BCG

Bacillus Calmette-Guérin

BMRC

British Medical Research Council

CIDA

Canadian International Development Agency

CME

continuing medical education

CPT

co-trimoxazole preventive therapy

CTBC

community TB care

CTD

Central TB Division

DALY

disability-adjusted life year

DFID

Department for International Development (UK)

DMC

designated microscopy centres

DOTS

the basic package that underpins the Stop TB Strategy

DRS

drug resistance surveillance

DST

drug susceptibility testing

DTO

District TB Programme Officer

FDC

fixed-dose combination (tablet)

FIND

Foundation for Innovative Diagnostics

GDF

Global Drug Facility

GDP

gross domestic product

Global Fund

Global Fund to fight AIDS, Tuberculosis and Malaria

GNI

gross national income

GNP

gross national product

GMSD

government medical stores depot

GLC

Green Light Committee

HIV

human immunodeficiency virus

HRD

human resources development

ICTC

integrated counselling and testing centre (HIV)

ICMR

Indian Council of Medical Research

IEC

information, education and communication

IMA

Indian Medical Association

IMAI

Integrated Management of Adult Illness

IMPACT

Indian Medical Professional Associations Coalition against TB

IRL

intermediate reference laboratory

ISAC

Intensified Support and Action Countries

ISTC

International Standards of TB Care

IUAT

International Union Against Tuberculosis

JMM

joint monitoring mission

KAP

knowledge, attitudes and practices

KNCV

KNCV Tuberculosis Foundation

MDG

Millennium Development Goal

MDP

WHO Model DOTS Project

MDR-TB

multidrug-resistant tuberculosis

MOTC

medical officer for tuberculosis control

NACP

National AIDS Control Programme

NGO

nongovernmental organization

NRHM

National Rural Health Mission

NRL

national reference laboratory

NSP

new smear positive

NSS

national sample survey

NTI

National Tuberculosis Institute, Bangalore

NTP

National Tuberculosis Control Programme

PAL

Practical Approach to Lung Health

PAS

para-amino salicylic acid

PHC

primary health-care centre

PHI

peripheral health institution

PMTCT

Prevention of Mother to Child Transmission

PPM

Public-Private Mix (engaging all providers)

PWB

Patient-Wise Boxes

RMC

RNTCP (see below) medical consultant

RNTCP

Revised National Tuberculosis Control Programme

SCC

short-course chemotherapy

SS+

smear positive

SS-

smear negative

STS

senior treatment supervisor

STLS

senior tuberculosis laboratory supervisor

TAI

Tuberculosis Association of India

TB

tuberculosis

TBCAP

Tuberculosis Control Assistance Programme
(USAID project)

TB/HIV

HIV-related TB

TRC

TB Research Centre

TU

tuberculosis unit

UNITAID

the international drug purchase facility

UT

union territory

USAID

United States Agency for International Development

WHO

World Health Organization

Summary

This report was prepared as part of a World Health Organization (WHO) project funded by the Bill & Melinda Gates Foundation to review the history of tuberculosis (TB) control in India, to assess the impact of the TB programme on the epidemiology of tuberculosis in India, and to outline directions for future progress.

In 2006, the population of India was 1.1 billion or 17% of the world's population. The country is divided into 35 states and union territories (UTs) which are subdivided into over 600 districts (1, 2). India has 299 people living with TB per 100 000 population or 3.4 million prevalent cases (1). Every year, 2 million people develop TB and 331 000 die due to TB (1).

The National TB Programme (NTP) was launched by the Government of India in 1961. In order to deal with some of the shortcomings of the NTP highlighted by the 1992 Joint Review by the Government of India, the Swedish International Development Agency and WHO, the Revised National TB Control Programme (RNTCP) was established in 1993 and the new programme, based on DOTS – the internationally-recommended strategy to control TB, was launched in 1997 (3). The RNTCP included flexible funding mechanisms, decentralization, an ensured supply of quality-assured drugs at all times, better supervision, monitoring and evaluation, and technical support via a country-wide network of consultants. By 2006, the whole country was covered under the RNTCP, and case detection and treatment success rates had improved significantly.

The challenge is now to sustain the existing DOTS-based programme while introducing all components of the new Stop TB strategy, including services to address TB/HIV, treatment for multidrug-resistant TB, strengthening laboratory services, and integrating TB services in all health facilities of both the public and private health-care sectors. The effectiveness of the TB control programme is likely to increase further with the focussed efforts being undertaken by the Government of India in strengthening the primary health-care system under the National Rural Health Mission (NRHM).

An estimated 2.5 million adults, or 0.4% of the adult population, are infected with HIV (4), but rates of infection are higher in four southern states, Andhra Pradesh, Karnataka, Maharashtra and Tamil Nadu, and within these states the distribution of infection is uneven (5). In a community-based prevalence survey in 15 districts, the prevalence of HIV among TB cases ranged from 1% to 14% (6). Although the HIV epidemic in India appears to have stabilized, HIV-associated TB continues to be an important challenge (7).

Based largely on a survey in Gujarat (8), 3.9% (4.9–6.2%; ranges are 95% confidence limits unless otherwise stated) of all TB cases have multidrug-resistant tuberculosis (MDR-TB), giving over 130 000 new cases every year (9). To manage MDR-TB will require a substantial increase in diagnostic and treatment capacity.

India has reached the target treatment success rate of 85% and the target case detection rate of 70%. Over the next few years, routine notification data supplemented by prevalence surveys may be used to determine the impact of TB control. India is in a position to achieve the Millennium Development Goal (MDG) 6 and Stop TB Partnership targets by 2015 but this will require increases in funding and human resources, more intensive engagement with all health-care providers and strengthened regulation of anti-TB drugs.

1. Tuberculosis control before 1993

India has been at the forefront of TB control and research since the start of the 20th century. The first open-air sanatorium was established in 1906 by a Christian organization in Tilounia, in the Ajmer district of the north Indian state of Rajasthan. In the following two decades, additional sanatoria, dispensaries and societies were established throughout the country (10). In 1929, India joined the International Union Against Tuberculosis (IUAT) and the King George V Thanksgiving Fund for TB control was established and administered through central, state and provincial committees to support TB education and prevention, establish clinics, and train health workers. In 1939, the TB Association of India (TAI) was established to develop standard methods for managing TB and to develop model training institutions (10). In 1943, the Health Survey and Development Committee was established, with Sir Joseph Bhore as its Chairman, and recommended re-modelling the health services to integrate curative and preventive medicine at all levels (11). In 1946, the committee outlined a plan for the management of the estimated 2.5 million TB patients with a TB clinic in every district and mobile clinics in rural areas. After independence in 1949, the Central Government of Independent India established a TB Division within the Directorate General of Health Services of the Ministry of Health to oversee the plan (10).

Over the next 20 years, new TB drugs became available: streptomycin in 1944; PAS in 1946; thiacetazone in 1950; isoniazid in 1952; and rifampicin in 1966. Although TB clinics were being established throughout the country, and X-ray and chemotherapy were becoming more accessible, coverage and access were still limited. In 1951, 65 million Indian children were vaccinated in a mass Bacillus Calmette-Guérin (BCG) campaign, but those conducting it concluded that TB infection rates were higher than expected in both rural and urban areas. To determine the prevalence of the disease (10), a national survey was undertaken by the Indian Council of Medical Research (ICMR) between 1955 and 1958, and the number of people with TB was estimated to be nearly 8 million, with 80% of cases residing in the rural areas (12).

In 1956, the TB Chemotherapy Centre, later re-named the TB Research Centre (TRC) was established in Chennai under ICMR, with the assistance of the British Medical Research Council (BMRC), WHO and the Government of India. The centre conducted a series of studies on the feasibility and effectiveness of mass ambulatory chemotherapy, (13) and showed that home-based treatment of tuberculosis was as successful as hospital treatment, greatly reducing costs (14).

In 1959 the Government of India, with the help of WHO, established the National TB Institute (NTI) in Bangalore to develop a national TB control programme (NTP), with the aim of establishing prompt diagnosis and ambulatory treatment which were integrated into general health services. The programme was pilot-tested in the southern Indian state of Andhra Pradesh in 1961, and then phased in throughout the country (10). By 1978, the NTP covered 390 districts, i.e. 81% of the districts in the country, with self-administered 12–18 month treatment regimens, developed by the TRC. However, case detection and treatment adherence levels remained low (10). Meanwhile, clinical trials of short-course chemotherapy (SCC) regimens containing rifampicin and pyrazinamide reduced the length of treatment from 12 to 6 months. In 1983, the TRC piloted the SCC regimen in 18 districts and it was extended in 1986 to 252 districts (10). However, even with the introduction of SCC regimens into the national TB control programme, compliance improved only marginally (10).

2. The Indian health-care system

The Ministry of Health and Family Welfare coordinates health services at the Federal level, but state governments deliver health care, including the services for TB patients. Federal and State Governments consult on goals and strategies for the development of five-year plans and specific health initiatives, for example TB control programme, which are jointly funded (15, 16).

In 1946, a report by the Health Survey and Development Committee, or Bhore Committee (11), recommended the equitable distribution of health services, particularly to the rural poor, based on a three-tier system with a district primary health-care centre as the first point of entry. The committee set specific targets for the number of health-care workers and services per head of population. During the first (1951–1956) and second (1956–1961) five-year plans, primary health centres (PHCs) were set up to provide integrated preventive, curative and rehabilitative services for rural populations (17).

Although the primary health-care system continued to expand until the 1990s, the targets set by the Bhore Committee were not reached and this may have been partly because of the emphasis on family planning campaigns in the 1960s (15, 16). Recognizing the lack of access to basic health care in rural areas, the first National Health Policy in 1983 emphasized primary care, a commitment to 'Health for All' by the year 2000 (18), centrally-coordinated disease control programmes and subsidies for the private sector to meet demand that the government could not meet. Nevertheless, by 2000, India had still not achieved most of the goals of the first national health policy (19), and from the mid-1980s to the mid-1990s the use of public health services and access to free health care decreased. However, the Government of India acknowledged that low investments in health had resulted in unacceptably high levels of morbidity and mortality (20) and developed the second National Health

Policy in 2002 with a commitment to achieve the goals of the first National Health Policy by 2010 and to increase public investment from 0.9% to between 2% and 3% of gross domestic product (GDP) (21).

Several major developments in health policy took place between 1990 and 2005,¹ (22) when the National Rural Health Mission (NHRM) 2005-2012 was launched to provide effective health care to rural populations, with a special focus on 18 states² with weak public health indicators and infrastructure in order to strengthen public health management and service delivery (23).

Despite the failure to reach many of the goals of the first and second national health policies, several health indicators have shown consistent improvement since the 1980s. Between 1980 and 2006, infant mortality fell from 113 to 59 deaths per thousand live births, total fertility from five to three births per adult female, and maternal mortality from seven to three deaths per 1000 live births (24) but with considerable variation among States. While per capita gross national product (GNP) only rose by about 10% between 1989 and 2002, it almost doubled between 2002 and 2006 and if funding for health increases as a proportion of GDP, public health should be greatly improved.

Right from the inception, the TB programme management units, both at the national and state levels, have been embedded within the respective health ministries and the directorates of health services. The TB programme is now a part of the NRHM. At the state and district levels a multi-stakeholder health society is responsible for planning, budgeting and decision making. NRHM annual plans include budgeted TB control plans, and TB care and control services are provided principally through general health facilities at all levels.

¹ These included, the 93rd and 94th Constitutional Amendments in 1992, a National Nutrition Policy in 1993, a National Health Policy in 2002, a National Policy on Indian System of Medicine and Homeopathy in 2002, a National Drug Policy in 2002, the introduction of Universal Health Insurance schemes for the poor in 2003, and the inclusion of health in the Common Minimum Programme of the United Progressive Alliance Government in 2004.

² Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Himachal Pradesh, Jharkhand, Jammu and Kashmir, Manipur, Mizoram, Meghalaya, Madhya Pradesh, Nagaland, Orissa, Rajasthan, Sikkim, Tripura, Uttaranchal and Uttar Pradesh.

3. The Revised National TB Control Programme (RNTCP)

3.1 Piloting DOTS: 1993-1997

In the early 1990s, the NTP was treating 1.3 million patients per year but there appeared to be little or no impact on the prevalence of TB (10). Following a review of NTP in 1992 which highlighted managerial weaknesses, the over-emphasis on X-rays for diagnosis, underutilization of laboratory services, frequent drug shortages, and low rates of treatment completion, the Government of India decided to revitalize NTP with the assistance of international agencies (10, 25).

In 1993, the Revised National TB Control Programme was piloted in a population of 2.4 million in the states of Delhi, Gujarat, Kerala, Maharashtra and West Bengal. This was later expanded to cover 13 million people by 1995, and 20 million by 1996. The programme was based on DOTS (the internationally-recommended strategy for TB control) which promotes diagnosis by sputum smear microscopy, direct observation of treatment, standardized regimens, recording and reporting of notified cases and treatment outcomes, and political commitment (3). The RNTCP used national procurement, supply, and distribution of quality-assured anti-TB drugs, allocated drugs for the entire course of treatment in individual patient-wise boxes, further decentralized diagnostic and treatment services, emphasized direct observation of treatment with short-course chemotherapy, provided additional supervision with sub-district level dedicated TB units, introduced systems for monitoring and evaluation, and developed a network of consultants to provide technical support to the programme (26).

In 1997, the RNTCP was launched as a national programme with a plan to scale up in a phased manner (10).

3.2 Programme implementation

The RNTCP was designed to deliver TB services through the general health service infrastructure, building on the network developed by the NTP. Sub-district and district

hospitals and medical colleges provide tertiary care, with community health centres acting as the first-level referral units, each serving 80 000 to 120 000 people, primary health centres, each serving 25 000 to 30 000 people, and sub-centres for every 3000 to 5000 people. When the RNTCP started scaling up in 1998, there were 446 district TB centres, 330 TB clinics and 49 600 TB beds (10).

The RNTCP services were launched district-by-district via an elaborate process of building capacity of the district and appraisal of preparatory activities prior to start of service delivery. When a decision was made to launch the RNTCP DOTS programme in a particular district, the district formed a “district TB control society” and prepared an implementation plan for the respective district (27). During the preparation phase, the district had to meet certain criteria, including upgraded microscopy laboratories, adequate staffing levels, recent training, functioning procurement mechanisms, established centres following the DOTS strategy and functional programme management units (10). The district would then be assessed by appraisal teams consisting of central, state, and district-level staff. Once any observed deficiencies had been corrected, and with the agreement of the state government, the central government provided the required anti-TB drugs, and the RNTCP services would begin in the respective district (28). The central government and state governments provide detailed quarterly feedback on the comparative performance of all states and districts respectively.

Supervision and managerial responsibility of the TB programme was further decentralized through the creation of a sub-district level supervisory team. A system for supervision, monitoring and feedback was developed for all levels of the management structure, and guidelines for evaluation were established before the start of the programme. The financial system was also decentralized to facilitate optimal and timely utilization of resources (27).

Donor funds to implement the RNTCP were initially provided by the World Bank and the governments of Denmark and the United Kingdom. Funds were provided centrally to the Government of India and then channelled to the respective district and registered charities, State TB control societies, their officers being government officials. Members now include private physicians and representatives of community organizations. Each society serves an average population of about two million, is able to hire contractual staff, purchase necessary items, and perform other functions more efficiently than through the usual government procedures (27).

The infrastructure and administrative resources as well as some of the human resources are the responsibility of the state governments and paid for from the state budget. Drugs are procured centrally and funds, sourced from donor funds, loans and government budget, are provided from the central level to the states through the respective TB control societies to cover additional human resources and support specific programme activities, e.g. training, supervision, etc.

3.3 Human resources and training

At the sub-district level, the RNTCP has one supervisory team per programme management unit (called a tuberculosis unit, or TU) composed of a Senior TB Treatment Supervisor (STS), a Senior TB Laboratory Supervisor (STLS), and a designated Medical Officer for TB Control (MOTC). The Senior TB Laboratory Supervisor provides quality control of sputum microscopy, and the Senior TB Treatment Supervisor monitors the observation of treatment and the accuracy of recording and reporting (27). A full time District TB Programme Officer (DTO), paid by the state, is responsible for programme implementation in his/her respective district. The DTO is trained for 10 to 12 days at a central institution using standard modules and field visits. The district TB society hires an STS and an STLS for each tuberculosis unit. Additional staff are provided in mountainous and tribal areas, and urban slums. Prior to being approved to implement the RNTCP services in the respective district, the district, with support from the state, must have trained at least 80% of the doctors and laboratory technicians and at least 50% of the general health staff, using modules designed for each category of staff (27). Tuberculosis units within the district cover an average population of 500 000 people, but 250 000 in tribal or mountainous areas, and diagnostic units serve 100 000 people, but 50 000 in tribal or mountainous areas (10, 27).

3.4 Supervision and monitoring

Routine monitoring is conducted by the Senior TB Treatment Supervisor, the Senior TB Laboratory Supervisor, and the designated Medical Officer for TB Control under the supervision of the District TB Programme Officer. Staff from the state and central governments also make regular site visits to identify problems and facilitate improvements, particularly in districts that are seen to be performing poorly.

A monthly programme management and logistics report is provided by all health facilities to monitor facility performance, and manage drug supply and laboratory consumables. Tuberculosis units submit quarterly reports to the district on case detection, treatment outcomes, and programme logistics. The respective district enters these reports into the RNTCP electronic information management system (Epi-Centre), and sends them to the respective state government TB cells and to the Central TB Division in the Ministry of Health and Family Welfare.

3.5 Technical assistance

Starting in 1999, in coordination with the central and state governments of India, and modelled on the polio consultants network, WHO hired, trained, and deployed local technical consultants to central, state, and local governments. These RNTCP Medical Consultants (RMCs), were selected by a joint committee from WHO and the Government of India, and salaries were funded by WHO via donor support, including initially the Canadian International Development Agency (CIDA), and latterly the Department for International Development, UK (DFID) and the United States Agency for International Development (USAID) (28). Each RMC was given an intensive two- to three-week training, and was provided with transportation, laptop computer, mobile telephone, and internet access (28). RMCs reported monthly to the state and central government as well as to WHO, were provided with technical supervision and support from WHO, and were responsible for covering a population of 10 to 40 million (27). They played a catalytic role in the expansion of the RNTCP, and during implementation promoted quality by providing technical support to the local TB officers in investigating deficiencies in the local programme and recommending solutions.

In 2001, areas with and without RMC support were compared using data from 160 implementing districts over 10 quarters (i.e. 2.5 years). In areas without consultants, it took a median of 18 months to begin

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service delivery, in those with consultants, nine months. Sputum conversion, cure, and treatment success were significantly higher in districts with RMCs in place (28).

3.6 Funding

Government spending on health is 1% of GDP but the government has pledged to increase this to between 2% and 3%. Private sector spending on health is 4% of GDP, of which 95% is out-of-pocket (Figure 1). The total expenditure on health increased slightly from 4.3% in 1995 to 4.9% in 2006 (29).

Between 2002 and 2009, the annual budget for TB control in India grew from US\$ 36 million to US\$ 100 million (Figure 2). The US\$ 20 million increase in 2006 was largely from loans, the Global Fund, and donor contributions (1). The anticipated available funding for the planned 2009 budget leaves a gap of US\$ 30 million (Figure 2) mainly due to an increase in core programme activities that support the new Stop TB Strategy, including US\$ 9 million on first line drugs, US\$ 11 million on staff, and US\$ 2.2 million on routine programme management¹. There are small budget increases of US\$ 2.2 million for PPM and US\$ 1 million for MDR-TB that are not yet funded (Figure 3).

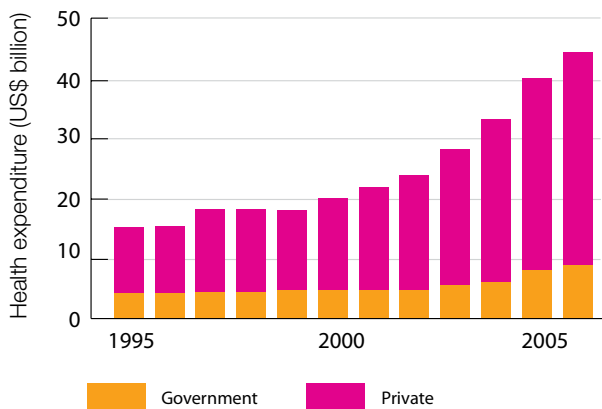


Figure 1. Trend in public health expenditures, India 1995–2006 (30). Expenditure on health as a proportion of GDP increased from 4.3% in 1995 to 4.9% in 2006

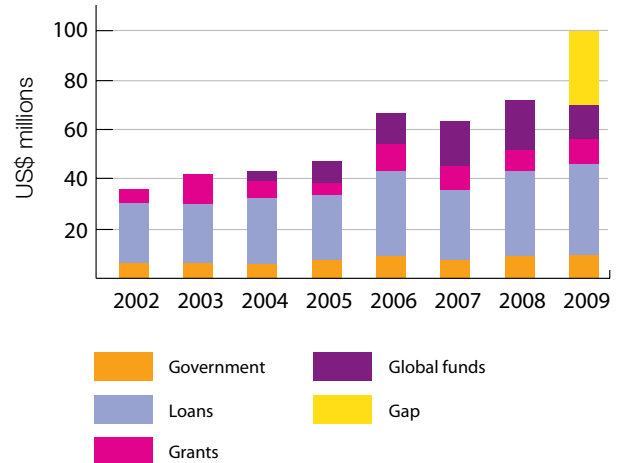


Figure 2. RNTCP budget for TB Control by contributor 2002–2009 (29).

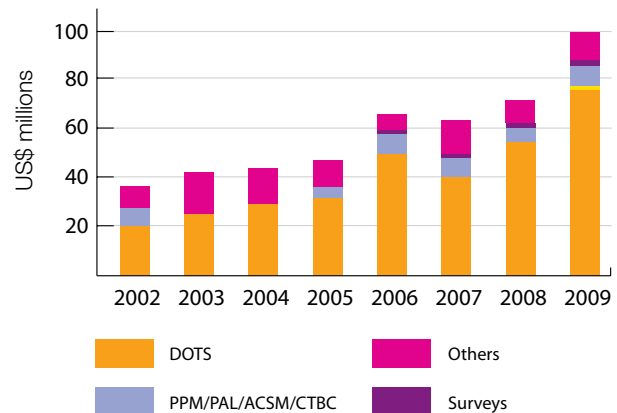


Figure 3. NTP budget by line item. PPM/PAL/ACSM/CTBC

¹ The first World Bank loan for TB control to the Government of India of US\$ 142 million covered the years 1999–2005, and the second loan, 2006–2012. Bilateral donors provided between US\$ 5 and US\$ 10 million annually. The Global Fund provided US\$ 8.6 million for TB control in Chhattisgarh, Jharkhand and Uttaranchal (now Uttarakhand) in round 1 (2004), US\$ 29 million for TB control in Bihar and Uttar Pradesh in Round 2 and US\$ 26 million to consolidate and maintain RNTCP activities in Andhra Pradesh and Orissa in Round 4.

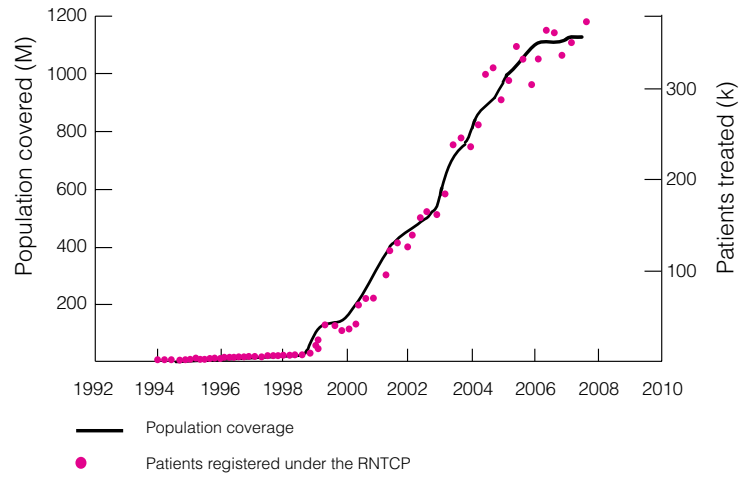


Figure 4. Trends DOTS population coverage (black line) and patients registered under the RNTCP (pink dots), 2004-2009 (30).

4. Scaling up DOTS: 1998–2006

DOTS was officially launched as the RNTCP strategy in 1997. By the end of 1999, the RNTCP had covered a population of over 140 million and by 2006 coverage was nationwide. External reviews in 2000, 2003, and 2006 (2, 25, 31, 32) remarked on the extraordinarily rapid rate of expansion (Figure 4) which was made possible by the carefully-designed implementation, increased financing through loans and bilateral donors, and a network of technical consultants coordinated by WHO.

4.1 Treatment outcomes and notification rates

Treatment outcomes under the RNTCP were already quite good in 1994 and continued to improve up to 2006 (Figure 5), reaching the target of 85% treatment success in 2001. Unfavourable outcomes fell and have remained consistently below 15% since 2001 (Figure 6).

Total notification rates fell slightly up to 2002 and then increased up to 2007 (Figure 7). Changes in notification rates over this time period may reflect the national transition from NTP services, where radiographic and SS- diagnosis was common and re-treatment cases not notified, to RNTCP services where sputum smears were emphasized.

4.2 Incidence

Full national coverage was reached in 2006 and therefore it is too soon to assess national trends in incidence directly from notification rates. However, a national tuberculin survey was carried out from 2000 to 2003 with the country stratified into four zones (north, west, south and east), with the same methodology used in each zone (33–39). Nationally the annual risk of TB infection (ARTI) was 1.5% (33), implying an incidence of 75 new smear positive pulmonary TB cases per 100 000 population, assuming a Stýblo number of 50, and a prevalence of 3.8 million bacillary cases in 2000 (40). The annual risk of infection was higher in urban areas (2.2%; 1.8%–2.6%) than in rural areas (1.3%; 1.0%–1.5%) (38)

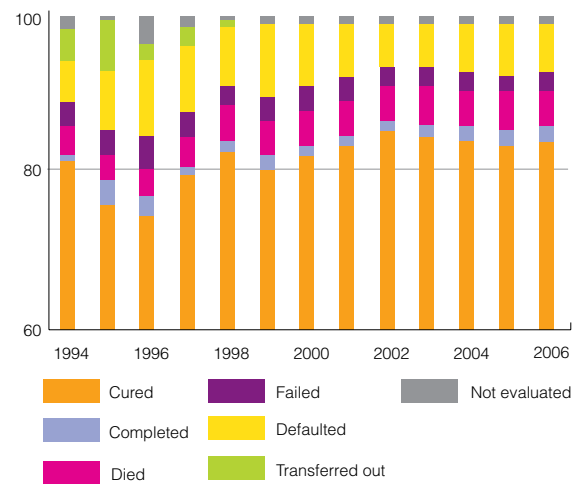


Figure 5. Treatment outcomes, 1994 to 2006, new SS+ patients (29).

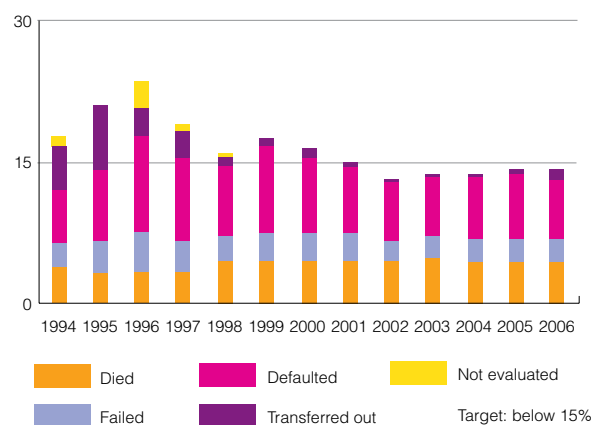


Figure 6. Unfavourable treatment outcomes, 1994-2006, new SS+ patients. Target: below 15%. (29)

and higher in the north (1.9%; 1.3%–2.5%) and west (1.6%; 1.0%–2.2%) than in the east (1.3%; 1.0%–1.6%) and south (1.0%; 0.7%–1.4%) (32). The results of the

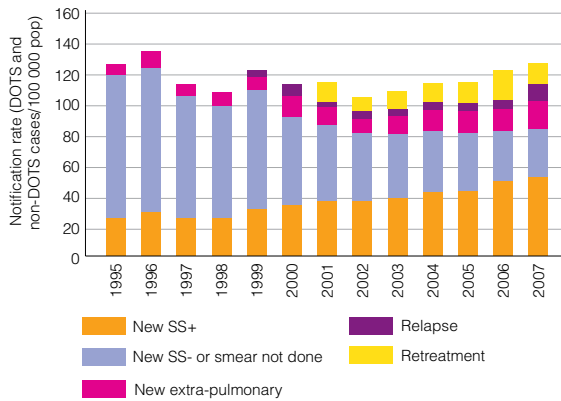


Figure 7. Notification rates 1995 to 2007.

second national ARTI survey, which was started in 2009, will be used to assess changes in the ARTI four to eight years after the implementation of the RNTCP.

There is evidence of a sustained decline in both incidence and prevalence from the collaborative TB Research Centre and WHO Model DOTS Project (MDP) carried out in Tiruvallur district, Tamil Nadu, south India. From 1968 to 1999, the prevalence of smear-positive pulmonary TB disease declined by 2.5% per year; following the implementation of DOTS under the RNTCP in 1999, it has declined by 5.6% per year (41–44) (Figure 9).

4.3 Prevalence of disease

The implementation of DOTS under the RNTCP has improved treatment success rates and probably led to a decline in the duration of disease (1, 2). WHO estimates

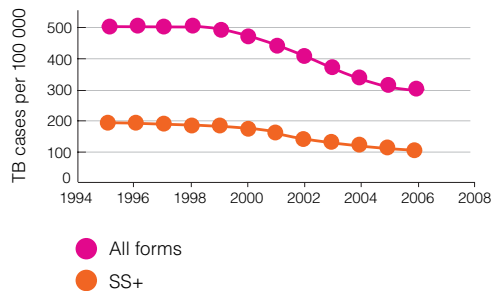


Figure 8. WHO estimated trends in TB prevalence per 100 000 in India(1).

suggest that the prevalence of all forms of TB decreased from 506 per 100 000 population in 1995 to 280 in 2007, at a rate of about 6% per year while new smear positive TB decreased from 190 cases per 100 000 in 1995 to 100 in 2007, at a rate of about 6% per year (1) (Figure 8).



Figure 9. Results of consecutive ARTI surveys in the MDP project area, Tiruvallur district, following RNTCP implementation(43).

4.4 Mortality

WHO estimates that the TB mortality rate decreased from 44 per 100 000 population in 1995 to 29 in 2007, a rate of about 4% decline per year, and giving about 335 000 deaths due to TB in 2007 (1). Under the RNTCP, case fatality in new cases has remained below 5% nationally but is significantly higher in districts where the prevalence of HIV in women attending antenatal clinics is greater than 3%. A community-based, verbal autopsy survey in Andhra Pradesh found that TB accounted for one third of infectious disease-related deaths, or 4% of overall mortality, and 11% of all mortality among children aged 5–14 years. Recent studies have also found a strong link between smoking and TB mortality in men (45, 46).

4.5 Drug resistance

The prevalence of TB drug resistance is an indicator of the effectiveness of TB control. Drug resistance surveillance (DRS) surveys have been ongoing since 2005 in Andhra Pradesh, Gujarat, Maharashtra, Orissa and Uttar Pradesh. The prevalence of multidrug-resistant

TB (MDR-TB) in new smear-positive pulmonary TB cases ranges from 1% to 3% among districts (9). In the state of Gujarat, the prevalence of MDR-TB in new TB cases was 2.4% (1.6–3.1) and in previously treated cases, 17.4% (15.0–19.7) (8). It is estimated that 5.4% of all TB patients in India have MDR-TB, so that there are about 131 000 incident MDR-TB per year (9).

The second-line drug sensitivity testing of MDR-TB isolates detected in the Gujarat DRS survey shows 4% extensively drug-resistant tuberculosis (XDR-TB) among the MDR-TB detected in the smear-positive re-treatment cases (8). The extremely high rate (>50%) of pre-treatment resistance to quinolones, observed among the first annual cohort of 60 MDR-TB cases diagnosed in the initial RNTCP DOTS-Plus site in Gujarat (47), is a matter of concern.

4.6 HIV in TB patients

India has a concentrated HIV epidemic with substantial geographical variation (5). The epidemic peaked in the 1990s and in 2007 there were an estimated 2.31 million (1.8–2.9 million) persons living with HIV/AIDS (48). Surveys of HIV in TB patients were carried out in four high HIV-prevalence districts in South India between 2005 and 2006, and in 15 districts in eight states from 2006 to 2009 (6).

The prevalence of HIV in TB patients ranged from 1% to 14%, was 30% higher in males than in females and 30% to 40% higher in smear-negative and extra-pulmonary than in smear-positive TB patients. In four districts with a high prevalence of HIV, it remained constant from 2005 to 2009 (6, 7). Models suggest that HIV will not greatly affect the incidence of TB in India (5).

4.7 Economic impact

TB is more prevalent in people living in poor circumstances (49–51) and the cost of TB to patients and their families is considerable. Direct costs include transportation, and in the private sector, diagnosis and medical treatment; indirect costs include work lost or school missed for children. Some TB patients spend 20% to 40% of their annual family income being treated for TB (49, 52) in the private sector before reaching the RNTCP services (53, 54).

TB morbidity and mortality mainly affect people in their most productive years, and impose a cost on the economy. In 1999, it was estimated that implementing DOTS in India would generate economic benefits equivalent to between 0.9% and 3.3% of GDP (55). An in depth economic analysis has been recently completed by WHO in collaboration with the RNTCP (56). This analysis shows that the number of disability-adjusted life years (DALYs) lost due to TB per 100 000 people in India has improved by 33% from 1990–2006. However, TB is still the cause of substantial economic loss. In 2006, TB caused a loss of 7.9 million DALYs and a reduction of US\$ 23.7 billion in economic well-being (equivalent to US\$ 21 per capita). The cost of TB control averaged just US\$ 26 per DALY gained over 1997–2006 and generated a return of US\$ 115 per dollar spent. Thus the return on investment has been exceptionally good from the perspective of the Government and donor agencies.

5. The Stop TB Strategy **2006–2008**

In 2006, WHO introduced a six-point Stop TB Strategy building on the success of DOTS, but also meeting new challenges (57) and in particular HIV-related TB and MDR-TB. At the same time, the Stop TB Partnership launched the Second Global Plan to Stop TB, 2006-2015 (57). The Plan provides a roadmap and budget to reach the Millennium Development Goals (MDGs) and related Stop TB Partnership targets for TB control by 2015 (57). The challenge in India is to maintain the present level of programme implementation, whilst incorporating the new components of the Stop TB Strategy, many of which require further policy development, planning and additional financing.

6. The way forward: 2009–2015

6.1 Engaging all providers (PPM)

India has a large private health sector with a diversity of providers including authorized allopathic, homeopathic, and traditional medicine practitioners, as well as unregulated practitioners with wide variations across India (10). Many TB patients first seek private health care, often many times, before approaching the RNTCP where services are free (53, 54, 58–61).

In India, 80% of qualified doctors, 95% of dispensaries and 60% of hospitals are in the private sector. In 2006 private sector expenditure on health was 80% of total health expenditure (30). Regulation of the private sector has not kept pace with expansion, despite concerns about quality of care (2). The RNTCP has made efforts for systematically engaging all care providers in TB control through a public-private mix DOTS (PPM-DOTS) approach and has developed guidelines for the involvement of non-governmental organizations (NGOs) and private providers, including medical colleges. These guidelines have been updated in 2008 (62). The RNTCP has engaged public sector departments that run their own health services¹ (63). There have also been initiatives to involve the business and corporate sectors in TB control, supported by the Confederation of Indian Industry and the Federation of Indian Chambers of Commerce and Industry (2).

The Indian Medical Association (IMA), which has 160 000 members, has endorsed the International Standards of TB Care (ISTC) (66), and has disseminated it widely (64). The Association has a project under Round 6 of the Global Fund to increase the involvement of private practitioners in five states and one union territory covering around 400 million people (62). Under the Global Fund Rolling Continuation Channel project with

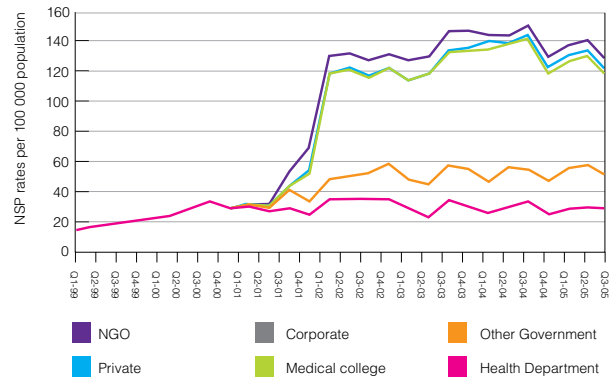


Figure 10. Number of new smear positive (NSP) cases diagnosed by source of referral, Bangalore, India PPM project (1999–2005) (65).

the Government of India, the IMA project has in 2009 been expanded to cover 15 states and one union territory covering 850 million people. The IMA has also taken the lead in bringing together other relevant professional medical associations under an initiative called the Indian Medical Professional Associations Coalition against TB (IMPACT), which is an important forum for the RNTCP to engage with the professional medical associations. A network of national, zonal and state task forces has been developed among the 267 medical colleges to promote training and teaching, service delivery, advocacy and operational research (62) and this has had a considerable impact.

¹ These include the ministries of railways, labour, steel, coal, mines, power, ports and the Central Government Health Services (serving Central Government employees and their families).

The intensified PPM DOTS activities that began in 2003 in 14 urban districts are now serving as sentinel sites providing important information on the contribution of different provider groups, including trends. By 2008, 2946 NGOs and 19 695 private practitioners were working under the RNTCP guidelines. PPM programmes in India have increased case notification rates and improved success rates, are cost effective, and have reduced the economic burden on patients (Figure 10) (53, 54, 65). Nevertheless, challenges still remain in regard to engaging the private sector including a common platform to reach the vast network, the years of unregulated practice with ready access to first and second-line anti-TB drugs, lack of feasible opportunities for continuing medical education, and the resistance of some academicians.

6.2 Laboratory and Diagnosis

India has four National Reference Laboratories (NRLs), one Intermediate Reference Laboratory (IRL) in each large state, and almost 13 000 designated microscopy centres (DMCs). Currently the capacity of IRLs are being built for undertaking mycobacterial culture and drug susceptibility testing. DMCs serve a population of 100 000, or 50 000 if in tribal or difficult/mountainous areas. All DMCs participate in regular External Quality Assessment activities.

Expansion of culture and drug susceptibility testing (DST) services are needed for the management of drug-resistant TB, and in future for the diagnosis of smear-negative pulmonary TB and extra-pulmonary TB. As of the end of 2009, 12 laboratories (nine in the public sector and three in the private sector) were accredited to perform culture and DST for the RNTCP, and a number of additional laboratories are undergoing accreditation.

The second tier of the network, IRLs providing culture and DST, is still not fully developed because of the lack of posts for microbiologists in a number of states and delays in procurement of equipment. As MDR-TB treatment programmes scale up and decentralize, demand for culture and DST services will grow. To fill this demand, additional culture and DST laboratories are being planned, and accreditation and engagement with private sector laboratories is ongoing. In addition, the programme, in collaboration with Foundation for Innovative Diagnostics (FIND) and WHO, is conducting validation and demonstration studies of line probe assay testing and liquid culture tests. Once the study results are available, these new tests would

be incorporated into the RNTCP laboratory services in order to expand the RNTCP's capacity to diagnose and manage cases of drug-resistant TB.

6.3 Drug supply and quality

From the launch of the RNTCP, all first-line anti-TB drugs have been procured centrally. In 2006, the United Kingdom's Department for International Development (DFID) provided a five-year grant to supply first-line drugs to about half of the country through the Global Drug Facility (GDF). First-line drugs for the rest of the population are acquired through the World Bank loan to the Government of India and Global Fund grants (63). India has developed a unique system of providing drugs in Patient-Wise Boxes (PWBs), which contain the drugs for a complete course of treatment for one patient.

In 2008, two sites in the states of Gujarat and Maharashtra were treating MDR-TB cases with second-line anti-TB drugs. By the end of 2009, MDR-TB patients were receiving treatment under the RNTCP from sites in ten states (Andhra Pradesh, Delhi, Gujarat, Haryana, Kerala, Maharashtra, Orissa, Rajasthan, Tamil Nadu and West Bengal). The MDR-TB treatment programmes in the states of Delhi, Gujarat, Maharashtra, Kerala, Rajasthan, Tamil Nadu and West Bengal, will receive second-line drugs procured centrally by the Government of India and funded by the World Bank. The states funded by Global Fund support (Andhra Pradesh, Haryana and Orissa) will receive second-line drugs procured through the Green Light Committee (GLC) mechanism (63).

Procurement of TB drugs for the RNTCP where the Government of India funds are supporting the programme, is achieved through an independent agency appointed by the Ministry of Health and Family Welfare and takes from 12 to 16 months. All drugs procured for the RNTCP, irrespective of the funding source or procurement mechanism, are delivered to six central government stores and/or to the 40 state-level TB drug stores. Drugs are delivered from the state stores downwards to the district drug storage facilities, onto the TB and peripheral units, then to sites participating in the RNTCP's PPM activities. Adequate buffer stocks are kept at all levels. Drug quality is ensured by an independent quality control laboratory that has been hired by the Central TB Division, and several measures have been put into place to inspect the quality of drugs at all stages of the manufacturing and distribution chain (64). A WHO- and DFID-supported agency based within the Central TB

Division (CTD) coordinates the in-country management, distribution and monitoring of drug stocks (63).

6.4 Monitoring and evaluation systems

The extensive monitoring and evaluation system, developed by the RNTCP, uses indicators of programme performance, quality, logistics, human resources, expenditure and budget, and advocacy, communication and social mobilization (ACSM) activities (63). The reporting system is fully computerized using EPICENTRE software. Aggregated data are entered into computers at district level and transmitted to state and national levels. At national level the data are cleaned, analyzed and reported quarterly and annually on the RNTCP web site (www.tbcindia.org) (10). Reports are compiled and reported upwards from the peripheral health institution (PHI), and monitoring capacity at the state level has been enhanced in order to provide regular analysis of quarterly reports and feedback to districts (63). The dedicated RNTCP contractual staff at the sub-district level Tuberculosis Units play a crucial role in ensuring the timely generation and transmission of reports. The network of WHO RNTCP medical consultants assists in the validation and quality assurance of the recorded and reported data.

State TB Officers are required to visit each district at least twice a year and the District TB Officers (DTOs), Senior TB Treatment Supervisors (STS), and Senior TB Laboratory Supervisors (STLS) in addition to regular field supervision visits, are required to meet monthly at the district TB centre to monitor the programme performance in the respective district. States conduct an in-depth evaluation of two districts per quarter and reports are distributed among DTOs to enable corrective actions to be taken, and these are regularly reviewed by the state (63). Central level internal evaluations are also conducted regularly by teams from the Central TB Division (CTD) and national level TB institutes. A WHO-coordinated joint monitoring mission carried out by external TB and public health experts is undertaken every three years, and the World Bank conducts regular monitoring missions of the states that they support.

6.5 Advocacy, communication, and social mobilization (ACSM)

A national ACSM strategy has been developed to implement a range of ACSM activities at different levels of the TB programme. In 2005, the RNTCP launched a web-

based Information, Education, and Communication (IEC) resource centre (2) to assemble IEC material produced at the national and state levels, but the full range of activities has yet to be undertaken in a coordinated manner (49). In 2009, RNTCP budgeted over US\$ 4 million for ACSM activities.

6.6 Drug-resistant TB

In the RNTCP Phase II Project Implementation Plan (2006–2011), the RNTCP aims to develop a network of accredited Intermediate Reference Laboratories (IRLs) and treatment sites in each state that has the capacity to diagnose and enrol 5000 or more new MDR-TB cases annually. High-risk patients will be screened first and all confirmed MDR-TB patients will be started on ambulatory treatment. Category IV services for MDR-TB patients were introduced in Gujarat and Maharashtra in March 2007, with the first patients initiated on treatment in August–September 2007. By the end of 2009, treatment was ongoing in sites of ten states, with a cumulative total of 1415 patients having been placed on RNTCP Category IV treatment since August–September 2007. The Second Global Plan to Stop TB projects that by 2009 over US\$ 170 million will be required annually to expand MDR-TB services. More recently, the RNTCP has developed an ambitious plan to scale-up MDR-TB services in order to treat annually at least 30 000 MDR-TB patients in the country, and has garnered support under Global Fund Round 9 and from UNITAID to enable a rapid expansion of MDR-TB services in the next few years. However, the current limited available capacity of laboratory infrastructure, and the human and financial resources required to establish and maintain each site remain a challenge.

6.7 TB/HIV

TB/HIV collaborative activities began in India in 2001 in six states with a high prevalence of HIV/AIDS, and eight additional states were added in 2004 (66). In 2008, TB/HIV collaborative services were extended to the whole country, with an intensified case-finding package implemented in the six states with higher HIV prevalence (47). This intensified combination of services included the offer of voluntary counselling and HIV testing of all TB patients.

In October 2009, a revised “National Framework for Joint TB/HIV Collaborative Activities” was launched by the RNTCP and the National AIDS Control Programme

(NACP) (67). By 2012, it is planned that the intensified TB/HIV package will be expanded in a phased manner to all remaining states and Union territories of the country. Training modules have been developed for all levels of staff within both the RNTCP and the NACP to facilitate the expansion and scale-up of activities.

Collaboration between the RNTCP and the NACP at the national, state, and district levels has led to more cross-referrals, better service delivery, coordination and involvement of NGOs, and improved infection control (67). In 2007, 50 586 HIV positive TB suspects were screened for TB and 7130 or 14% were diagnosed with TB. 80 425 or 5% of all notified TB patients were tested for HIV on the basis of a high risk screening process and 9324, or 12%, were sero-positive. In 2008, over 200 000 TB suspects were referred from HIV Integrated Counselling and Testing Centres (ICTCs) to the RNTCP for investigation, and over 25 000 were found to have active TB disease. Over 132 000 TB patients were tested for HIV in 2008, with almost 12 000 being found to be sero-positive (30).

7. Health systems

The diagnosis and treatment of TB is fully integrated into the general health system. Service delivery is carried out by general health staff, whilst organization of services, provision of guidelines and financial resources, drug supply, and most of the supervision and monitoring are carried out by the RNTCP. Deficiencies in the general health system are a major barrier to effective TB service delivery, and states with weak health systems have poorer TB programme performance. Low national investment in infrastructure and personnel leads to low staff salaries, vacant posts, high turnover and absenteeism (2).

The National Rural Health Mission is aimed at improving the access to, and the quality of, health care, especially for the poor. This mission is regarded as a positive step towards improving general health systems, particularly if government contribution to health care is increased from 0.9% to 2–3% of GDP. In addition to the National Rural Health Mission, the World Bank has contributed to strengthening primary health care in five states.

7.1 Human resource development

The RNTCP supports human resource development. Job functions at all levels are fully described in technical and operational guidelines, and there is a three-tiered training structure in operation. Training materials for basic TB control and for several of the components of the new Stop TB Strategy are available, with the remaining materials under development. This system is coordinated by a specialized human resources development (HRD) unit within the Central TB Division. However, a programme review (2) noted that the concept of HRD was not well understood at the state and district level, and there were insufficient staff dedicated to manage the development process at the central and state level (2). The 2009 the RNTCP budget allocates US\$ 34 million for human resources to ensure adequate numbers of TB dedicated staff and to fill gaps in essential general health services posts, e.g. medical officers, laboratory technicians, etc.

7.2 Funding needs

In 2009, there was a 30% budget rise over 2008, accounted for mainly by more expensive staff costs due to higher salaries and intensified activities to fill gaps in human resources, and a larger requirement of first-line drugs to meet increases in case notifications and to maintain adequate buffer stocks at all levels. However, there was an identified lack of US\$ 30 million in the budget.

Much of this gap will be covered by the Global Fund's Rolling Continuation Channel mechanism. If the resources required to maintain optimal performance of the programme cannot be found, then the latter will not be able to undertake further initiatives such as broadened engagement with the private sector, expansion of MDR-TB treatment, increase in the number of laboratories and development of the intensified package of collaborative TB/HIV services. The recent approval of a UNITAID grant and the success of the Global Fund Round 9 application will go a long way in meeting the financial means required for the scaling-up of the management of drug-resistant TB in India.

In the long run, if the proportion of government funds dedicated to health expenditure is increased from 0.9% to between 2 or 3% over the next several years, the governmental TB budget itself could potentially cover all of the activities planned, and the scale-up of new initiatives will be possible. If the governmental expenditure does not increase or not to the benefit of the RNTCP, then other sources of additional funding will have to be identified to ensure the long-term sustainability of the programme.

8. Conclusion

Over the last decade, the RNTCP has expanded TB services to over 1.1 billion people, has met the WHO objectives for case detection and treatment success, and is close to fulfilling the TB-related Millennium Development Goal indicators and the Stop TB Partnership targets by 2015. It has also proved that ensuring free TB services via both the public and private sector is a cost-effective and sound investment, providing a significant economic return to the country.

Most of the work of the RNTCP has been achieved even though the public health infrastructure remains weak and the success is primarily due to careful planning, thorough implementation, stable funding and the use of an innovative network of technical consultants. In order to maintain the current programme activities, an annual amount of at least US\$ 100 million is required. However, to expand them further and fully implement all components of the Stop TB Strategy to achieve the targets outlined in the Second Global Plan to Stop TB, the programme's budget needs to be doubled by 2012 to allow for expansion of services, particularly in the areas of MDR-TB, TB/HIV and PPM.

This level of expenditure on TB control activities is unprecedented in India; however the achievements of the RNTCP, with emphasis on the cost effectiveness of the programme, should help to convince both the Government of India and donors to increase their investment in the country with the world's greatest TB burden, both in terms of drug-susceptible and drug-resistant disease.

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