

Document of  
The World Bank

Report No: ICR2598

IMPLEMENTATION COMPLETION AND RESULTS REPORT  
(IDA-42280)

ON A

CREDIT

IN THE AMOUNT OF SDR 115.7 MILLION  
(US\$178.85 MILLION EQUIVALENT)

TO THE

REPUBLIC OF INDIA

FOR A

SECOND NATIONAL TUBERCULOSIS CONTROL PROGRAM

April 30, 2013

Human Development Unit  
South Asia Region

CURRENCY EQUIVALENTS  
(Exchange Rate Effective September 30, 2012)

Currency Unit = Indian Rupee (INR)  
US\$1.00 = INR 52.75  
US\$1.00 = SDR 0.648

FISCAL YEAR  
April 1 – March 31

ABBREVIATIONS AND ACRONYMS

ARTI	Annual Risk of Tuberculosis Infection
ACSM	Advocacy Communication and Social Mobilization
ASHA	Accredited Social Health Activist
CAS	Country Assistance Strategy
CMO	Chief Medical Officer
CSO	Civil Society Organization
CTD	Central TB Division
DALY	Disability Adjusted Life-Year
DCA	Development Credit Agreement
DFID	UK Department for International Development
DIR	Detailed Implementation Review
DMC	Designated Microscopy Center
DOTS	Directly-observed therapy, short-course
DOTS Plus	DOTS plus for multi-drug resistant TB
DRS	Drug Resistance Survey
DST	Drug Susceptibility Testing
DTC	District TB Center
DTO	District TB Officer
EPW	Empowered Procurement Wing of the MOHFW
FM	Financial Management
FMR	Financial Management Reports
GAAP	Governance and Accountability Action Plan
GDP	Gross Domestic Product
GF	Global Fund
GMP	Good Manufacturing Practices
GNI	Gross National Income
GOI	Government of India
HIV/AIDS	Human Immuno Deficiency Virus/ Acquired Immuno- Deficiency Syndrome
HNP	Health, Nutrition and Population
ICMR	Indian Council for Medical Research
IDA	International Development Association
IEC	Information, Education and Communication
IMA	Indian Medical Association
IO	Intermediate Outcome
IRL	Intermediate Reference Laboratory
ISR	Implementation Status Report
IT	Information Technology
JMM	Joint Monitoring Mission
JRM	Joint Review Mission
KAP	Knowledge Attitude and Practice
LT	Lab Technician

M&E	Monitoring and Evaluation
MDG	Millennium Development Goal
MDR-TB	Multi-drug Resistant Tuberculosis
MIS	Management Information System
MOHFW	Ministry of Health and Family Welfare
NACO	National AIDS Control Organization
NGO	Non-Governmental Organization
NRHM	National Rural Health Mission
NRL	National Reference Laboratory
NSP	National Strategic Plan
OD	Operational Directive
OR	Operational Research
PAD	Project Appraisal Document
PDO	Program Development Objective
PIP	Project Implementation Plan
PMDT	Programmatic Management of Drug Resistant Tuberculosis
PP	Private Practitioner
PPM	Public-Private Mix
PPP	Public- Private Partnership
QA	Quality Assurance
QALP	Quality Assessment of the Lending Portfolio
QER	Quality Enhancement Review
RNTCP	Revised National TB Control Program
SA	Social Assessment
SDS	State Drug Store
STDC	State TB Training and Demonstration Center
STLS	Senior TB Laboratory Supervisor
STO	State TB Officer
STS	Senior Treatment Supervisor
SWAp	Sector-Wide Approach
TAP	Tribal Action Plan
TB	Tuberculosis
TDP	Tribal Development Plan
TU	Tuberculosis Unit
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

Vice President:	Isabel M. Guerrero
Country Director:	Onno Ruhl
Sector Manager:	Julie McLaughlin
Project Team & ICR Leader:	Patrick M. Mullen
ICR Author:	Nadwa Rafeh



**India**  
**SECOND NATIONAL TUBERCULOSIS CONTROL PROGRAM**

**CONTENTS**

A. Basic Information.....	v
B. Key Dates .....	v
C. Ratings Summary .....	v
D. Sector and Theme Codes.....	vi
E. Bank Staff.....	vi
F. Results Framework Analysis .....	vii
G. Ratings of Project Performance in ISRs .....	xii
H. Restructuring (if any).....	xiii
I. Disbursement Profile .....	xiii
1. Project Context, Development Objectives and Design.....	1
2. Key Factors Affecting Implementation and Outcomes .....	6
3. Assessment of Outcomes .....	14
4. Assessment of Risk to Development Outcome.....	26
5. Assessment of Bank and Borrower Performance .....	27
6. Lessons Learned.....	30
7. Comments on Issues Raised by Borrower/Implementing Agencies/Partners.....	31
Annex 1. Project Costs and Financing.....	32
Annex 2. Outputs by Components .....	33
Annex 3. Economic and Financial Analysis.....	37
Annex 4. Bank Lending and Implementation Support/Supervision Processes.....	41
Annex 5. Borrower's ICR.....	43
Annex 6. List of Supporting Documents .....	60



<b>A. Basic Information</b>			
Country:	India	Project Name:	India: Second National Tuberculosis Control Project
Project ID:	P078539	L/C/TF Number(s):	IDA-42280
ICR Date:	04/27/2013	ICR Type:	Core ICR
Lending Instrument:	SIL	Borrower:	GOVERNMENT OF INDIA
Original Total Commitment:	XDR 115.70M	Disbursed Amount:	XDR 115.70M
Revised Amount:	XDR 115.70M		
<b>Environmental Category: B</b>			
<b>Implementing Agencies:</b> Central Tuberculosis Division, Ministry of Health and Family Welfare			
<b>Cofinanciers and Other External Partners:</b> USAID GFATM DFID World Health Organization (WHO) Global Drug Facility			

<b>B. Key Dates</b>				
Process	Date	Process	Original Date	Revised / Actual Date(s)
Concept Review:	06/17/2004	Effectiveness:	11/22/2006	11/22/2006
Appraisal:	04/02/2005	Restructuring(s):		03/30/2012
Approval:	08/22/2006	Mid-term Review:	04/29/2009	04/29/2009
		Closing:	03/31/2012	09/30/2012

<b>C. Ratings Summary</b>			
<b>C.1 Performance Rating by ICR</b>			
Outcomes:	Satisfactory		
Risk to Development Outcome:	Low or Negligible		
Bank Performance:	Satisfactory		
Borrower Performance:	Satisfactory		
<b>C.2 Detailed Ratings of Bank and Borrower Performance (by ICR)</b>			
Bank	Ratings	Borrower	Ratings
Quality at Entry:	Satisfactory	Government:	Satisfactory
Quality of Supervision:	Highly Satisfactory	Implementing Agency/Agencies:	Satisfactory

<b>Overall Bank Performance:</b>	Satisfactory	<b>Overall Borrower Performance:</b>	Satisfactory
----------------------------------	--------------	--------------------------------------	--------------

### C.3 Quality at Entry and Implementation Performance Indicators

Implementation Performance	Indicators	QAG Assessments (if any)	Rating
Potential Problem Project at any time (Yes/No):	No	Quality at Entry (QEA):	Satisfactory
Problem Project at any time (Yes/No):	No	Quality of Supervision (QSA):	Satisfactory
DO rating before Closing/Inactive status:	Satisfactory		

### D. Sector and Theme Codes

	Original	Actual
<b>Sector Code (as % of total Bank financing)</b>		
Central government administration	8	8
Health	72	72
Sub-national government administration	20	20
<b>Theme Code (as % of total Bank financing)</b>		
Decentralization	17	17
HIV/AIDS	17	17
Health system performance	33	33
Tuberculosis	33	33

### E. Bank Staff

Positions	At ICR	At Approval
Vice President:	Isabel M. Guerrero	Praful C. Patel
Country Director:	Onno Ruhl	Michael F. Carter
Sector Manager:	Julie McLaughlin	Anabela Abreu
Project Team Leader:	Patrick M. Mullen	Birte Holm Sorensen
ICR Team Leader:	Patrick M. Mullen	
ICR Primary Author:	Nadwa Rafeh	



## F. Results Framework Analysis

### Project Development Objectives (from Project Appraisal Document)

(i) to achieve the global targets of 70% case detection and 85% cure rate in 100% of the districts; and (ii) for the zones where DOTS has been under implementation for five or more years, the incidence of smear-positive TB starts to decline.

### Revised Project Development Objectives (as approved by original approving authority)

Not applicable.

#### (a) PDO Indicator(s)

Indicator	Baseline Value	Original Target Values (from approval documents)	Formally Revised Target Values	Actual Value Achieved at Completion or Target Years
<b>Indicator 1 :</b>	Annual Risk of TB Infection (ARTI) in zones where Directly Observed Therapy Short-course (DOTS) has been implemented for more than five years			
Value quantitative or Qualitative)	1.5%	1.34%		1.1%
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	118% of target achieved			
<b>Indicator 2 :</b>	No. of districts which have reached the global targets for cure rate and case detection rates			
Value quantitative or Qualitative)	111	450		508 districts reached treatment success rate target; 269 districts reached case detection rate target; 222 districts reached both targets
Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	113% of target reached for treatment success rate (508/450 districts); 60% of target reached for case detection rate (269/450 districts). 222 districts reached both global targets. Treatment success rate is now used instead of cure rate.			

#### (b) Intermediate Outcome Indicator(s)

Indicator	Baseline Value	Original Target Values (from approval documents)	Formally Revised Target Values	Actual Value Achieved at Completion or Target Years
<b>Indicator 1 :</b>	Number of People receiving TB treatment in accordance with WHO-			

	recommended DOTS																					
Value (quantitative or Qualitative)	0			8,695,790																		
Date achieved	12/31/2005			09/30/2012																		
Comments (incl. % achievement)	100% of target achieved. This IDA core indicator was mandatorily added during implementation. In line with policy, the baseline is set at '0' although in 2006, an estimated 1.4 million patients received WHO recommended DOTS treatment.																					
<b>Indicator 2 :</b>	No. of states which have reached the global targets for cure rate and case detection rate																					
Value (quantitative or Qualitative)	8	28		13 states reached the case detection rate target; 27 states reached treatment success rate target; 10 states reached both targets																		
Date achieved	12/31/2005			12/31/2011																		
Comments (incl. % achievement)	46% of target reached for case detection rate (13 states); 96% of target reached for treatment success rate; 10 states reached both global indicator targets (38% of 28 states).																					
<b>Indicator 3 :</b>	No. of zones which have reached the global targets for cure rate and case detection rate																					
Value (quantitative or Qualitative)	0	4		1 zone reached the case detection rate (CDR) target and 5 zones reached the treatment success rate (TSR) target; 1 zone reached both targets																		
Date achieved	12/31/2005			12/31/2011																		
Comments (incl. % achievement)	25% of target achieved for CDR (1 zone); 125% of target achieved for TSR (5 zones); 1 zone reached both targets. <table border="0" style="margin-left: 40px;"> <tr> <td></td> <td>CDR</td> <td>TSR</td> </tr> <tr> <td>North</td> <td>77%</td> <td>89%</td> </tr> <tr> <td>South</td> <td>65%</td> <td>86%</td> </tr> <tr> <td>West</td> <td>65%</td> <td>88%</td> </tr> <tr> <td>East</td> <td>59%</td> <td>87%</td> </tr> <tr> <td>North East</td> <td>68%</td> <td></td> </tr> </table>					CDR	TSR	North	77%	89%	South	65%	86%	West	65%	88%	East	59%	87%	North East	68%	
	CDR	TSR																				
North	77%	89%																				
South	65%	86%																				
West	65%	88%																				
East	59%	87%																				
North East	68%																					
<b>Indicator 4 :</b>	Population/administrative areas with DOTS coverage/total country population																					
Value (quantitative or Qualitative)	87%	100%		100%																		
Date achieved	12/31/2005			09/30/2012																		
Comments (incl. % achievement)	100% of target achieved.																					
<b>Indicator 5 :</b>	Increase in TB suspects examined per 100,000 population annually																					

Value (quantitative or Qualitative)	138/100,000	Increasing trend		162/100,000
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	100% of target achieved.			
<b>Indicator 6 :</b>	Increase in the level of awareness about TB diagnosis and DOTS treatment amongst practitioners			
Value (quantitative or Qualitative)	a) 45% of private providers aware of TB diagnosis b) 52% of health care providers are aware of DOTS	Increasing trend		a) 90% of private providers aware of TB diagnosis b) 97% of health care providers are aware of DOTS treatment
Date achieved	08/01/2007			12/31/2010
Comments (incl. % achievement)	100% of target achieved. Baseline is from 2007 Knowledge Attitude and Practice (KAP) study; end-project estimates are from 2010 KAP study.			
<b>Indicator 7 :</b>	Increase awareness in target groups being reached with information that DOTS is the correct treatment, and that it is available free in patient-wise boxes			
Value (quantitative or Qualitative)	16% of community aware that drugs are free and available in patient-wise boxes	Increasing trend		Awareness of DOTS in community: 49% DOTS is the way to complete cure of TB: 51% Free cost of TB treatment at government health facility: 84%
Date achieved	08/01/2007			12/31/2010
Comments (incl. % achievement)	100% of target achieved. Baseline is from 2007 KAP study; end-project estimates are from 2010 KAP study.			
<b>Indicator 8 :</b>	Increase in state and district level capacity to plan and execute Information, Education and Communication (IEC) activities			
Value (quantitative or Qualitative)	0 IEC officers in place	Increasing trend		35 IEC officers have been trained, 1 per state. Each officer underwent 1 main training and 3 refresher trainings.
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	100% of target achieved. The IEC officer position was created after 2006. There are noted increases in IEC activities. The program was successful in staffing this important position as part of capacity building. Several IEC trainings were provided.			

<b>Indicator 9 :</b>	Performance level achieved in pre-determined set of predominantly tribal districts will reach 70% case detection and 85% cure rate.			
Value (quantitative or Qualitative)	Tribal districts: 79% case detection 86% treatment success rate Poor districts 55% case detection 85% treatment success rate	> or =70% case detection > or = 85% cure rate		Tribal districts: 80% case detection; 88% treatment success rate Poor districts: 67% case detection; 89% treatment success rate
Date achieved	12/31/2006			12/31/2011
Comments (incl. % achievement)	Tribal: 114% of CDR target and 103.5% of TSR target achieved Poor: 96% of CDR target and 105% of TSR target achieved. 85 districts with 50% Scheduled Tribe population and 145 districts identified as poor and backward are monitored.			
<b>Indicator 10 :</b>	Number of NGOs participating in RNTCP			
Value (quantitative or Qualitative)	1,000	Increasing trend		2,325
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	100% of target achieved.			
<b>Indicator 11 :</b>	Number of private (non-public) health care providers involved in RNTCP			
Value (quantitative or Qualitative)	5,000	Increasing trend		13,397
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	100% of target achieved.			
<b>Indicator 12 :</b>	Treatment outcomes from the different provider groups in the 14 cities with intensified Public Private Mix (PPM) activities			
Value (quantitative or Qualitative)	Treatment success rate: Private practitioners: 86% Corporate and NGO organizations: 88%	Increasing trend		Treatment success rate: Private practitioners: 88% NGOs: 83% Corporate: 92%
Date achieved	02/08/2006			09/30/2012
Comments (incl. % achievement)	100% of target achieved.			
<b>Indicator 13 :</b>	Number of persons suspected to have TB disease, and referred from Voluntary Counseling and Testing (VCT) services			
Value (quantitative or Qualitative)	11,331	Increasing trend		435,880

Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	100% of target achieved. Annual number.			
<b>Indicator 14 :</b>	Number of persons diagnosed with TB disease, having been referred from VCT services			
Value (quantitative or Qualitative)	3,034	Increasing trend		37,865
Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	100% of target achieved. Annual number			
<b>Indicator 15 :</b>	Number of persons diagnosed with TB disease, having been referred from VCT services, who are placed on DOTS			
Value (quantitative or Qualitative)	2,047	Increasing trend		34,355
Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	100% of target achieved. Annual number.			
<b>Indicator 16 :</b>	Number of children under 15 years of age receiving DOTS			
Value (quantitative or Qualitative)	59,846	Increasing trend		84,064
Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	100% of target achieved. Annual number.			
<b>Indicator 17 :</b>	Patients of DOTS under 15 years of age/all patients on DOTS			
Value (quantitative or Qualitative)	6%	7%		7%
Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	100% of target achieved.			
<b>Indicator 18 :</b>	Number of quality assured Intermediate Reference Laboratories (IRL) available to undertake Drug Susceptibility Testing (DST) under RNTCP			
Value (quantitative or Qualitative)	0	24		42
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	175% of target achieved			
<b>Indicator 19 :</b>	Number of DOTS Plus sites initiated			

Value (quantitative or Qualitative)	0	21		71
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	338% of target achieved.			
<b>Indicator 20 :</b>	Number of Category II failures receiving a drug sensitivity test/total number of Category II failures reported in respective states with an RNTCP DOTS Plus site			
Value (quantitative or Qualitative)	0	70%		67% (17222/25812) of all retreatment cases received a drug sensitivity test
Date achieved	12/31/2005			12/31/2011
Comments (incl. % achievement)	96% of target achieved. A close proxy has been used for the endline. Provision of drug sensitivity tests has expanded to all retreatment cases (not only Category II failures)			
<b>Indicator 21 :</b>	Number of Multi-Drug Resistant (MDR) TB cases started on DOTS Plus treatment			
Value (quantitative or Qualitative)	0	4,150 (cumulative)		16,826 (cumulative)
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	405% of target achieved.			
<b>Indicator 22 :</b>	Number of MDR TB patients who have successfully completed DOTS Plus treatment/number of MDR-TB patients put on DOTS Plus treatment			
Value (quantitative or Qualitative)	0	70%		49%
Date achieved	12/31/2005			09/30/2012
Comments (incl. % achievement)	69% of target achieved. (Patients in the initial phases of scale-up are likely to be suffering from advanced stages of the disease, while the 24-month course of treatment and adverse drug reactions cause defaulting.			

### G. Ratings of Project Performance in ISRs

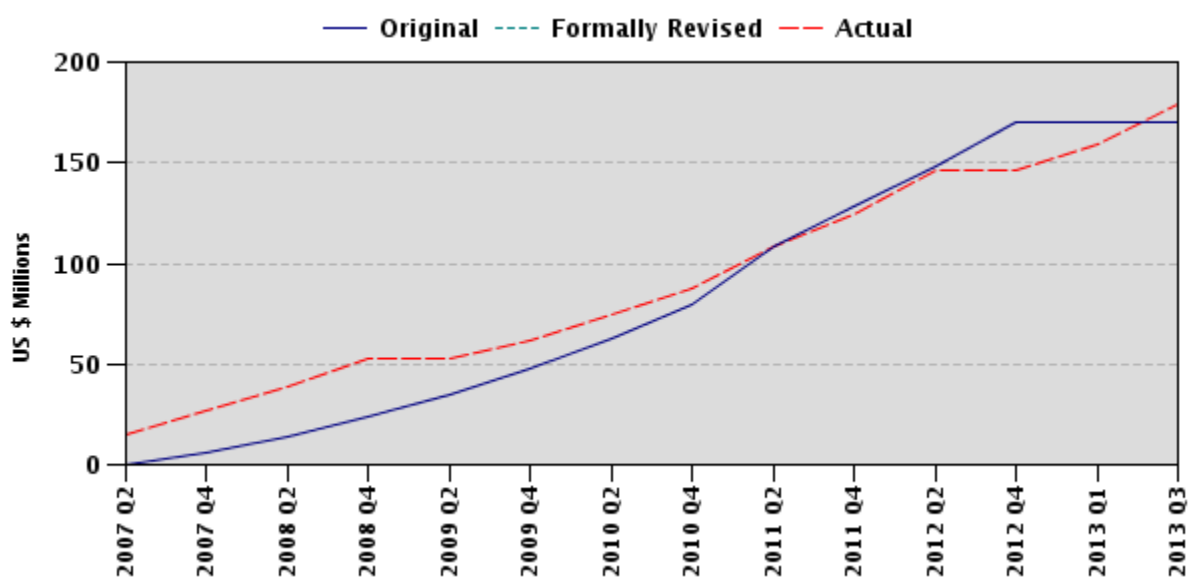
No.	Date ISR Archived	DO	IP	Actual Disbursements (USD millions)
1	12/17/2006	Satisfactory	Satisfactory	0.00
2	04/25/2007	Satisfactory	Satisfactory	15.00
3	09/25/2007	Satisfactory	Satisfactory	27.23
4	02/27/2008	Satisfactory	Satisfactory	38.84
5	08/15/2008	Satisfactory	Satisfactory	52.30
6	02/09/2009	Satisfactory	Satisfactory	60.12

7	08/24/2009	Satisfactory	Satisfactory	61.22
8	02/26/2010	Satisfactory	Satisfactory	87.76
9	10/17/2010	Satisfactory	Satisfactory	107.04
10	06/27/2011	Satisfactory	Satisfactory	124.61
11	02/22/2012	Satisfactory	Satisfactory	146.41
12	11/27/2012	Satisfactory	Satisfactory	159.14

## H. Restructuring (if any)

Restructuring Date(s)	Board Approved PDO Change	ISR Ratings at Restructuring		Amount Disbursed at Restructuring in USD millions	Reason for Restructuring & Key Changes Made
		DO	IP		
03/30/2012	N	S	S	146.41	Extension of closing date by six months to September 30, 2012

## I. Disbursement Profile







## **1. Project Context, Development Objectives and Design**

### **1.1 Context at Appraisal**

In 2005, India's population was an estimated 1.15 billion with gross national income (GNI) per capita of US\$ 730. The economy was growing rapidly at an annual rate of 9.3% while 27.5% of the population was estimated to be living below the national poverty line. Overall health indicators were improving: for example, the infant mortality rate fell from 73 to 55 per 1,000 births between 1995 and 2005, while life expectancy rose from 60 to 63 years during the same period. Public spending on health, however, remained low at only 0.9% of gross domestic product (GDP), compared to a figure of 3.9% for private spending on health care (World Bank, 2012; GOI Press Information Bureau, 2007).

Tuberculosis (TB) is a highly-fatal bacterial disease that spreads through the air and attacks the lungs but can also infect other parts of the body. Not all infections lead to active disease, but left untreated, each person with infectious TB will spread the germs to 10-15 people every year. When a person with infectious TB is identified (using a microscope to look for TB bacilli in a smear of the person's sputum), a full course of treatment over six to eight months can usually cure the disease. DOTS (directly-observed treatment, short-course) is the internationally-recognized cost-effective public health strategy for diagnosis and treatment. At the same time, multi-drug resistant TB (MDR-TB) can develop when the disease becomes resistant to the standard treatment due to misuse of anti-TB drugs and/or interrupted or incomplete treatment. HIV infected persons are at a significantly higher risk of contracting TB infection.

Although TB affects all socio-economic groups in India, the disease is disproportionately borne by the poorest and marginalized sections of society. It often affects the most productive age groups, and can pull households deeper into poverty due to the long course of treatment and cost of drugs, as well as foregone productivity and wages. It was estimated that in 2005 the direct costs of TB in India were US \$300 million annually while the indirect costs were US \$3 billion (GOI MOHFW, 2006).

The World Health Organization (WHO) estimated that annual TB incidence in India in 2005 was 209 new infections per 100,000 population. This translated to about 2.4 million new cases each year. Prevalence (new plus existing cases) was estimated at 358 per 100,000 population, or around 4.1 million cases. Mortality due to TB was estimated at 36 per 100,000 population, or about 410,000 deaths annually. (WHO, 2011) WHO estimated that 5.7% of TB cases had HIV infection, and based on small studies it was speculated that MDR-TB could be present in up to 3% of new TB cases (i.e. 55,000 cases) (WHO, 2006b).

In order to address a number of weaknesses of the existing national TB program, between 1993 and 1997, the Revised National TB Control Program (RNTCP) piloted the DOTS strategy in several states. The strategy involved highly-standardized systems for

diagnosis, treatment, supply, administration, and monitoring. Drugs were centrally-procured and entire courses of treatment were made available in individual “patient-wise” boxes, administered to patients under direct observation. Dedicated TB program staff were put in place at the sub-district (i.e. TB Units), district, state, and central levels, and a network of externally-financed consultants provided technical support (WHO, 2010). After 1997, RNTCP was scaled-up nationally in phases, notably supported by an International Development Association (IDA) credit of US\$100 million between 1997 and 2006. The IDA credit represented the majority of program financing, while other international partners also provided significant support (WHO, 2010). Starting in 2000, international partners contributed to a Joint Monitoring Mission (JMM) every three years, coordinated by WHO, while annual missions led by the World Bank also included other partners. As RNTCP continued to expand coverage, its annual budget rose from US\$36 million in 2002 to US\$57 million in 2006 (WHO, 2006a).

**Table 1. RNTCP indicators, 1998-2006**

year	population coverage (million)	patients initiating treatment (million)	new smear-positive detection rate (%)*	cure rate of new smear-positive patients (%)*
1998	18	0.03	-	-
1999	130	0.14	-	-
2000	287	0.25	47	82
2001	450	0.47	47	82
2002	530	0.62	59	84
2003	778	0.91	69	86
2004	947	1.19	72	85
2005	1,080	1.29	66	84
2006	1,114	1.40	66	83

\* Rates were reported only for districts where RNTCP services had been established.

Sources: GOI MOHFW (2012); WHO (2003)

From covering 18 million people in 1998, by March 2006, RNTCP had achieved nationwide coverage; that is, TB services were made available to the entire population according to the program’s norms (i.e. one TB Unit per 500,000 population) (GOI MOHFW, 2007). From around 30,000 patients initiating treatment under the program in 1998, by 2006, 1.4 million received treatment annually from RNTCP. In 2006, case detection and cure rates were close to the international targets of 70% and 85% respectively. (Table 1) Since 1997, the program had evaluated more than 24 million people with suspected TB and treated more than 6 million patients (GOI MOHFW, 2007). WHO estimated that TB prevalence had declined from 550 per 100,000 population in 1995 to 280 in 2007, while estimated mortality declined from 44 per 100,000 to 29 in the same period (WHO, 2010), suggesting that the program was having a significant impact on disease prevalence (by shortening the average duration of infection) and mortality (by successfully treating a large proportion of cases). RNTCP reported that its services had saved 1.2 million lives by 2006 (GOI MOHFW, 2007).

By 2005-06, after achievement of large-scale expansion in the availability of standardized TB services, a number of other challenges came to the fore. They were described by a 2006 joint mission involving international partners. The mission report suggested that rapid expansion of the program had outpaced the health system's capacity to effectively supervise and ensure quality, and that systems for procurement, human resource development and monitoring needed further strengthening. Capacity at the state level needed to be further developed, particularly in the poorer-performing states. More work was needed on increasing community awareness of the availability of TB services. The mission report stated that coordination with the national HIV/AIDS program had started but required expansion. It acknowledged that effective implementation of RNTCP was the best strategy for preventing MDR-TB but urged the program to implement a strategy for diagnosis and management of MDR-TB. It indicated that although there has been progress, involvement of the private sector in the program was not yet sufficient (WHO, 2006a).

In 2006, the Stop TB Partnership (which includes the World Bank) adopted the Stop TB Strategy, including the overall objectives of achieving universal access to high-quality care for all people with TB and protecting vulnerable populations from TB, TB/HIV and MDR-TB. The Millennium Development Goal (MDG) of halting and beginning to reverse the incidence of TB by 2015 was adopted. Six areas of focus were emphasized: (i) expansion and enhancement of high-quality DOTS; (ii) addressing TB/HIV, MDR-TB and the needs of poor and vulnerable populations; (iii) contribution to health system strengthening; (iv) engagement with all care providers; (v) empowerment of people with TB and communities; and (vi) promotion of research (WHO and Stop TB Partnership, 2006).

In 2005-06, development of the second phase of RNTCP (RNTCP II) (which was indistinguishable from preparation of the second IDA credit) reflected the challenges facing the program as well as strategies being adopted at the international level.

The Government of India's (GOI) Eleventh Five Year Plan (2007-12) included continued commitment to TB control and emphasized integration of RNTCP and other disease-specific programs into the National Rural Health Mission (NRHM) that was launched in 2005 (GOI Planning Commission, 2008). The World Bank's 2005-08 Country Assistance Strategy (CAS) described the planned program's contributions to the MDGs, and stated that because infectious diseases are of global concern, with MDR-TB presenting a particular threat, and that they disproportionately affect the poor, the Bank would continue to support India's efforts to control TB and other diseases.

## **1.2 Project Development Objectives (PDO) and Key Indicators (as approved)**

The PDO stated in the Project Appraisal Document (PAD) was: (i) to achieve the global targets of 70% case detection and 85% cure rate in all districts of the country; and (ii) for the zones where DOTS has been under implementation for five or more years, the incidence of smear-positive TB starts to decline.”

The Development Credit Agreement (DCA) stated the PDO more broadly, “to support the Borrower’s Revised National Tuberculosis Control Program Phase II (the Program), aimed at treating and reducing the incidence of tuberculosis (TB) throughout its territory.” The DCA formulation is consistent with the higher level objectives to which the program contributes as stated in the PAD: “The proposed operation would help reduce mortality and morbidity due to TB and interrupt transmission of infection through consolidating program performance and expanding program coverage.”

The PDO was to be measured by two outcome indicators as well as 22 intermediate outcome indicators (see the ICR Datasheet) above.

### **1.3 Revised PDO (as approved by original approving authority) and Key Indicators, and reasons/justification**

The PDO and/or indicators were not revised.

### **1.4 Main Beneficiaries**

The main beneficiaries of the program were to be people infected with TB in India, as well as their families and communities. In addition, groups who were singled out for particular attention were to be: (i) poor, tribal, and other “hard to reach” populations; (ii) HIV/AIDS patients; (iii) children suffering from TB; (iv) MDR-TB patients; and (v) TB patients who seek care from the private sector.

### **1.5 Original Components (as approved)**

The project can be considered analogous to a sector-wide approach (SWAp) in that the IDA financing was contributing to an overall program (i.e. RNTCP II) which domestic and other external financing also supported. The operation supported two “outputs” (components) of the RNTCP II program, as follows:

#### *1. RNTCP services consolidated*

This component aimed at consolidating and sustaining the quality of the RNTCP services that had been established across the country over the previous eight years. This included the following:

- (i) Improvement in the quality of laboratory services, including establishment of intermediate reference laboratories (IRL), introducing a laboratory quality assurance (QA) system, and ensuring routine reporting of QA results in order to inform measures for improvement.
- (ii) Improvement in supervision and monitoring, including field monitoring, a computerized management information system (MIS), surveys to estimate incidence, and staff increases in low-performing areas.

- (iii) Strengthening of information, education and communication (IEC), including creating awareness among patients and health care providers of the free-of-charge RNTCP services, advocating for commitment to TB control, and enhancing provider-patient communication.
- (iv) Development of institutional capacity, including strengthening the Central TB Division (CTD) of the Ministry of Health and Family Welfare (MOHFW); developing managerial capacity at the state and district levels; supporting further decentralization of program management and strengthening staff in large and poorly-performing states, providing quality training, and supporting public and private medical colleges on DOTS training and implementation.

## *2. RNTCP outreach to target special groups expanded*

This component aimed to maximize access to TB services by under-served and other vulnerable groups. This included the following:

- (i) Improvement of coverage of poor, tribal and other “hard to reach” groups, including implementing activities identified by a social assessment (SA) and tribal action plan (TAP), using incentives for health staff in difficult and tribal areas, and providing additional financial and managerial support to poor-performing areas.
- (ii) Promotion of the involvement of private health care providers in RNTCP and DOTS provision, including continuing with ongoing public-private mix (PPM) efforts and drawing from their experience, developing a plan for further expansion of PPM, providing additional training, and undertaking operational research.
- (iii) Deepening of HIV/TB coordination, including strengthening of joint planning, health communication, training, surveillance and case-finding, as well as increasing staffing.
- (iv) Improvement in the care of pediatric cases, including introducing standardized drug regimens, ensuring availability of diagnostic facilities, training, and reporting.
- (v) Development of the program’s response to MDR-TB, including establishing laboratory capacity, improving surveillance, establishment of clinical centers, and “gradual expansion” of access to drug resistance testing and MDR-TB treatment for patients who fail treatment under the RNTCP’s base program.

### **1.6 Revised Components**

Components were not revised.

## 1.7 Other Significant Changes

In 2009, an amendment to the DCA changed the reimbursement percentage for eligible expenditures from 80% to 90%, excluded from reimbursement laboratory consumables and printing (which are procured at decentralized levels), and modified the monetary thresholds for the use of shopping as a procurement method.

In 2012, the project Closing Date was extended from March 31, 2012 to September 30, 2012 to allow additional time for the preparation and approval of Additional Financing that had been requested by the Government of India.

## 2. Key Factors Affecting Implementation and Outcomes

### 2.1 Project Preparation, Design and Quality at Entry

The following factors in the preparation process affected the implementation and outcomes of the project.

**Soundness of the background analysis.** Project design was informed by the lessons learned from the first IDA-financed TB program, other Health Nutrition and Population (HNP) projects, and international best practices. Several lessons learned and gaps were highlighted and addressed in the design. These included: (i) the need to ensure that core human resources are available at the state, district and sub-district levels to implement the program; (ii) the need to decentralize operations and build ownership at the state level; (iii) the need to assess implementation capacities at the district level prior to the start of service delivery; (iv) the need to address weak procurement processes to ensure uninterrupted supply of drugs; (v) the need for strong engagement with the private sector; and (vi) the need for an effective advocacy and health communication strategy to increase case detection and demand for services.

Other lessons that informed the design of the project were: advocacy and IEC strategies implemented by India's National Leprosy Elimination Program; Malawi's experience in improving the performance of program staff at sub-national levels; and China's experience in controlling TB through adoption of technical guidelines for DOTS as recommended by WHO and other international organizations.

**Government ownership, commitment, and institutional readiness.** IDA had supported the TB control program in India since 1997 which was and continues to be a priority for the GOI. Thus, project implementation was grounded in (i) GOI strong commitment and ownership to the RNTCP, (ii) strong leadership in CTD of MOHFW for managing the TB program, (iii) an existing TB program with established implementation capacities.

**Project design.** The design of the project was technically sound, informed by scientific evidence, and consistent with the internationally accepted approach for TB care. The overall objectives of the project were highly consistent with the GOI priorities and sector issues identified. The project was designed to support a single national program also

financed by domestic funding and other development partners, with a common technical strategy, performance indicators, etc. It encompassed a large scope, covered a vast and diverse geographical area, included multiple sectors (private, public, medical schools, private drug agencies), and addressed several medical challenges (drug resistance, HIV-TB co-morbidity, pediatric TB). This was clearly an ambitious undertaking reflecting a comprehensive approach. In order to extend the reach of TB services, the project design focused on reaching out to the poor, tribal people and other “hard to reach groups”. This was complemented with other mechanisms to expand outreach such as: (i) using IEC to create awareness for TB diagnosis and treatment and generate demand for services; (ii) strengthening public-private partnership (PPP); and (iii) developing institutional arrangements to strengthen capacities at the state and district levels for implementation.

While the design was based on global knowledge and best practice, it must be noted that one overall project objective of reaching 70% coverage and 85% cure in all districts was ambitious given the wide disparities among the districts and the challenges faced in some poor and hard-to-reach districts. Also, achieving global targets across all districts in India is an outcome that would likely materialize beyond the life of the project.

**Assessment of risk.** In designing the project, the Bank team was aware of the critical risks to achieving program objectives and accordingly, the project risk was rated as “Substantial”. The design identified twelve risks, three of which were rated substantial.

- i. Inability of the program to monitor program achievements in targeted sub-groups. Mitigation measures included development of special schemes and monitoring of tribal, poor and other vulnerable groups.
- ii. Deficiencies in the procurement system including pharmaceutical quality control. Mitigation measures included agreement with the GOI on a comprehensive Governance and Accountability Action Plan (GAAP).
- iii. Lack of interest among private and public providers in using DOTS for treatment of TB patients. Mitigation measures included the development of a health communication strategy and incentive schemes to encourage the adoption of DOTS.

One risk that could have been rated higher at appraisal was the weak health systems and lack of institutional capacities to deal with the rapid expansion of RNTCP II operation. This risk was rated as moderate and later proved to be a challenge (further described in Section 2.2).

**Quality at Entry.** A total budget of US\$ 410,000, including US\$ 155,000 trust funds was spent on project preparation. A Quality Enhancement Review (QER), involving several high-level experts on TB control in India from outside the Bank, was held in March 2005. The QER raised several issues which were later addressed in the design, notably relating to institutional capacity, monitoring and evaluation, procurement, and the respective roles of the public and private sectors. In November 2008, a Quality Assessment of the Lending Portfolio (QALP) evaluated the overall probability of achieving development objectives as “Likely,” and concluded that quality of design was “Satisfactory.” The main strengths in the design that the review identified were: (i) the development objectives were “highly relevant, appropriate, and well aligned to the country’s social and economic

development priorities;” (ii) the design was consistent with the government’s strategy and the internationally-accepted approach for TB control; (iii) there was careful attention to coordination with other development partners with harmonization of procedures; (iv) report-based disbursements were used to fill the program’s funding gaps; (v) monitoring and evaluation relied on a well-established and functioning national system; and (vi) the project emphasized reaching the poor, tribal and hard to reach groups. The design weakness identified by the QALP was that the risk of human resource constraints at the service provision level should have been explicitly recognized.

The following readiness steps were completed by project approval: (i) development of a detailed Project Implementation Plan (PIP) by the RNTCP that specified all activities and budgets for the program; (ii) preparation of a Procurement Manual by the CTD along with annual plans for the full project period for contracts to be awarded, and procurement schedules for the first 18 months of project implementation; (iii) a social assessment study and tribal action plan; and (iv) development of the GAAP by the MOHFW in consultation with the Bank.

## **2.2 Implementation**

### **Factors that favorably contributed to the project implementation**

**Support to ongoing program.** Because the project supported an ongoing program, implementation started immediately after credit effectiveness.

**Establishment of institutional arrangements.** Several institutional arrangements were established. These included: (i) decentralization mechanisms and expanding the role of State TB cells and TB Units; (ii) establishment of five additional units in CTD to manage supervision, human resource management, advocacy and communication, finance, and procurement and hiring of contractual staff; (iii) establishing an Empowered Procurement Wing (EPW) within the MOHFW; (iv) development of an IEC strategy for hard-to-reach groups; and (v) development of a national PPM framework.

**Strong government commitment and leadership.** After its rapid expansion between 1997 and 2006, the government was strongly committed to the further development of RNTCP. There was also strong leadership and management of the program by MOHFW. The 2008 QALP singled out these factors as strengths of project implementation.

**Strong supervisory and M&E system.** RNTCP II was supported by a strong reporting system that has been in place for several years. The program had dedicated supervisory staff at the TB Unit (TU), state, district and national levels, who implemented regular and structured field monitoring. This well-established system supported the problem identification process and technical support to states and expedited the progress toward achieving the set targets. The 2008 QALP emphasized the positive effect on implementation of proactive staff in CTD in tracking implementation progress and supporting states in resolving issues as they arose.



**Effective partnership arrangements.** Several bilateral and multilateral partners supported the RNTCP II, with each financing different activities in different states and districts. The GOI was successful in coordinating this support and in establishing one set of systems and procedures to be used by all. Joint Monitoring Missions were led by WHO every three years, while annual joint missions were organized by the Bank. These provided a single forum for technical supervision and support to the program by the Bank and other partners (for example, the 2009 JMM served as the Mid-Term Review of the IDA project).

**Contracted technical assistance.** WHO played an important role in ensuring supervision and technical assistance at the state and district levels. The role of WHO consultants was critical in providing technical assistance and supervision needed for project implementation.

**Harmonization with National Rural Health Mission.** NRHM (launched in 2005) is a central government program designed to strengthen basic health care services in rural areas, including integrating disease-specific programs, such as RNTCP, into sector-wide systems. Therefore, at the time of project preparation, the project team paid adequate attention to ensuring the linkages between the NRHM and project design. During the course of project implementation, the government progressively integrated its financial management systems with those of the project. However, there was variation in the level of harmonization with NRHM across states, as some states used flexible NRHM funding to support TB services, while others did not.

**Focus on governance.** A Detailed Implementation Review (DIR) of procurement under health sector projects financed by IDA in India contributed to a 15-month period between appraisal and Board approval of the TB project (World Bank, 2007). As a result, procurement arrangements for the project were further strengthened, including outsourcing procurement management, and adopting various other accountability measures in the GAAP. These measures may have contributed to some delays in implementation later on, but overall, the strengthened procurement, drug quality, and other measures were implemented and had a positive impact on overall project quality and outcomes. The 2008 QALP found that proactive implementation of the action plan by CTD was one of the main strengths of project implementation.

### **Factors that negatively affected project implementation**

**Human resource constraints.** The rapid expansion and scale up of the RNTCP II presented challenges to the central and state levels to effectively manage the program. Key impediments included shortages of staff at all levels, delayed hiring for key positions (such as IEC Officers), insufficient and high turnover among laboratory technicians, and additional workload and stress on existing human resources due to the introduction of MDR-TB services.

**Difficulties in engaging the private sector.** Two-thirds or more of all health care provision in India is in the private sector and effective engagement between government

and private providers is a challenging issue across the sector. During project implementation, RNTCP successfully engaged with private medical colleges and developed a variety of PPM schemes to collaborate with other for- and non-profit health care providers. However, partly due to administrative inefficiencies, such as delayed payments, the scale of many of the PPM schemes has been limited.

**Integration with general health system administration.** One rationale for the creation of a disease-specific program implemented by state-level “TB Societies” was to avoid the limitations of the overall government health system’s routine administration and procedures. The TB program represents just 2% of the NRHM budget; as the TB program’s administration has become progressively integrated into management of the general health system, some processes have experienced delays, notably relating to financial disbursements and audits.

### **2.3 Monitoring and Evaluation (M&E) Design, Implementation and Utilization**

**M&E Design.** The Results Framework included 2 PDO and 22 intermediate outcome indicators, most of which were technically sound. However, there were a number of deficiencies worthy of notice: (i) the denominator (incidence) for the PDO indicator relating to district-level case detection rates has proven to be flawed in that incidence estimates are based on surveys that are representative of much larger geographic areas (zones) (see Section 3.2); (ii) out of 22 intermediate outcome indicators, 12 had “increasing trends” for targets; (iii) out of the 22 intermediate outcome indicators, 8 did not have a baseline established at project approval, (iv) the use of the international targets for case detection rate (70%) and cure rate (85%) to measure performance at the district level may not have been appropriate, as these rates were already high and increasing them even by a small margin would likely take more time than the life of the project.

The RNTCP II benefited from an existing well-functioning national M&E system which monitored the overall program regardless of financing source. There was a robust national recording and reporting system, with a good structure and well-defined supervision roles and responsibilities at each level.

**M&E implementation.** The program implemented a structured supervision and reporting schedule that cascaded down from the central level to the periphery. Bi-annual national reviews and quarterly state and district reviews were performed using standard indicators, supervision checklists and reporting formats. Data on service delivery are aggregated at the district level which is then compiled at the state level using a computer-based system. The program is currently scaling-up a web-based reporting system which should improve the notification of TB cases.

**M&E utilization.** The program has a well-established review mechanism using the data from the system and the results of the field assessments. Periodic internal and external reviews take place where CTD conducts one thorough state review annually while each state performs its own internal reviews in two districts each quarter. The CTD and states analyze the quarterly reports received from the states and districts and provide feedback

to the districts for further analysis and corrective action. In these evaluations, the focus is on a range of issues including validating program data, sharing implementation experiences by states and districts, and garnering and encouraging administrative and political will and support. In 2011, all states were provided feedback on their quarterly reports while more than 60% of the states provided feedback to their districts for all quarters (GOI MOHFW, 2012a). The M&E data are compiled into numerous quarterly reports and one annual report throughout the year that are publicly available on the web (GOI MOHFW, 2012b). The program also had external reviews by the World Bank team and WHO-coordinated Joint Monitoring Missions were carried out every three years to review progress.

## **2.4 Safeguard and Fiduciary Compliance**

**Safeguard Compliance.** There was full compliance with the Bank safeguard policies during project implementation. The project triggered the Bank's Environmental Assessment safeguard policy, classified as Category B (due to site-specific and manageable environmental impacts). The main environmental issue relates to occupational health and safety and management of infectious medical waste generated from the activities being undertaken at the clinics. At the beginning of the project, the CTD developed an Infection Management & Environmental Plan, which included a strategy for capacity building, waste management and monitoring. The Plan included a caveat that, final disposal from TB centers would be the responsibility of overall facility management of the health system institutions where centers are located, and their scope of influence is therefore limited. The CTD implemented the environment management plan during project implementation, which included revision of training modules, ongoing training of health staff, and encouragement of hepatitis B immunization for health staff, dissemination of guidelines on occupational practices and standard precautions, and establishment of a reporting system on medical waste. During various assessments and supervision mission reviews, it was found that in a majority of facilities, training on the subject had been undertaken satisfactorily, medical waste management systems were in place, and supplies were adequate. Treatment and disposal of sputum cups and slides were being done as per the guidelines disseminated by RNTCP. Many of the facilities have functioning Waste Management Monitoring Committees in place. In Addition to CTD's specific environmental guidelines, the program was also covered under the GOI's national policy of infection control and waste management which allowed this component to be managed under a more integrated approach for various common activities such as training, dissemination of guidelines, budgetary allocations and monitoring.

The project triggered the Bank's Indigenous Peoples safeguard policy, Operational Directive (OD) 4.20, and therefore adopted a Tribal Action Plan, also referred to as the Tribal Development Pan (TDP) in the PAD. This was informed by a 2005 Social Assessment that surveyed TB patients and community members among tribal populations, migrant workers, slum inhabitants, and industrial workers. Based on the Social Assessment, Component 2 aimed at strengthening program outreach to cover marginalized and hard to reach groups such as tribal, rural poor and urban slum dweller

communities. The measures proposed to address this issue were focused on “increasing access of “hard to reach populations” to treatment by bridging information, access and provider gaps; and enabling the disadvantaged groups to overcome socio-economic and cultural barriers. The TAP was prepared in consultation with tribal groups, women, and Civil Society Organizations (CSOs), compliant with OD 4.20 and the measures to address social issues were captured in the DCA. Overall, the project design went beyond the compliance requirements of OD 4.20 to address social inclusion issues.

During implementation, the RNTCP took a number of measures in tribal areas to improve access to TB services, including doubling the per capita number of TB Units and microscopy centers, providing travel allowances to patients and attendants, and funding salary incentives and increased travel allowances for health staff. The program monitored its performance in tribal and poor areas. In 2011, the program completed a second Social Assessment, focusing on tribal and urban slum populations which captured achievements, lessons learned, and the way forward. The TAP was implemented in 85 districts in 19 states, covering 55.4 million people. The SA of 2011 showed that performance of tribal districts with regard to case detection and treatment success was better compared to the poor/backward districts although the number of suspects examined per 100,000 was low in both the tribal and poor/backward districts. Treatment services under RNTCP have performed well; and data recorded in the SA of 2011 suggest that once a TB patient enters the program, the chance of her/his completing treatment and getting cured are high. From a baseline of 79% case detection rate and 86% treatment success rate in 2006, the averages in 85 predominantly tribal districts in 2011 were 80% and 88% respectively. Community participation was encouraged through tribal schools and local bodies; Non-Governmental Organization (NGO) participation was not prominent. Operational research covered tribal areas and other hard to reach populations. The qualitative study examined the knowledge and experience of TB patients (both those who received care from RNTCP and those who did not), as well as other community members. Some respondents went to government health services because of their low cost and the availability of drugs, while others preferred private health care providers due to ease of access and better service. A number of other issues were identified by the SA, including the often long pathway between start of symptoms and initiation of treatment, and economic barriers to treatment such as transport cost and lost wages. Overall, the implementation of TAP was effective and the client continues to expand measures beyond the project to enhance implementation quality and outreach to the hard to reach populations.

**Financial Management Compliance.** Financial management was carried out using the same systems and procedures developed under the first IDA-financed project. These were implemented by CTD and state-level TB “societies,” separate from regular government systems. During project preparation, as part of the broader reforms in the implementation of centrally funded health projects, the government indicated its intention to consolidate the state level health "societies" using common financial management systems for all health programs under the NRHM umbrella. While the Bank supported the overall reforms, it was recognized that this would entail substantial changes at the state level and was flagged as a risk in the PAD. Also specified as financial management risks were the

challenges of ensuring consistency in the quality of financial management arrangements across the states and districts, delays in submission of audit reports, and staffing gaps at the state level. These challenges indeed became evident during implementation. Merging of RNTCP financial management with that of NRHM was a factor in delayed audit reports, including in one case at the end of the project implementation period where a government investigation of alleged corruption under NRHM prevented one state audit report to be submitted. External audit reports continued to point to weaknesses in compliance with the internal control framework, especially with respect to the management of advances, preparation of bank reconciliation statements, uneven quality of accounting records, etc., which often resulted in qualified audit reports. However, the impacts of these issues were successfully mitigated through active follow up by CTD and implementation of remedial action plans. Despite the large scope of the project, the submission of semi-annual Interim Financial Reports was timely and of acceptable quality. Overall, the financial management arrangements were satisfactory.

**Procurement Compliance.** With regard to procurement implementation, MOHFW established an EPW, although during initial implementation of the project there was a lack of clarity about the division of responsibility between this new entity and CTD. Procurement implementation by a contracted agency was planned as an interim measure while MOHFW capacity was developed. A first agent was not contracted until 2007, delaying initial procurement. A second agent was contracted in 2010, and procurement was overall managed satisfactorily although the MOHFW lengthy approval process added significant time to the process. Technical support on inventory management by WHO contributed to effective pharmaceutical supply management by the program. The interim measure of an external procurement agent continued until project closure, while technical assistance to the EPW by the Bank and the UK Department for International Development (DFID) has had limited impact. Nevertheless, there was progress in the development of MOHFW procurement capacity with the establishment of a Central Procurement Agency, while several state governments put in place health sector procurement agencies.

During project implementation, problems were found with procurement at the state and district levels in some states, so that the Bank declared mis-procurement for some contracts. Some items normally procured at those levels were excluded from IDA financing. CTD also enhanced procurement training and on-the-job support, and increased post-procurement audits. These steps were effective in that procurement problems were not evident subsequently.

During project implementation, the government successfully implemented the GAAP. In the area of quality assurance, MOHFW adopted mandatory WHO Good Manufacturing Practices (GMP) certification of bidders, audited the GMP status of winning bidders before contract award (although this led to delays in the contracting process), ensured pre-dispatch and post-delivery quality testing of all procured pharmaceuticals, and sourced first-line TB drugs from manufacturers with WHO prequalified products. The sustainability of some of these measures after project closure is not known, although the

government has stated its intention to strengthen national pharmaceutical quality assurance systems.

Overall, procurement under the project was successful in terms of final outcomes in that all planned procurements were completed, quality assurance measures were implemented, and there were no drug stock-outs throughout project implementation.

## **2.5 Post-completion Operation/Next Phase**

In 2010-2011, the Bank team supported the development of the RNTCP's 2012-2017 National Strategic Plan (NSP), which adopted the objective of "Universal access for quality diagnosis and treatment for all TB patients in the community." This proposed a significant increase in program resources to over US\$ 1 billion in the five year period, about a tripling of the program's budget during the previous five years. The National Strategic Plan involved further expansion of RNTCP's diagnosis and treatment services, scale-up of its response to MDR-TB, piloting of new diagnostic technology, development of information technology (IT) systems, and improved and scaled-up engagement with the private sector. India's recently-adopted government-wide 12<sup>th</sup> Plan (2012-17) endorsed the TB program's objectives along with significant increases in overall government health spending. The government initially requested the Bank for Additional Financing to the project in order to support the RNTCP's new strategy, with particular focus on innovations and pilots in the areas of public-private engagement, IT systems, diagnostic systems, and urban TB services. However, given the large planned increase in domestic funding for the health sector and a focus on fully integrating administrative procedures under NRHM, the MOHFW decided in September 2012 that Additional Financing from the Bank for the TB program would not be required at that time.

## **3. Assessment of Outcomes**

### **3.1 Relevance of Objectives, Design and Implementation (Rating: High)**

#### **Objectives**

**Relevance to current status of TB epidemic.** The objectives of the project remain highly relevant to the current health priorities of India and its efforts to control the TB epidemic. Despite the significant progress achieved by the GOI in curtailing the spread of the disease, India continues to have the largest number of new TB cases annually worldwide with an estimated 2.2 million new cases occurring each year. Moreover, TB continues to be the third most common cause of death due to infectious diseases with an estimated 300,000 Indians dying of TB every year. India's TB epidemic is exacerbated by an increasing number of drug-resistant cases. About 1 in 20 cases in India or an estimated 100,000 annually have drug-resistant TB which requires more aggressive TB control efforts as well as a significantly higher level of resources (WHO, 2012b).

**Alignment with national TB strategy, CAS, and MDGs.** The objectives remain well-aligned with India's latest TB national strategic plan for 2012-2017. The draft plan states the program's vision for a "TB-free India," and articulates the goal of achieving

“Universal Access for quality diagnosis and treatment for all TB patients in the community.” The plan is a continuation of the previous program, building on its achievements while addressing the gaps that existed at the end of the project. The project is similarly highly relevant to GOIs commitment to Goal 6 of the UN MDGs. The program continues to contribute to the global public good of TB control, including reducing the risks of expansion across borders of drug-resistant TB. The project is also consistent with the Bank’s 2009-12 CAS which focuses on increasing the effectiveness of service delivery in the health sector. Since poor and deprived populations are disproportionately affected by TB, this project clearly contributes to the Bank’s mission of reducing poverty.

## **Design**

The design of the project continues to be highly relevant to country conditions. Component 1 (RNTCP services consolidated) remains relevant in that development of the capacities of the program, along with its further expansion, is an ongoing agenda. The 2012-17 draft strategic plan includes continued improvements in information systems, management systems, and human resource development, along with substantial expansion of decentralized administrative and service delivery capacity. Component 2 (RNTCP outreach to target special groups expanded) similarly remains highly relevant, as improvement and expansion of TB services to reach poor and tribal groups continues to be a priority, pediatric TB requires ongoing attention, and drug-resistant TB and engagement with the private sector are major areas of focus for the program’s 2012-17 draft strategic plan.

## **Implementation**

The implementation strategy remains highly relevant, as it continues after the end of the project with domestic funding. The implementation strategies and structures are indeed mainstreamed as an ongoing government program, while the TB program (as was foreseen by the PAD) is being mainstreamed into the broader government health system. The implementation strategy for addressing drug-resistant TB (establishment of the necessary diagnostic and treatment capacity) remains highly relevant. Also, the principles of engagement with the private sector based on incentives and enabling factors remains relevant today as it did at project appraisal. These were applied during project implementation as the public private mix schemes were developed and continue to be highly relevant as the program aims to increase the scale and effectiveness of its engagement with private providers.

### **3.2 Achievement of Project Development Objectives (Rating: Satisfactory)**

The formulation of the PDO in the PAD consists of two elements, each of which is equivalent to a PDO indicator. These PDO elements, bolstered by the various intermediate outcome indicators, can also be considered to reflect aspects of the “higher level objectives” stated in the PAD as well as the project objective as stated by the DCA (see Section 1.2 above).

## **A: Methodology for measuring program performance:**

**PDO 1: to achieve the global targets of 70% case detection and 85% cure rate in all districts of the country.** This first part of the PDO provides an indicator of progress on the broader objective to further expand program coverage to reach vulnerable and other groups with particular needs. This aspect of the PDO is the focus of Component 2 of the project (RNTCP outreach to target special groups expanded) for which 13 intermediate outcome indicators were also specified.

**PDO 2: the incidence of smear-positive TB starts to decline in zones where DOTS has been under implementation for five or more years.** This second part of the PDO is an indicator for broader health outcome objectives relating to reducing incidence, morbidity and mortality due to TB, as well as development of the overall TB program. Component 1 (RNTCP services consolidated) focuses on continued development of the overall TB program in support of these broad objectives, with nine intermediate outcome indicators specified.

## **B: Progress towards achievement of the PDO:**

Overall, the program shows significant achievements with the majority of its indicator targets met. One of the two PDO indicators was over-achieved while the other was substantially achieved. While four intermediate outcome indicators surpassed their targets, 14 were fully achieved and four others showed varying levels of improvement (see Table 2 below).

**Table 2: Progress against indicator targets**

<b>Achievement against targets</b>	<b>Project Outcome Indicators</b>	<b>Intermediate Indicators</b>
Surpassed target (> 100% of target)	1	4
Achieved target (= 100% of target)	0	15
Substantially achieved target ( $\geq$ 60% of target)	1*	1
Partly achieved target (< 60% of target)	0	2**

\*This PDO indicator #2 is counted as “substantially achieved” given that 113% of the target was reached for district treatment success rates and 60% of the target was reached for district case detection rates.

\*\*For both of these indicators (IO #2 and #3) treatment success rate was achieved at 96% for states and 125% for zones. Despite this, these indicators are considered as “partly achieved” because the case detection rate was achieved at 46% of states and 25% of zones.

### **PDO 1: Achieve global targets of 70% case detection and 85% cure rate in all districts of the country (Rating=Satisfactory)**

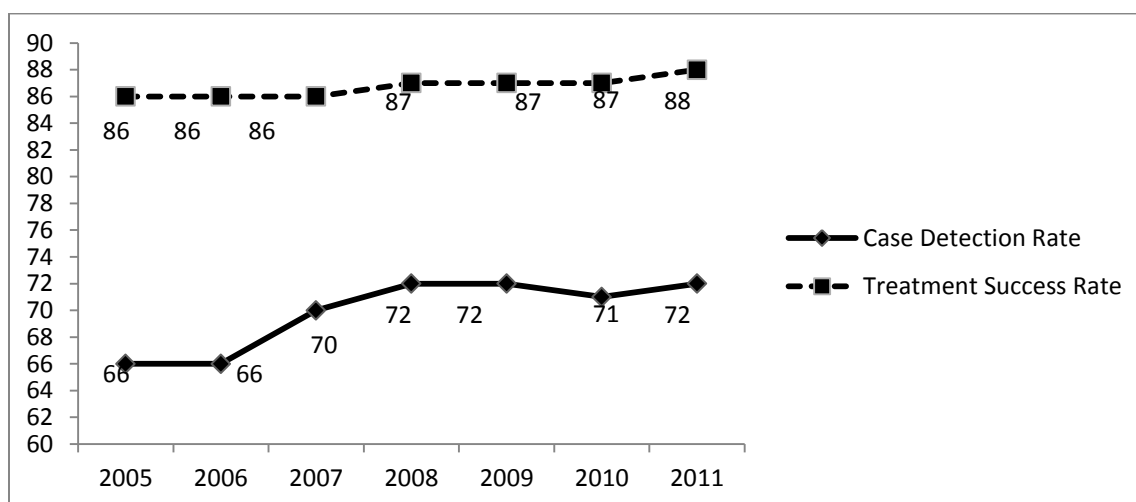
This PDO was chosen to reflect the priority given to improving TB service coverage (and program performance) in districts that were under-performing in relation to internationally-adopted indicators and targets. Detecting at least 70% of estimated smear-positive new TB cases (i.e. the TB bacilli can be observed in sputum smear through microscopy), and curing 85% of those cases, were performance indicators linked to MDG



6, adopted by WHO in 1991 and affirmed by the Stop TB Partnership in 2006 (WHO and Stop TB Partnership, 2006).<sup>1</sup>

Nationally, the program has met the global targets, exceeding 70% case detection (72% in 2011, compared to 66% in 2005) and exceeding 85% treatment success rate (88% in 2011, compared to 86% in 2005). Figure 1 shows that the program maintained high levels of case detection and treatment success rates during the life of the project.

**Figure 1: New Smear-positive TB Case Detection and Treatment Success Rates, 2005-2011 (%)**



Source is GOI MOHFW (2012c).

The target for this PDO indicator was set at 450 districts. Starting from a baseline of 111 districts, 222 districts reached both global indicator targets in 2011. Considering the two global indicators separately, 269 districts reached the case detection target, while 508 districts reached the treatment success target in 2011. There has been substantial improvement since baseline: the number of districts that reached the case detection target between 2005 and 2011 increased by 42% (from 189 to 269), while the number of districts that reached the treatment success rate target increased by 58% (from 322 to 508). The number of districts that reached both targets increased by 100% (from 111 to 222).

The realism of a target of 100% of the districts across India can be questioned given the wide disparities in socio-economic conditions and health system capacities across the country. In addition, although the program continues to monitor case detection statistics at the district level, in 2010, RNTCP suggested to the Bank team that this indicator is flawed in that the denominator – the estimated total number of smear-positive cases in each district, or incidence – is based on data that are not representative of the district

<sup>1</sup> Currently, the internationally-accepted indicator is “treatment success rate,” which refers to patients who are (i) cured or (ii) completed treatment but did not meet the criteria for either cure or failure. (WHO, 2012b) “Cure rate” is no longer reported by RNTCP or WHO.

level (the data are representative of each of four large “zones” into which the country is divided for purposes of incidence surveys).<sup>2</sup>

Like this PDO indicator, several intermediate outcome indicators pertain to improving geographic coverage of TB services. With a baseline of 8 and a target of 28 (the total number of states in the country), the number of states that have reached the global smear-positive case detection and treatment success rate targets was 10 in 2011 (Intermediate Outcome (IO) 2). Thirteen states exceeded the case detection target, while 27 states exceeded the treatment success target. An intermediate indicator and target adopted by the project was to achieve the two targets in four zones.<sup>3</sup> With a baseline of zero, both global targets were achieved in one zone (North) in 2011 (IO 3). While one zone exceeded the case detection target, all five zones exceeded the treatment success rate target. Finally, an intermediate outcome target of 100% population coverage (i.e. availability of RNTCP services according to its norms) was reached as early as 2006 (IO 4).

#### TB Services for Poor and Tribal Populations

An important part of this aspect of the PDO is to improve TB services for poor and tribal populations. The program targeted 145 poor and 85 tribal districts. These districts were provided with special incentives in the form of additional financial and managerial support and implemented special activities to improve detection and treatment success rates. An intermediate outcome indicator referred to the global targets for case detection and treatment success rates in these districts (IO 9). In tribal districts between 2006 and 2011, the average case detection rate increased from 79% to 80% while the average treatment success rate increased from 86% to 88%. With these figures, the program met its targets in tribal districts. In districts designated as poor, between 2006 and 2011, the average case detection rate increased from 55% to 67% and the average treatment success rate increased from 85% to 89%. Thus, the program substantially increased its detection rate and exceeded its target treatment success rate in poor districts.

#### Development of TB/HIV Services

Increasing HIV/TB coordination has been a very positive contribution by the project given the importance and risk of co-infection. Several intermediate outcome indicators are relevant. From 11,331 in 2005, the annual number of people referred for TB testing from voluntary counseling and testing (VCT) services in 2011 was 435,880 (with a cumulative total of almost 1.8 million during the course of the project) (IO 13). The annual number of HIV/AIDS patients referred from VCT services and diagnosed with TB increased significantly from a baseline of 3,034 patients in 2005 to 37,865 in 2011 (with a cumulative total of 189,982 during the course of the project) (IO 14). Similarly, this coordination increased the annual number of HIV-TB patients placed on DOTS, going from 2,047 patients in 2005 to 34,355 in 2011 (cumulative total of 161,288). The

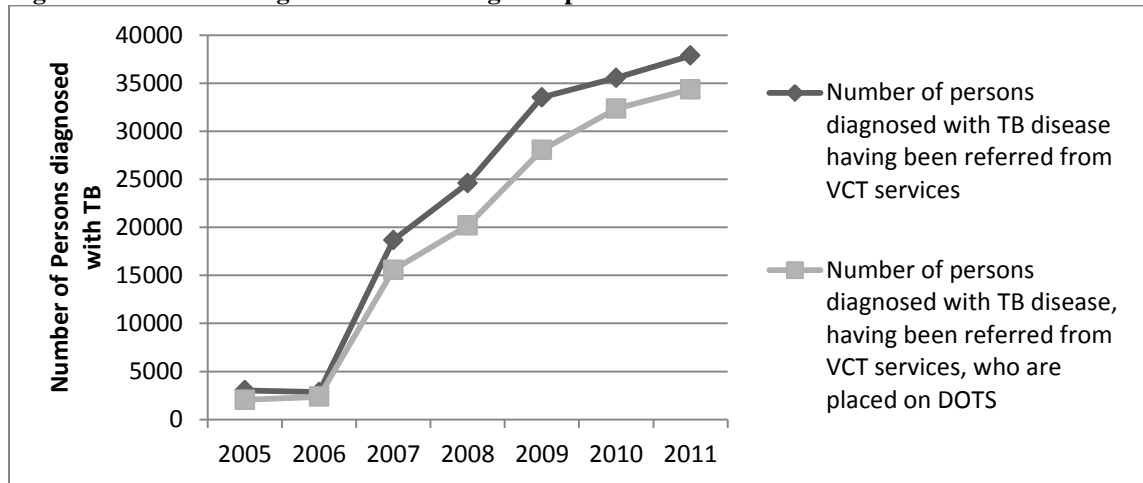
---

<sup>2</sup> It should also be noted that WHO and the Stop TB Partnership no longer emphasize the case detection rate partly due to uncertainties about estimated TB incidence. (WHO and Stop TB Partnership, 2011)

<sup>3</sup> Although incidence surveys are representative of four zones, the program has added a fifth zone (North East) for reporting purposes.

program is making strides in improving the diagnosis of TB among HIV positive patients; however, there still remains room for improvement as the number of HIV positive patients diagnosed with TB, who are referred from VCT services and put on DOTS treatment still lags behind the total number of persons diagnosed with TB after being referred from VCT services as seen in Figure 2.

**Figure 2: Trends in Diagnosis of TB among HIV positive Patients**



#### Improvement in Services for Children with TB

The actual burden of pediatric TB in India is not known due to diagnostic difficulties, but it has been estimated to be around 10% of the total TB load (GOI MOHFW, 2012c). With children constituting 36% (400 million) of the total population, this has important implications on the health system in general and on the TB control program in particular. Pediatric patients put on DOTS increased significantly from a baseline of 59,846 cases in 2005 to 84,064 in 2011 (cumulative total of 598,869 during the project period) (IO 15). With these figures, the program exceeded its targets.

#### Development of Services for Patients with Drug-Resistant TB

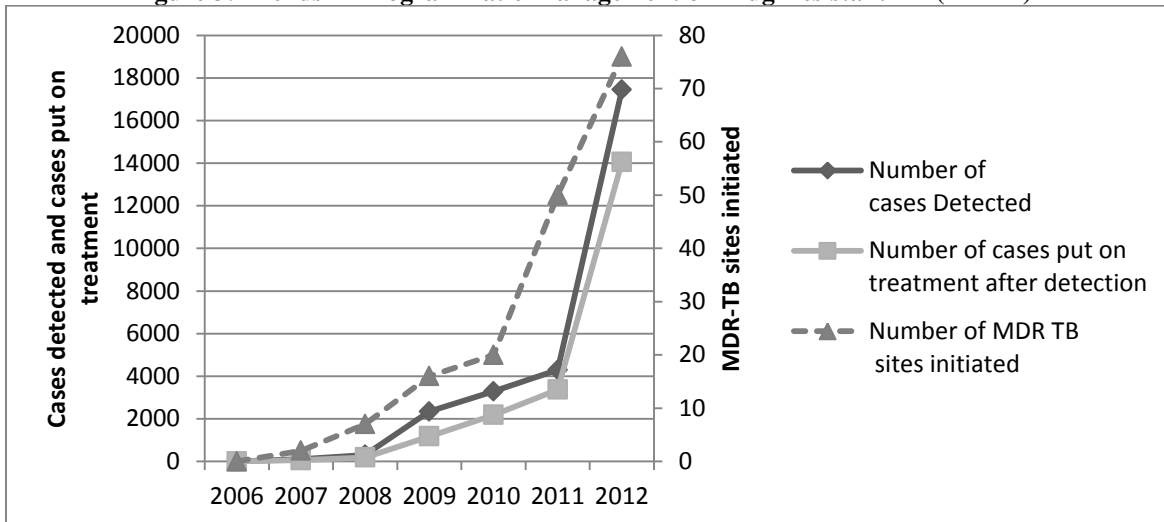
In 2006, it was estimated that MDR-TB contributed 3% of all new TB cases in India and around 15% of retreatment cases. Acknowledging the urgent need to respond to MDR-TB, the program targeted this group with the objective of (i) increasing the number of DOTS Plus sites, (ii) increasing the number of MDR-TB patients put on DOTS Plus treatment, and (iii) increasing the proportion of MDR-TB patients completing treatment.

The MDR-TB program had a slow start, but by 2010, a national scale-up plan was put in place which led to a substantial increase in the number of patients diagnosed and treated (Figure 3), despite the complex challenges. The program was successful in putting a cumulative total of 16,826 MDR-TB patients on DOTS Plus treatment (the intermediate outcome indicator cumulative target was 4,150) (IO 21)<sup>4</sup> and achieved significant

<sup>4</sup> Although the number of MDR-TB patients reached by the program is still small in relation to the total estimated burden, more rapid scale-up was not envisioned by RNTCP during this phase and indeed would have been very difficult given the cost and complexity of diagnosing and treating drug-resistant TB.

expansion of DOTS Plus sites, reaching 71 sites nationwide (compared to a target of 21 sites) (IO 19). However, not all patients completed their treatment. Program results show that 49% of patients completed their treatment compared to a target of 70% (IO 22), illustrating the challenges of MDR-TB treatment.<sup>5</sup>

**Figure 3: Trends in Programmatic Management of Drug Resistant TB (PMDT)**



#### Reaching TB Patients who Seek Care in the Private Sector

A greater engagement of the private sector is essential for increasing TB case detection and treatment and for improving the quality of TB diagnosis and treatment. The private sector plays an important role in the provision of care in India with around 80% of first patients' visits occurring with private providers (Uplekar *et al*, 2001). TB patients are no exception. It is estimated that about two thirds of TB patients treated by the RNTCP have first sought care in the private sector (Kapoor *et al*, 2012). To this end, increasing the engagement of the private sector is crucial for increasing case detection and cure rates.

RNTCP started implementing in 2006 a variety of PPM schemes. The program was successful in reaching the target by increasing the number of NGOs from a baseline of 1,000 to 2,325 participating NGOs (IO10), and from a baseline of 5,000 participating private practitioners to 13,397 (IO11). However, these numbers can be considered inadequate when compared to the size of the private sector in India. Further review of program data in this area shows mixed results (Table 3). While the program made good progress in engaging medical colleges, it was less successful with private providers and NGOs. Medical colleges' contribution to new case detection reached 23% compared to only 5% by private providers and NGOs. This is attributed to several factors including inadequate financial incentives for private providers to engage with RNTCP, delayed payments under the PPM schemes, and lack of capacity at the local levels to fully engage with large numbers of private providers.

<sup>5</sup> Patients identified most easily in the initial phases of scale-up are likely to be suffering from advanced stages of the disease (leading to mortality despite treatment) while the 24-month course of treatment and adverse drug reactions can lead to significant defaulting.

**Table 3: Contributions of the Private Sector to the TB Program**

	Contribution to referral of TB suspects	Contribution to New Case Detection Rate	Contribution to DOTS provision	Contribution to treatment success rate
NGOs	6%	5%	8%	8%
Private Providers	3%	5%	9%	10%
Corporate	1%	1%	1%	1%
Medical Colleges	25%	23%	7%	6%
Gov't, other than Health Dept.	8%	10%	4%	3%
Health Dept.	58%	55%	70%	73%

Source: GOI MOHFW, 2012a

### **PDO 1 achievement: summary**

The number of districts that met the global targets increased significantly during the project period even though it did not reach 100% (which was likely an unrealistic aspiration). Most of the intermediate outcome indicator targets measuring progress towards the broader goal of expanding services to poor and vulnerable groups were fully met while the other indicators were substantially achieved. Therefore, on balance, this PDO can be considered as having been achieved.

### **PDO 2: The incidence of smear positive TB starts to decline in zones where DOTS has been implemented for five or more years. (Rating=Satisfactory)**

This PDO indicator was achieved, surpassing the target of 1.34%. The estimated nationwide incidence of TB declined from the baseline of 1.5% (estimated from a 2000-2001 survey) to 1.1% (estimated from a 2009-10 survey). In spite of issues with the measurement of incidence (WHO and Stop TB Partnership, 2011), there are indications that the risk of TB infection has indeed decreased in India. WHO estimates for annual TB incidence decreased from 209 per 100,000 in 2005 to 181 per 100,000 in 2011. (WHO, 2011; WHO, 2012b) Program performance indicators are suggestive of a decline in incidence. For example, the number of suspects examined for each smear positive case identified has been increasing. The project objective as stated in the legal agreement mentions incidence, reducing transmission, and morbidity. Incidence and transmission are closely-related concepts, while morbidity (which can be measured by prevalence) depends on both incidence and duration of illness. While estimated incidence has decreased, it is also widely understood that RNTCP has reduced the duration of disease by treating a large proportion of cases. This is reflected by declines in estimated prevalence, falling from 358 per 100,000 in 2005 to 249 in 2011.<sup>6</sup> (WHO, 2011; WHO, 2012b)

---

<sup>6</sup> Incidence measures new cases of a disease in a defined time period (i.e. one year), while prevalence measures all cases of a disease (i.e. new plus existing cases) in a time period.

The legal agreement also mentions an aim to reduce mortality, and the program has indeed done so by treating and curing millions of TB patients, many of whom would not have been received care or would have received poor quality treatment. WHO estimated that the TB mortality rate in India was 36 per 100,000 population in 2005 and 24 per 100,000 in 2011. (WHO, 2011; WHO, 2012b)

As indicated earlier, the stated project objective of decreasing incidence is a function of how well the program performs in setting up the systems needed for implementation. This was to a large extent achieved through service consolidation and quality (Component 1) which are analyzed in the following section:

Overall program performance in terms of global indicators is described in Figure 1 above. Table 3 below provides absolute numbers of suspects tested, cases identified, and cases cured, through RNTCP’s network of more than 13,000 designated microscopy centers (DMCs) and 400,000 DOTS providers, as well as the program’s private sector partners. This data shows that the program successfully maintained the achievements after its rapid scale-up before 2006, while continuing to expand coverage. In addition, as mentioned above, during the project period, RNTCP has started to scale-up services for drug-resistant TB, providing care to a total of 16,826 cases.

**Table 4. RNTCP beneficiary numbers, 2006-11 (million)**

	suspects examined	smear-positive cases diagnosed	smear-positive TB cases put on treatment	total TB cases put on treatment
2006	6.22	0.83	0.75	1.40
2007	6.48	0.88	0.79	1.47
2008	6.82	0.91	0.82	1.52
2009	7.25	0.93	0.83	1.53
2010	7.55	0.94	0.83	1.52
2011	7.88	0.95	0.84	1.52
Total	42.2	5.44	4.86	8.96

Source: GOI MOHFW, 2012c

The program identified four areas in Component 1 that are critical for consolidating and improving the quality of services. This included improvements of laboratory services, supervision and monitoring, operations research, advocacy and health communication, and strengthening of institutional capacity to implement the program.

Quality of laboratory services: Part of the program’s success for improving TB case detection involved the support for substantial physical expansion of laboratories at the state level that provide quality diagnostic services. By 2012, a network of 42 IRLs was established, exceeding the intermediate outcome indicator target of 24 laboratories (IO 18). This was supported by the development of an accreditation system that was put in place to monitor the quality of diagnosis and staff performance. Nevertheless, despite the progress made in achieving the targets set by the project, several evaluation reports

indicate that systemic problems exist that hinder program progress in this area – mainly, poor quality of the lab infrastructure and high turnover rate among lab technicians.

Supervision and monitoring: The project started with an existing well-functioning and robust national monitoring system and continued to strengthen the system of supervision at all levels. Several achievements were made including systematizing the evaluation process of states and districts' operations, standardizing the bi-annual and quarterly reviews that led to doubling the number of districts for in-depth evaluation per month, improvement actions, and computerizing the system at the state level with the introduction of a web-based reporting system. Having a strong and improved monitoring system contributed directly to improving the quality of TB services.

Operational Research (OR): The purpose of OR is to generate an appropriate and continuous flow of information around priority topics that will strengthen service delivery and demand for TB services. Several achievements have been made during the course of the project lifetime including, establishing a State and National Steering Committees, identifying 70 OR areas and engaging medical colleges in the process. Efforts by the RNTCP have been encouraging, and in 2011 alone, there were a total of 62 OR proposals submitted to the zonal OR committee for review. In 2011, the CTD also established its first OR course in collaboration with a number of partner agencies.

Information Education and Communication: An important element for reaching program objectives was to address the social determinants of the disease through community-based approaches. In that regard, the project aimed to focus on three IEC strategies: (i) creating awareness of TB symptoms and demand for DOTS services; (ii) advocating for policy, and (iii) enhancing patient-provider communication and counseling.

Achievements in IEC were slow at the beginning of the project but picked up at a later phase. Several organizational issues were needed to lay the ground for IEC operations such as establishing, staffing and training IEC officers at state levels and communication facilitators at the district levels. The program surpassed its targets with indicators showing a substantial increase in the level of awareness about free cost of TB drugs for TB diagnosis and treatment, from a base-line of 16% in 2007 to 84% by 2011 (IO7). 51% of targeted communities were also aware that DOTS is the right way for treatment and 84% were aware that TB treatment is free at government facilities (IO7). Awareness among government providers showed even a more dramatic increase going from 52% in 2007 to 97% in 2011 (IO6).

To focus and strengthen IEC activities, the project also established two posts to support states and districts in their activities. At the state level an IEC officer post was established and at the district level, communication facilitators were put in place to encourage and strengthen the IEC component within the program. Despite this progress, it must be noted that during ICR interviews some partners expressed concern that achievements in IEC need to be sustained in order to continue to underline the seriousness of the TB epidemic which may not be sufficiently realized outside the RNTCP.

Institutional capacity: Overall, the program supported the expansion of institutional capacities and the effective implementation of national strategies and policies under the stewardship of the MOHFW. The project assisted in establishing and staffing several key positions and initiated a wide range of capacity building and training activities. As of 2012, the majority of the endorsed positions were filled and trained. This included 90% of District TB Officers (DTOs), 82% of DOTS-Plus and HIV-TB supervisors, 94% of Senior TB Lab Supervisors (STLS), 100% of data entry operators.

### **3.3 Efficiency (Rating: High)**

Disability-adjusted life years (DALYs) are a frequent measure of health benefits in a population. DALYs are the years of life saved due to an intervention, adjusting for disability incurred by a disease over the course of individuals' lifetimes. Generally, health interventions that cost less than US\$ 100 per DALY gained are considered highly cost-effective. Among many other studies, The Disease Control Priorities Project, supported by the World Bank, has analyzed the cost-effectiveness of the DOTS strategy and found it to be "among the most cost-effective of all interventions available to improve health" in low and middle-income countries (Jamison *et al.*, 2006).

In 2007, a study estimated the cost-effectiveness of the RNTCP program between US\$16 (for smear positive patients) and US\$63 (for smear-negative patients) per DALY gained (Chow *et al.* 2007). In 2011, another study estimated the cost-effectiveness ratios between US\$21 and US\$35 per DALY gained between 1997-2006. Data also suggest that cost per DALY gained in 2006 was as low as US\$ 19 (Goodchild *et al.*, 2011). RNTCP is by far situated at the lower end of the cost per DALYs gained when compared to other health interventions (See Annex 3).

Cost-benefit analyses have been conducted to determine the economic burden of the TB program in India. In a 2007 study that projected the cost-benefit ratio of DOTS from 2006-2015, it was estimated that provision of DOTS in India would avert 3.2 million deaths with an economic benefit of more than US\$ 350 billion or US\$ 191 per dollar spent (Laxminarayan *et al.*, 2007) (See Annex 3).

Between 1997-2006, RNTCP treated 6.3 million patients. This led to a total health benefit of 29.2 million DALYs gained and 1.3 million deaths averted. Analyses also indicate that in terms of TB patients, each case treated under DOTS in India results in a gain of 4.6 DALYs and US\$13,935 in economic benefits. The total economic gain was US\$19.7 billion in 2006 and US\$88.1 billion from 1997 to 2006. The return per dollar spent was US\$115 from 1996 to 2006. Following full DOTS coverage in 2006, the return per dollar spent increased to US\$155. The cost per DALY gained from 1997 to 2006 was US\$26. After introduction of countrywide DOTS coverage, the cost per DALY gained fell to US\$19 per DALY gained (GOI MOHFW, 2012c). The scale-up of TB control in India is therefore highly cost-effective and yields very high rates of return.



### **3.4 Justification of Overall Outcome Rating**

The project's overall outcome rating is considered Satisfactory based on the following justifications:

- (i) Project relevance was, and remains high and alignment with country priorities and development strategies.
- (ii) Most of the PDO objectives and supporting indicators including addressing inequities were achieved and several were surpassed.
- (iii) Strong, robust supervision and M&E system.
- (iv) The project was implemented in an efficient way and the credit was fully disbursed at closing.
- (v) The project yielded high returns on investment.

### **3.5 Overarching Themes, Other Outcomes and Impacts**

#### **(a) Poverty, Gender Aspects, and Social Development**

TB is widely recognized as a disease of poverty which is associated with major relevant risk factors such as over-crowding, under nutrition, and poor environmental conditions. Also, the negative economic impacts of TB on the population have been well documented. The disease disproportionately affects the most productive age groups thus reducing their ability to work and resulting in lost potential earning. To this end, the control of the disease clearly contributes to poverty reduction and addresses inequities in health service provision. Research on health seeking behavior among RNTCP patients has also found that lowest income quintiles typically take a longer time to seek medical care (5.8 months) when compared to other income quintiles (Kapoor *et al.*, 2012). Thus, while the project clearly targets special groups with an explicit focus under Component 2, more focus could have been given to targeting equally vulnerable groups such as prisoners, persons living with TB patients, and urban slum populations.

The project did not have a gender-based approach. It would have been useful to address it since the impact of the disease and health seeking behavior related to it is affected by gender. While two thirds of all the TB cases in India are male (1.8:1 male to female patients diagnosed with pulmonary TB in a study conducted in 2012 (Kapoor *et al.*, 2012)), TB significantly affects young females with 50% of the cases occurring before the age of 34. Research on RNTCP patients has also found that females typically obtain care later (6.3 months) than men (3.8 months) (Kapoor *et al.*, 2012). Similarly, ICR team discussions with MDR-TB providers indicated that the majority of current MDR-TB patients are males and that females tend to seek treatment at a more advanced stage of the disease than men. Despite this, however, successful treatment outcomes are found to be higher among females (84%) than men. Clearly, more analysis needs to be done in this area to better understand gender determinants of care.

#### **Institutional Change/Strengthening**

Institutional strengthening has been a central theme of the Bank's engagement in the TB program. Progress in the area of institutional building includes:

- The formulation of the RNTCP's National Strategic Plan (2012-2017). The Bank team worked closely with the CTD to develop a comprehensive strategic plan, building on what has been achieved so far and focusing on the priorities in the next phase.
- Strengthening governance and setting accountability measures. Despite apparent deficiencies in procurement at the early stages of the project, several procurement arrangements and accountability measures were put in place. This included establishing the Central Procurement Agency, while several state governments put in place health sector procurement agencies, out-sourcing procurement management, and adopting quality assurance measures through the WHO GMP certification of bidders.
- Strengthening decentralization mechanisms and expanding the role of State TB cells and TB units.
- Improving the capacity for IEC as evident with the formulation of an IEC strategy for hard to reach groups, establishing an IEC unit at the central level to plan and oversee the program, and hiring and training of 35 IEC officers.
- Continued strengthening of the supervisory and monitoring system evident in the well-established review mechanism with periodic internal and external reviews at all levels. States typically conduct internal evaluations of two districts per quarter while the center also provides quarterly feedback to a minimum of two states (GOI MOHFW, 2012c). Improvements also included automation at the state level and the introduction of a web-based reporting system.

### **3.6 Summary of Findings of Beneficiary Survey and/or Stakeholder Workshops**

Not applicable.

## **4. Assessment of Risk to Development Outcome**

### **4.1 Assessment of Risk Development Outcome (Rating: Low)**

The GOI is highly committed to the RNTCP agenda and is continuing to support it. This is reflected in its draft National Strategic Plan for TB Control (2007-2012) which adopted a new objective of Universal Access to quality TB services along with significant planned increases in the program's budget, in line with overall government health spending. There is strong ownership of the program by the MOHFW supported with effective and strong leadership in CTD. Capacities have been built at central and decentralized levels and better fiduciary management and procurement systems are in place. The robust M&E system continues to provide a solid foundation for implementing the program with improved data recording and supervisory capacities at state and district levels. All of this provides a sound basis for sustaining project momentum and results. Therefore, the risk to development outcomes of the project is rated as Low.

Moving forward, however, the TB program faces several challenges. The ambitious scale-up of the RNTCP and the technical rigor required to effectively manage and implement the program may be beyond the current institutional capacities to implement the program with adequate supervision and quality control. According to the draft of the

2012 JMM report, the strategy to achieve universal access will require a threefold increase in the number of senior treatment supervisors along with training and capacity building of staff. Similarly, scaling up of the MDR-TB program will require strong health systems, advanced diagnostic technologies, and high level of technical skills that are not adequately available and may take a long time to develop. The low participation of the private sector in RNTCP and its low contribution to case detection rates is a critical hindrance to reaching the program's goal of universal access.

Another challenge is the integration of the program with NRHM, particularly as the program becomes less independent with regard to human resource and financial management. According to several supervisory and monitoring reports and to ICR team discussions with state-level administrators, the program is experiencing delays in the release of funds, in payment of salaries, and in filling currently vacant posts (around 20%). Moreover, there are complaints of the high turnover rates among staff associated with increased workload as state and district officials are charged with several tasks besides TB. There needs to be continued efficient streamlining of RNTCP operations within NRHM structures along with systemic improvements and strong technical support to the states and district levels. The RNTCP is aware of all these challenges and is actively addressing these issues in the new strategy.

## **5. Assessment of Bank and Borrower Performance**

### **5.1 Bank Performance (Rating: Satisfactory)**

#### **(a) Bank Performance in Ensuring Quality at Entry: (Rating: Satisfactory)**

The Bank team worked closely with GOI and other stakeholders, including donor partners, to design a technically sound project. The project was responsive to an urgent need to improve TB control and response in India which was a global and local public good. The risk assessment was comprehensive and the ratings on (i) strategic relevance and approach, (ii) technical, financial and economic context, and (iii) environmental and social safeguards policies were appropriate.

In 2005, a QER was conducted, the results of which were addressed by the team in the project design. During preparation, the Bank worked with partners (Global Fund, USAID, DFID, and WHO) and GOI and agreed on a shared results framework and on the estimated costs and overall financing plan for the program. The Bank team also took adequate measures to mitigate procurement risks by establishing mechanisms and processes. The Bank team collaborated well with the CTD regarding the Detailed Implementation Review (DIR) which led to strengthening of financial and procurement arrangement and to the implementation of the GAAP.<sup>7</sup>

---

<sup>7</sup> A Detailed Implementation Review (DIR) of five health projects in India, including the RNTCP I was initiated in September 2006, completed in October 2007 and made public in January 2008.

The Bank team demonstrated good coordination with CTD in resolving implementation issues. For the triggered environment and social safeguard policies, to mitigate the negative impacts on the project, a biomedical waste management plan and a tribal action plan were developed, as required by the Bank policy. The results framework was on balance sound. However, as mentioned previously, the decision to target 100% of districts reaching global targets was ambitious. Likewise, measurement problems with the use of districts, instead of zones, to measure case detection rates, did not provide accurate data regarding district level achievements. Importantly, however, the team worked closely with the Government and other partners to align the results framework with the overall program and to measure outcomes against the same set of indicators.

**(b) Quality of Supervision (Rating: Highly Satisfactory)**

This project required intensive supervision given its large scope, wide range of activities, and multiple partners involved. Supervision was also made more challenging with the initiation of the DIR which coincided with project effectiveness. These were challenging times for the health sector in India, but despite that, the Bank team handled the situation very well and continued to work closely with the counterparts. The team worked effectively to incorporate lessons and findings into several readiness steps and mitigation measures which subsequently led to the strengthening of the project, especially in terms of procurement and financial management.

The Bank maintained close supervision of the operation and provided intensive support and oversight during project implementation. The supervision missions were critical for problem identification and solving, hence facilitating project implementation, as highlighted by government counterparts during the ICR mission in January 2013. Two large Joint Monitoring Missions (JMM) (2009 and 2012) were conducted with international partners and GOI, while the Bank led annual review missions involving other partners. Six annual reports, eight Aides Memoire and 12 Implementation Status Reports (ISRs), adequately and candidly documented project implementation progress, key implementation issues and actions to be taken to resolve them. Implementation Progress towards the PDO was thoroughly reviewed and the key indicators and assessment results systematically documented.

During the five years of project implementation, the task leadership on the Bank side changed three times. However, this did not negatively impact the ability of the team to ensure effective implementation support. Hand-over arrangements were successful throughout project implementation.

Bank supervision paid adequate attention to all financial management (FM) aspects: detailed verification of financial management reports (FMRs) which provided the basis for disbursement of Bank funds, successful mitigation measures to delays in audit reports caused by the merging of RNTCP financial management with that of NRHM, and active dialogue with CTD on shortcoming in the accounting procedures of states as identified in audit reports and field visits.

Overall, the ICR team received very positive feedback from counterparts and partners regarding the role of the Bank during the course of the project. They praised and commended the Bank team for its supportive supervision and the rigor with which the Bank team helped to keep the project on track. They also emphasized the important role the Bank played in providing high quality technical skills and in keeping operations focused on achieving program objectives.

What also stands out in this project is the effort to which the Bank team went to establish collaboration and effective relationship with partners. The team was successful and effective in establishing a common and consistent approach among the partners to achieve program goals.

**(c) Justification of Rating for Overall Bank Performance**

The overall Bank performance is rated as Satisfactory. The project was well prepared despite the measurement problems with some indicators, and extremely well supervised. The Bank team was responsive to emerging situations and collaborated well with the GOI to implement the results of the DIR.

**5.2 Borrower Performance**

**(a) Government Performance (Rating: Satisfactory)**

The strong commitment and ownership of the GOI to health in general, and to the RNTCP in particular, is evident. A national strategic plan for 2012-2017 has been developed and institutional arrangements to sustain the program were put in place before the end of the project. Total central GOI spending on health is planned to increase from around US\$ 16 billion in 2002-2007 to an anticipated US\$ 55 billion for the period 2007-2012. Consequently, GOI's allocation to the RNTCP is planned to increase from 1.3% of total spending in 2002-2007 to 1.5% in 2007-2012, thus tripling the amount (in absolute terms) spent on TB. Considering that a large proportion of the TB program's funding for the period 2012-2017 is planned to come from central government funding reflects a serious commitment by the government to the control of TB. Moreover, the program is embedded in state government health services where it is executed through a five tiered network, comprising the Central TB Division in the Ministry of Health and Family Welfare, State TB officers, District Tuberculosis Centers, Tuberculosis Units, and peripheral health facilities. Administrative and clinical staff are available at each of these levels to implement the program.

The emergence of the NRHM with RNTCP falling under its umbrella ensured the highest levels of political commitment and ownership to the program at all levels within the country. This integration offered some opportunities to strengthen the RNTCP as demonstrated by additional resources in terms of laboratories, stores, lab technicians and the involvement of Accredited Social Health Activists (ASHAs) as DOTS providers. This integration, however, was challenged by the weak fiduciary and management capacities at the state and district levels which led to delays in recruitment and disbursement of funds.

**(b) Implementing Agencies' Performance (Rating: Satisfactory)**

The CTD showed strong commitment to program objectives and implementation strategy and ensured effective coordination among partners. It has demonstrated solid managerial and technical skills. CTD established an appraisal system which standardized the selection process of districts for DOTS implementation. It focused on strengthening supervision and technical assistance at central and state levels and continued to regularly review performance at the state and district levels and intervene with targeted strategies in low performing districts. CTD has been proactive and cooperative in implementing the post DIR action plan, and in adopting the GAAP which focused on mitigating procurement deficiencies by setting relevant arrangements that had a positive impact on the project. However, the chronic human resource deficiencies during project implementation and the slow disbursement of funds in some states as a result of program integration within the NRHM structures negatively affected the progress in program implementation.

**(c) Justification of Rating for Overall Borrower Performance (Rating: Satisfactory)**

A satisfactory rating for government performance and a satisfactory for the implementing agency performance resulted in an overall borrower performance rating of Satisfactory.

**6. Lessons Learned**

A number of country-wide lessons and recommendations to improve performance of this program have been made in numerous assessments and reports over the last several years. The following are key lessons that have been derived from the implementation of this project:

**Government commitment, leadership and support are paramount for increasing case detection and cure rates.** There are several examples that attest to the important role the central government can play in pushing implementation forward towards achieving program goals. For example, the MDR-TB scale-up plan that the government set in late 2010 led to a dramatic increase in the number of MDR-TB cases detected and put on treatment. Similarly, the “National framework of Joint TB/HIV” set in 2009 led to a significant increase in case detection of HIV patients with TB and their referral for DOTS. Similar focused efforts are needed to increase the engagement of the private sector and NGOs and increase their potential for case detection and notification. Without involving the private sector many TB patients will continue to be outside the reach of the RNTCP.

**Sharpening the focus on targeted groups and setting realistic project targets.** Combatting TB is a complex and a long term operation. Increasing prevention, case detection and treatment of TB and reflecting that in national figures will take a long time to become visible. When high levels have already been achieved, further increases in case detection or cure rates will be more difficult to achieve. Hence, having realistic project targets within the life of the project are critical to guide future implementation. This should be associated with a strategic selection of targeted groups. Sharpening the focus of the program on specific groups with higher probability of TB case concentration will

bring more return on investment. This indicates focusing efforts on groups such as the urban poor and slum areas, prisons, and individuals living with TB patients.

**Investing in new technologies is essential for moving the program to its next phase of universal coverage.** Adopting newer diagnostic technologies is more technically appropriate and cost effective in the long run. It will ensure early detection of cases with greater sensitivity and will reduce diagnostic delays, thus slowing down the chain of transmission and preventing drug resistant TB. Similarly, leveraging the growth in information communication technology by using more integrated information systems will expedite the transfer of test results between laboratories and treatment services, and will allow for timely referrals and treatment.

**The need for more information regarding the emergence of MDR-TB in India.** More work should be done to find out the reasons behind the emergence of MDR-TB and how to mitigate the incidence through lessons from other countries. Understanding the gaps in DOTS program operations that may have contributed to MDR-TB is crucial for developing an effective MDR-TB strategy. While the draft National Strategic Plan for 2012-2017 puts a lot of emphasis on MDR-TB detection and treatment, more concurrent efforts should be given to MDR-TB prevention.

**More focus on quality.** As the program expands rapidly to reach its objective of universal access, more attention and diligent efforts should be given to the quality of services through a systematic approach using quality improvement methods and approaches. There is a critical need for high quality DOTS and DOTS Plus diagnosis and follow-up and that would require high quality centers and institutions. Improving the quality of physical infrastructure of the laboratories, improving biosafety measures and medical waste management practices, strengthening the training and technical capacity of providers to improve the quality of clinical care, and improving the quality of supervision and reporting are critical for the success of the program.

**Addressing gender issues should be integral to program design and operations.** The current program does not focus on the impact of the disease on gender. While research studies have been conducted on the differentials in health seeking behavior among males and females under RNTCP, more work needs to be done to incorporate this research into policy by integrating such findings into the program to ensure that services are being accessed and preventive efforts are in place to mitigate relapse rates among males and females alike. Such targeted efforts will help yield better program results by reducing transmission rates and incidence of MDR-TB, in addition to many other health outcomes. Documenting health seeking behavior by gender and the social factors that impact it could provide useful lessons for TB program in India and for other countries.

## **7. Comments on Issues Raised by Borrower/Implementing Agencies/Partners**

Not applicable.

## Annex 1. Project Costs and Financing

### (a) Project Cost by Component (in USD Million equivalent)

Components	Appraisal Estimate (USD millions)	Actual/Latest Estimate (USD millions)	Percentage of Appraisal
<b>Total Baseline Cost</b>	212.5	232.2	109%
<b>Total Project Costs</b>	212.5	232.2	109%

### (b) Financing

Source of Funds	Type of Cofinancing	Appraisal Estimate (USD millions)	Actual/Latest Estimate (USD millions)	Percentage of Appraisal
Borrower		42.50	55.2	130%
International Development Association (IDA)		170.00	178.85	105%



## Annex 2. Outputs by Components

<b>Component 1: RNTCP Consolidated</b>
Establishment of IDA mission and launch of project with key staff
Establishment of a network of National and Intermediate Reference Laboratories <ul style="list-style-type: none"> <li>- 1 new National Reference Laboratories (NRL) established in Agra (3 others already established in Chennai, Bangalore, Delhi)</li> <li>- 31 state level IRLs</li> <li>- 3 Accredited private IRLs.</li> <li>- Provision of culture and drug susceptibility testing (DST) equipment in 13 laboratories</li> <li>- Culture and anti-TB drug susceptibility testing available in 43 laboratories</li> <li>- 7 culture and DST labs in the private health sector have been established</li> </ul>
Accreditation protocol and External Quality Assessment for Smear Microscopy established
Manual on Fluorescent Microscopy developed for use as reference materials by IRLs and other labs.
29 Laboratories (4 NRLs, 16 IRLs, 6 medical colleges, 3 NGOs/Private Labs) are providing line probe assay services for programmatic management of MDR-TB
Establishment of 13,039 Designated Microscopy Centers <ul style="list-style-type: none"> <li>- One DMC per 100,000 population and one DMC per 50,000 population in tribal and hilly areas</li> <li>- Quality Assurance consisting of “on-site evaluations” regularly conducted by Senior Tuberculosis Laboratory Supervisors</li> </ul>
Assessment of 11 laboratories for culture and DST conducted by Bank Consultant
Supervision and Monitoring Strategy established: CTD conducts in-depth supervision for 2 states per month while states conduct in-depth supervisions at least 2 districts in their state per month. DTO prepares district-level quarterly reports.
Establishment of Supervision and Monitoring Component by doubling the number of districts for in-depth evaluation per month
Windows-based EPICENTRE software developed and piloted in 5 states to collect, transmit, validate, analyze and provide feedback of program surveillance data
Establishment of National Steering Committee and State Committees for Operational Research
Development of Operations Research Action Plan
Identification of 70 priority research areas/topics through extensive consultative process
Establishment of Central level Procurement of drugs through RITES (GOI procurement agency) for World Bank funded states
Procurement of goods of the following value using Bank funding: <ul style="list-style-type: none"> <li>- Pharmaceuticals and Medical Supplies: USD 9.344 million</li> <li>- Goods, works, services, and incremental operating costs: USD 146.3 million</li> <li>- Consulting services: USD 927,000</li> </ul>
Disbursement profile on Oct 2012 at 89% of original credit of SDR 115.7 million
Development of simplified booklet on procurement for states and districts
Development of a procurement monitoring and complaints database <ul style="list-style-type: none"> <li>- System in place to collect state/district level procurement related data</li> </ul>
Development of a software for use in early identification of indicators of fraudulent or corrupt practices

Establishment of Working Group for Procurement and Supply Management issues - Report produced and included in JMM 2009 document
Establishment of IEC Advisory Group including 7 RNTCP members and 10 outside members drawn from government, academia, NGOs, and professional communication groups.
IEC Baseline Data established
Development of IEC Baseline document
Conducted a media campaign - Three radio and TV spots developed
IEC officers provided to each State to plan and implement Advocacy Communication and Social Mobilization (ACSM)
Communication facilitators, provided to districts to help plan and implement ACSM activities
Expansion of Institutional Capacity - 92% sanctioned District TB officers in place of which 91% are trained - 82% of sanctioned DOTS Plus and TB-HIV supervisors in place of which 76% are trained - 94% of sanctioned Senior TB lab supervisors trained - Almost 100% of sanctioned data entry operator positions filled by trained staff
Completion of the following trainings - Training for master trainers from Gujarat and Maharashtra on DOTS-Plus activities conducted - 25 IEC officers trained in a five day course - 285 Program Managers trained - 130 staff trained on procurement and drug logistics in five workshops - 334 personnel and master trainers (DTOs, STOs, State TB and Demonstration Center (STDC) directors and faculty from medical colleges) underwent training - 108 DOTS-plus implementers trained - 39 medical officers trained on TB-HIV collaborative activities - Data management team training - National DOTS Plus trainings undertaken in Orissa, Uttar Pradesh, Andhra Pradesh, Rajasthan, Tamil Nadu, West Bengal, Gujarat and Maharashtra - 25 batches of National PMDT trainings organized in 2011 where about 800 key officials from the state and district levels were trained
Other Training related Activities Completed - Development of manual for laboratory technicians on infection control, waste treatment and disposal. - Guidelines for storage of 2 <sup>nd</sup> line Anti-TB drugs at State Drug Stores (SDS), District TB Center (DTC), and TB Unit levels finalized and circulated to all states for implementation - Revision of training modules and refresher training - Development of modules for training of private practitioners - Training on external quality assurance - Training on use of pediatric boxes - Use of existing clinical, financial, and administrative data for decision-making and ensuring equity - Video conferences by CTD every six months with State TB Officers, Chief Medical Officers, and District TB Officers - Undertaken review of Training modules for program managers
Completion of the following workshops - Review of RNTCP training activities organized by Indian Council for Medical Research (ICMR) and WHO

<ul style="list-style-type: none"> <li>- 9 zonal task force meetings conducted to involve medical colleges</li> <li>- National workshop for state presidents/secretaries and RNTCP coordinators in Haryana where Indian Medical Association (IMA) formulated the National Action Plan</li> <li>- 8 National PMDT Committee Meetings held</li> <li>- 6 regional PMDT review meetings conducted in 2011-12</li> <li>- Workshop with corporate companies like Jubilant Organosys etc.</li> <li>- 4 National level orientation workshops on revised External Quality Assessment guidelines for implementation of quality improvement processes in RNTCP lab network</li> <li>- Combined training workshop for STOs and IEC officers</li> <li>- Capacity building OR workshop conducted</li> <li>- National OR dissemination workshop</li> <li>- Four workshops arranged in Bihar, Jharkhand, West Bengal, and Haryana for staff handling procurement at state and district levels</li> <li>- 3 workshops conducted in 2011 that identified 16 research topics, development of study protocols, reviews of literature, ethics committee clearances, administrative approvals, data collection and analysis and final presentation of research papers</li> <li>- Workshop on TB disease burden estimation for India, 2010 was organized by Central TB Division at LRS Institute of TB and Respiratory Diseases, New Delhi</li> <li>- An 'Intermediate Reference Laboratories Experience Sharing Workshop' was held in December 2011 for State TB Officers, Microbiologists and RNTCP Consultants</li> </ul>
<p>Undertaken the following studies</p> <ul style="list-style-type: none"> <li>- 2 Annual Risk of TB Infection (ARTI) studies conducted in Andhra Pradesh and Kerala</li> <li>- 7 Prevalence Surveys</li> <li>- Operational feasibility and cost-effectiveness study for the use of new rapid molecular diagnostic technology for MDR-TB in 18 sites being conducted.</li> <li>- 7 OR studies approved by the National OR Committee of which 2 have been completed and 5 are ongoing</li> </ul>
<p>Terms of Reference developed for collaboration with an institute for designing and implementing a workshop for STOs and IEC officers</p>
<p><b>Component 2: RNTCP Outreach to target Special Groups Expanded</b></p>
<p>Establishment and development of Tribal Action Plan</p>
<p>Integration of RNTCP Action Plan with The NRHM Program Implementation Plan</p>
<p>Conducted Social Assessment to determine who was not being reached during RNTCP Phase I</p>
<p>Expansion of Public-Private Mix Activities with involvement of:</p> <ul style="list-style-type: none"> <li>- 297 medical colleges</li> <li>- 1971 NGOs</li> <li>- 10,894 private practitioners</li> <li>- 150 corporate sector facilities</li> </ul>
<p>Intensified TB-HIV package is being rolled out in 29 states</p>
<p>TB/HIV and DOTS-Plus supervisor post established in all districts</p>
<p>Establishment of National Technical Working Group</p>
<p>Establishment of Joint TB/HIV framework in 14 states with high HIV prevalence outlining collaborative activities between the programs</p>
<p>“10 point counseling tool” on TB developed by RNTCP for use by counselors in Voluntary Counseling and Testing Centers.</p>
<p>Pilot testing of decentralized mechanism for cotrimoxazole preventive therapy for HIV positive TB patients undertaken in collaboration with National AIDS Control Organization (NACO) in 3</p>

districts of Andhra Pradesh
The training of trainers in Intensified TB-HIV package for the four UTs of Puducherry, Andaman & Nicobar Islands, Dadar & Nagar Haveli and Daman & Diu was held in October 2011.
Patient Treatment boxes with different color codes designed and distributed with adult treatment boxes for Pediatric cases.
National Consultation on management of childhood tuberculosis in Jan 2012
Establishment of guidelines for MDR TB management
Establishment of 49 MDR-TB management sites
Completion of the Drug Resistance Survey (DRS) conducted in Maharashtra, and Gujarat
Micro planning exercise on drug logistics undertaken to expand DOTS-Plus under RNTCP
Development of guidance note on the linkage to other social welfare programs <ul style="list-style-type: none"> <li>- Note included formatting information for leaflets to be distributed to patients and a directory of possible NGO resources</li> </ul>
National PMDT scale-up plan 2011-12 established
Strategy for supervision, monitoring, evaluation and job aides for PMDT developed
Central PMDT Appraisals conducted in 2011 for 138 districts across 31 states
Guidance document for healthcare providers on the prevention and management of drug resistance TB called “The Chennai Consensus Statement”
The status of DOTS Plus services for Multi-Drug Resistant TB was reviewed in Guwahati in July 2011 for all the North-Eastern states

## **Annex 3. Economic and Financial Analysis**

### **Cost-Effectiveness**

During the period 2006-11, simply dividing the total RNTCP budget (US\$ 317 million) by the number of cases put on treatment (7.45 million) provides an average direct cost per treated case of around US\$ 43. Added to this are other health system costs that are estimated to account for about 60% of total costs, (Goodchild *et al.*, 2011) resulting in a total estimated cost per treated TB case of around US\$ 100. This can compare to average unit costs of other health interventions in India, such as treatment of non-severe pneumonia (US\$ 61 at the community level and US\$ 133 in a health facility), treatment of severe pneumonia (US\$ 4,366 in a hospital), delivery in a health center (US\$ 453), or one year of anti-retroviral therapy for HIV (US\$ 80). (Chow *et al.*, 2007)

However, standard practice to measure the efficiency of health interventions is to estimate cost-effectiveness ratios. Effectiveness is often defined in terms of disability-adjusted life years (DALYs), which are a composite measure of both years of life saved and disability averted by an intervention. The Disease Control Priorities Project, supported by the World Bank, has analyzed available information on the cost-effectiveness of a range of health interventions, including TB interventions. It estimated that the cost per death averted of a 10-year program providing TB diagnosis and treatment services (like RNTCP) is between US\$ 150 and 750, while the cost per DALY gained is between US\$ 5 and 35. The cost of MDR-TB diagnosis and treatment was estimated at over US\$ 2,000 per death averted and between US\$ 70 and 450 per DALY gained. The study concluded: “The treatment of all forms of active tuberculosis (TB) using the directly observed treatment strategy based on short-course chemotherapy is among the most cost-effective of all interventions available to improve health in LMICs [low and middle income countries].” (Jamison *et al.*, 2006)

RNTCP is situated at the lower end of these ranges of estimates. A 2007 study estimated the cost-effectiveness of the program at between US\$ 16 (for smear-positive patients) and 63 (for smear-negative patients) per DALY gained.<sup>8</sup> (Chow *et al.*, 2007) Another study estimated cost-effectiveness ratios of between US\$ 21 and 35 per DALY gained during the period 1997-2006. (Goodchild *et al.*, 2011).

### **Cost-Benefit**

Several studies have estimated the total economic benefit of the TB program in India as well as cost-benefit ratios. These are based on epidemiological estimates of the mortality averted (or life-years or DALYs gained) by the TB program, combined with assumptions about the economic value of a statistical life-year. A 2007 World Bank study made

---

<sup>8</sup> Around two-thirds of TB patients treated under RNTCP are smear-positive (i.e. TB bacilli can be observed in their sputum).

projections for 2006-15, estimating that provision of DOTS in India would avert 3.2 million deaths during that period, with an economic benefit over US\$ 350 billion, or a benefit of US\$ 191 per dollar spent. (Laxminarayan *et al.*, 2007)

A 2011 study used cost and patient number data for the period 1997-2006, estimating that the cost of government-provided TB services (including the RNTCP budget and other health system costs) at US\$ 768 million. A total of 6.3 million patients were treated during the period, saving an estimated 1.3 million lives and gaining 29.2 million DALYs. Using an assumed value of a statistical life-year of US\$ 1,892,<sup>9</sup> the study estimated that the program's economic benefit was US\$ 88 billion during 1997-2006 or US\$ 19.6 billion in 2006 alone. This represented an economic benefit of US\$ 115 per dollar spent during 1997-2006 or US\$ 155 in 2006 alone.

## Equity

TB is widely considered to be a disease of poverty, associated with crowding and poor living conditions. An analysis of the 2005-06 Third National Family Health Survey (NFHS-3) found that self-reported experience of TB was five times higher in the lowest wealth quintile compared to the highest. Low body-mass index and exposure to indoor air pollution were significant risk factors. (Oxlade and Murray, 2012) At the same time, the poorest have the greatest difficulty in accessing treatment due to both the direct costs of paying for health care and medicines and the indirect costs associated with transport and wage losses. Studies done pre-RNTCP found that poor TB patients seeking care from private providers incurred significant economic costs due to health care expenses and lost income (and also suffered from poor quality care). (WHO, 1997; Nair *et al.*, 1997) TB treatment involves repeated diagnostic tests and months-long courses of treatment. Diagnosis and treatment of MDR-TB in the private sector, costing thousands of dollars, are entirely out of financial reach for poor households in India. Overall, government health spending is low in India, about 1.2% of GDP and accounting for only around a fifth of total health spending, while most private spending is out-of-pocket. The RNTCP's provision of TB diagnosis and treatment free-of-charge therefore represents an important economic benefit to poor patients while removing a large part of the financial barriers to access to care.<sup>10</sup>

Nonetheless, more needs to be done, as a significant proportion of TB patients continue to pay for care in the private sector. A study of the private market for TB drugs in India estimated that sufficient volumes were being sold annually to provide treatment courses

---

<sup>9</sup> This was based on a figure used by the US government, adjusting for India's per capita income level.

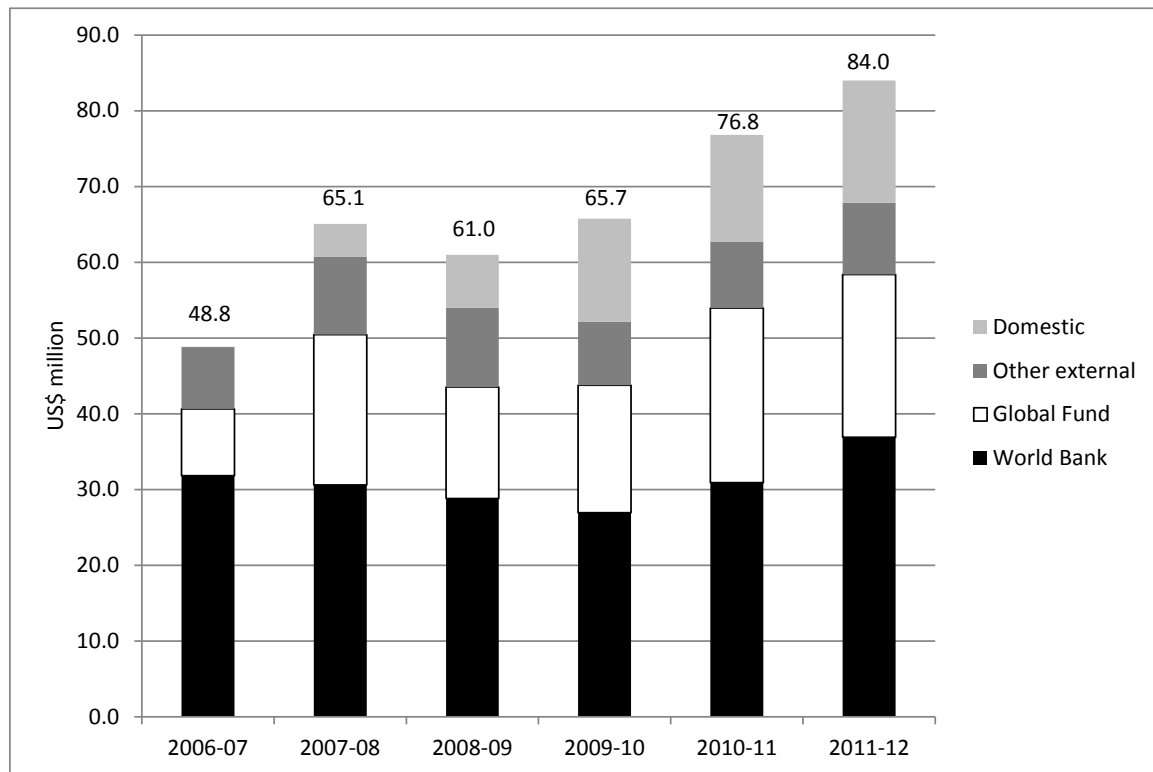
<sup>10</sup> It is also thought that the RNTCP services provide significant health benefits to the poor in that they are often of higher quality than what is delivered by private sector providers. Studies have found significant use in the private sector of inappropriate diagnostic tests (Jaroslowski and Pai, 2012) as well as wide variation in prescribed drug regimens. (Udwadia *et al.*, 2010) Inappropriate and interrupted TB treatment in the private sector is thought to be a significant factor in the development of MDR-TB.

to over 2 million patients, costing an estimated \$75 million (at wholesale prices). Even those patients who eventually receive care free-of-charge from government services incur expenses by seeking care from two or more private providers (i.e. informal providers, chemists) before that point. A 2012 study in Delhi found that two-thirds of TB patients interviewed had sought care from informal providers before going to a government health service (Kapoor *et al.*, 2012), while a 2007 study in Chennai found that over 80% of surveyed TB patients incurred medical expenses before starting treatment under RNTCP and these as well as other costs averaged Rs 3,211 (US\$ 70). (Ananthkrishnan *et al.*, 2012)

### Financial Analysis

RNTCP expenditures during the six fiscal years from 2006-07 to 2011-12 totaled about US\$ 400 million, of which the IDA credit of US\$ 170 million represented around 43%. Other external funding, notably from the Global Fund, totaled about US\$ 160 million or 40%. Domestic funding totaled around US\$ 55 million or 14%, but showed a significant increasing trend, rising from close to zero in 2006-07 to US\$ 16 million in 2011-12. (Figure 1) Nor does this take in account the value of support to TB services provided by state health systems, which as mentioned above are estimated at 60% of total costs – which would value this support at around US\$ 600 million over the six year period.

**Figure 1. RNTCP sources of financing, 2006-12 (US\$ million)**



As noted above, government spending on health in India is considered low by international standards. It has been increasing however, as central government health

spending rose from around US\$ 13 billion during the government's 10<sup>th</sup> Plan (2002-07), or US\$ 2.40 per capita, to around US\$ 24 billion, or US\$ 4.00 per capita, during the 11<sup>th</sup> Plan (2007-12). RNTCP's expenditures represented 1.3% of the 10<sup>th</sup> Plan amount and 1.5% of the larger 11<sup>th</sup> Plan total.

The government has expressed a commitment to further increase support to the health sector, planning to triple in absolute terms central government spending on health during its 12<sup>th</sup> Plan (2012-17). The budget of RNTCP is planned to similarly increase, to over one billion US dollars during the five year period, compared to about US\$360 million during the 11<sup>th</sup> Plan. Although RNTCP's share of total health spending may rise to 1.9%, this proportion is such that the overall increased commitment to government health spending means that increases in the program's budget should fairly easily be met from domestic sources. The main constraints under this scenario would be absorptive capacity (including the scale-up potential for strategies to reach the significant proportion of TB patients who receive care in the private sector).



## Annex 4. Bank Lending and Implementation Support/Supervision Processes

### (a) Task Team members

Names	Title	Unit
<b>Lending</b>		
Hadi Abushakra	Chief Counsel	LEGMS
Maria E. Anderson	Consultant	SASHD
Shellka Arora	Legal Assistant	LEGMS
Philip Beauregard	Senior Legal Counsel	LEGMS
Peter A. Berman	Lead Health Specialist	SASHD
Mam Chand	Senior Procurement Specialist	SARPS
Anthony T. D'Souza	Consultant	SASHD
Hugo Diaz-Etchevehere	Lead Operations Advisor	SASHD
Victoria Francis	Consultant	SASHD
Mohan Gopalakrishnan	Financial Management Specialist	SARFM
Meri Heleranta	Junior Professional Officer	WBI
Mohammad Khalid Khan	Program Assistant	SASHD
Joan M. MacNeil	Senior HIV/AIDS Specialist	HDNHE
Nga Nguyet Nguyen	Senior Economist	EASPR
Holger Sawert	TB Specialist	SASHD
Rashmi Sharma	Consultant	SASHD
Nira Singh	Program Assistant	SASHD
Suneeta Singh	Senior Public Health Specialist	SASHD
Esben Soenderstrup	Consultant	SASHD
Birte Holm Sorensen	Senior Public Health Specialist	SASHD
Ruma Tavorath	Environmental Specialist	SASES
Soren Thybo	Consultant	SASHD
Varalakshmi Vemuru	Senior Social Development Specialist	SASES
Alejandro Welch	Information Assistant	SASHD
<b>SUPERVISION</b>		
Maria E. Anderson	Consultant	SASHN
Peter A. Berman	Lead Health Specialist	SASHN
Asha Bhagat	Financial Management Specialist	SARFM
Anne Bossuyt	Operations Officer	SASHN
Emanuele Capobianco	Senior Health Specialist	SASHN
Snehashish Rai Chowdhury	Operations Officer	SASHN
Victoria Francis	Consultant	SASHN
Navneet Kumar Jain	Consultant	SASHN
Mohammad Khalid Khan	Program Assistant	SASHD
Gerard Martin La Forgia	Lead Health Specialist	SASHN
Shanker Lal	Senior Procurement Specialist	SARPS
Onika Vig Mahajan	Team Assistant	SASHN
Manvinder Mamak	Senior Financial Management Specialist	SARFM
Arun Manuja	Senior Financial Management Specialist	SARFM

Mariko Minamikawa	Consultant	SASHN
Satya N. Mishra	Social Development Specialist	SASDS
Patrick M. Mullen	Senior Health Specialist	SASHN
Shyama Nagarajan	Health Specialist	SASHN
Somil Nagpal	Senior Health Specialist	SASHN
Jayati Nigam	Consultant	SASHN
Sangeeta Carol Pinto	Operations Officer	SASHN
Meera Priyadarshi	Senior Nutrition Specialist	SASHD
Shafali Rajora	Team Assistant	SASHD
Ghulam Dastagir Sayed	Senior Health Specialist	SASHN
Nira Singh	Program Assistant	SASHD
Andreas Seiter	Senior Health Specialist	HDNHE
Birte Holm Sorensen	Senior Public Health Specialist	SASHN
William Starbuck	Senior Operations Officer	SASHN
Ruma Tavorath	Senior Environmental Specialist	SASDI
Soren Thybo	Consultant	SASHN

**(b) Staff Time and Cost**

Stage of Project Cycle	Staff Time and Cost (Bank Budget Only)	
	No. of staff weeks	USD Thousands (including travel and consultant costs)
<b>Lending</b>		
<b>FY04</b>	13.14	16,736.82
<b>FY05</b>	49.54	36,445.22
<b>FY06</b>	17.25	60,267.85
<b>FY07</b>	5.8	24,801.73
<b>Total:</b>	<b>85.73</b>	<b>238,251.62</b>
<b>Supervision/ICR</b>		
<b>FY07</b>	11.5	31,392.62
<b>FY08</b>	23.67	50,160.60
<b>FY09</b>	21.76	37,363.08
<b>FY10</b>	34.2	103,151.12
<b>FY11</b>	31.69	107,393.77
<b>FY12</b>	27.87	106,936.38
<b>FY13</b>	35.94	134,407.10
<b>Total:</b>	<b>186.63</b>	<b>570,804.67</b>

## **Annex 5. Borrower's ICR**

### **Implementation Completion Report – January 2013**

#### **1. Assessment of the Project's Rationale and Objectives**

India is a low-income country with a gross national income per capita of US\$ 620 (2004) and a population of 1.21 billion people. The economy grew around 6% annually in the 1990s, a period during which India made impressive progress towards reducing poverty. Overall health conditions have also experienced improvements during the last decades, e.g. life expectancy has increased, infant mortality rate has been halved and fertility has declined.

Health is a major contributor to poverty in India. The share of public spending on health is a modest 0.9% of gross domestic product' (below Brazil (3.4) and Thailand (2.1) but similar to Pakistan (0.9)). Public health care services are generally perceived to be of low quality and the poor are often misinformed about the availability and cost of services. As a consequence, more than 70% of outpatient care for those below the poverty line is provided by the private sector, much of which is of low quality provided by unregistered practitioners. In spite of the positive growth rate, poverty reduction remains India's most compelling challenge. Twenty-nine per cent of the population lives below the national poverty line while almost half of India's 266 million poor live in only three states: Uttar Pradesh, Bihar and Madhya Pradesh.

Communicable diseases continue to account for nearly half of India's disease burden, of which Tuberculosis (TB) is among the most widespread cause of morbidity, disability and mortality. About 40% of the adult population is infected by Mycobacterium Tuberculosis, causing more than 1.8 million new cases and 400,000 deaths annually. Of the new cases, nearly 800,000 are infectious; each of these, on an average, infects ten people. TB afflicts nearly all age groups although most cases are among adults aged 15 to 59 years, the most economically productive segment of society. As a result, the disease brings about enormous social and economic disruption to the patients and their dependent families, and slows down India's overall economic growth. It is estimated that TB causes the society nearly US\$ 3 billion annually in indirect costs.

To address this large and costly burden of disease, the Government of India (GoI) is currently implementing the Revised National Tuberculosis Control Program (RNTCP). Revised National TB Control programme, which is an application of the WHO recommended DOTS strategy in India, came into effect in 1997 with support of World Bank credit amounting US\$ 142 million. This end date of this credit was 31 December 2002. But due to various reasons there was underutilization of funds. However, all physical targets were achieved and so the project was granted a no-cost extension on two occasions: once in 2002 for two years and again in 2004 for one year. The project has been extended for the Drug component only till March 2006 so as to enable the project to complete payments for drugs procured during the project.

The second credit of Bank to RNTCP was from October 2006 to September 2011 with a value of US\$ 170 million. Again the project got two six month, no cost extensions and the credit ended on 30 September 2012. Since the country had already covered 100% of the districts under the program therefore during the second credit from bank was utilized implement the program throughout the country.

Although the country has achieved the global targets of 70% case detection rate and 85% cure rate on a nationwide basis in the area where DOTS was being implemented in 2004. However

there were large differences in program performance across the country, and with full coverage and inclusion of larger more difficult states, the overall case detection has dropped to 64% with many districts not achieving the global targets.

RNTCP II was developed based on the lessons learnt from the implementation of the programme over a 12-year period (1993-2005). RNTCP II was designed to consolidate the gains achieved in RNTCP I and to initiate services to address TB/HIV, MDR-TB and extend RNTCP to the private sector. Systematic research and evidence building to inform the programme for better design was also an important component of the programme. The emerging needs of Advocacy, Communication and Social Mobilization were addressed in the new phase. The challenges imposed by the structures under NRHM were also taken into account for RNTCP II. Therefore the program development objective of this credit was following:

- a) To achieve the global targets of 70% case detection and 85% cure rate in all the districts of the country
- b) For the zones where DOTS has been implemented for five or more years , the incidence of smear positive TB starts to decline

The project did not specify project components but did specify the following “outputs”: (1) RNTCP services consolidated, and (2) RNTCP outreach to target special groups expanded. There were no budget allocations to these two outputs, as relevant activities cut across the program’s budget categories. Since 2007, the programme has been consistently achieving a treatment success rate of >85% and a new smear positive (NSP) case detection rate (CDR) of >70%. In 2011, RNTCP achieved the NSP CDR of 72% and treatment success rate of 88%, which is in line with the global targets for TB control.

## **2. Assessment of Project Design:**

The program was based on the lessons learnt from RNTCP I (ICR No. 34692 dated June 30, 2006), from other health, nutrition and population projects supported by IDA and by International best practice. In continuation of the RNTCP 1 activities the project also included components like Multi Drug resistant TB, PPM etc.

RNTCP II was focused on two major Outputs which were as per the strategy paper of RNTCP for 11<sup>th</sup> five year plan (2007-12):

Output One: RNTCP services consolidated

Output Two: RNTCP outreach to Target special Groups expanded

## **3. Assessment of Project Implementation and Operations:**

Implementation of the revised paradigm of TB control known as the DOTS strategy throughout the country has been the most important achievement of this project. 100% of the districts and states have been covered under the program. The total population covered under program is 8159 lakhs. The World Bank funded areas have been covered (730 million population as per 2001 census). This includes full coverage of 35 states/union territories. 100% of the country’s population had accessed to DOTS. RNTCP is the largest TB control programme in the world. Even after the nationwide scale up the program has maintained quality of services.

- a) **Infrastructure Augmentation/Development for TB Control:**

The implementation arrangement of the program remained the same as it was in RNTCP I. The lowest level of service delivery point under the project is Designated Microscopy Centres (DMC) which is established on a population of 50000. Above that Tuberculosis units are there which are lower than District TB cell (DTC). DTC are under State TB cell (STC). In the phase II two more TB delivery points were added to the program these were Intermediate reference laboratory (IRL) and MDR-TB centres with designated categories of staff. By the end of project, year wise numbers of STCs, IRLs, MDR-TB centres, DTCs, TUs and DMCs established under the program are as follows:

Year	STC&SDS	STDC	IRL	DT TB center	DTC	TU	DMC
2012	28	22	21	53	460	1853	9220

The above mentioned units were strengthened with the recruitment of designated contractual staff at each level.

One of the key aspects during RNTCP II was setting up of procedures and systems for case finding, treatment, case holding, monitoring and supervision, recording and reporting.

Between 1997 and 2006 a World Bank credit of US\$ 96.7 million was instrumental to the scaling up of DOTS to provide coverage to the entire country. Subsequently, the current credit of US\$ 170 million accounted for around half of the RNTCP's central-level financing during 2006-12. The Bank-financed project has consistently been rated satisfactory on implementation and progress towards its development objectives. The program is integrated in the National Rural Health Mission (NRHM), a central government program designed to strengthen basic health care services, while the majority of implementation resources (i.e. health facilities, staff) are provided by state health systems. Since 1997, the program has initiated treatment for over 12.8 million TB patients, and saved an estimated 2.3 million lives. TB mortality is estimated to have been reduced by 45% in comparison to 1990. In 2011, RNTCP examined 7.87 million suspected cases and provided treatment to 1.52 million people diagnosed with TB. The program has exceeded since 2008-09 the internationally-adopted targets of 70% detection of new smear positive TB cases (73.5% to the third quarter of 2011) and successfully treating over 85% of those cases (87.6% to the third quarter of 2011).

**b) Supervision & Monitoring and Evaluation:**

RNTCP has established a robust recording and reporting system since the start of the programme in the country based on quarterly and annual cohort of TB patients registered for treatment. The program has developed a strategy document for supervision and monitoring of RNTCP. The same was updated in 2011. This strategy defines the role of each staff and officer in supervision & monitoring of the programme from the most peripheral level to central level. Frequency of visits, checklists for supervision, and indicators for monitoring their interpretation and possible solution and corrective actions are defined in the strategy. The major highlights of supervision, monitoring and evaluation are the following:

**Programme review and monitoring indicators at various levels:**

Review of progress and programme performance is review at various levels on a regular basis in a structured manner. This included biannual national review meeting of STOs and Consultants. Quarterly review of District TB Officers and programme partners at state level including the State Task Forces for medical colleges is a regular feature. District-wise programme performance is

reviewed using Monitoring Indicators published by Central TB Division on a quarterly and annual basis. Epi-Info based EPI-CENTRE is used for compilation of TU wise aggregated information on case finding, smear conversion and treatment outcome reports throughout the country. Programme management information at TU and district level is also compiled in the same manner.

**Programme Evaluations:**

Each State/UT is expected to carry out state level Internal Evaluation of RNTCP implementation in at least two districts per quarter. Central Internal Evaluation of at least two states is carried out per quarter with two districts in each state. Use of Epi data software for quick data entry of findings from visits to DOT Centres, DMCs, TUs and patient visits has been recently introduced and the analysis of the same gives the objective insight in programme evaluation of the districts. Structured Programme Evaluation has been a very important tool for systematic feedback to the programme implementation at district and state level.

**Composite Indicators:**

For more than a decade, the focus of the programme was on achievement of the global targets in terms of 70% case detection rate amongst the new smear positive cases. Many challenges were found to be associated with this approach including less focus on the processes and the inputs as compared to the outputs and undue pressure on the RNTCP staff to achieve these targets, at times in the absence of the optimal inputs and support for necessary activities. With an objective to ensure balanced approach with equal emphasis on inputs and processes as with outputs, the programme developed a composite indicator. This composite indicator is calculated with weights to 15 indicators under five thematic areas viz. Human Resource Management, Financial Management, case finding efforts, Quality of services and Drugs & Logistics management. The indicators in each thematic area were selected based on relevance, replicability, information availability, possible automation in to epi-centre, relatively longitudinal performance as against the cross-sectional performance, depicting programme change and needs. This tool is evolving and may not be an ultimate solution as a single wonder indicator but feasible option being tested for its utility in programme implementation.

**Focused Action Plan:**

Despite of regular supervision, monitoring and evaluation, there is a wide variation in performance of the state/UTs and districts throughout the country. In many instances, the reason is that there was no systematic attempt to find the reasons of underperformance of these areas at local level or inadequate capacity building and support from the state level. These districts were identified by CTD in consultation with the State/UTs. With the objective to improve the performance in such areas, the special guidance was given by Central TB Division to the State teams to conduct situational analysis in an objective manner. Based on the situational analysis, focused action plans were prepared by the state teams for each of these listed underperforming districts in the country. The same were shared with CTD and feedback on each plan was given to prioritize and strategize high impact activities for each of these districts. With the specific action suggested to the state teams including the concentrated efforts by the state teams for supportive supervision of these districts and hand holding for planning and conducting activities in these districts by state and district teams in a coordinated manner. Action Taken Reports on plan for each of these districts in an ongoing activity since Jan 2012. The impact of the Focused Action Plan strategy will be assessed in the year 2013.

**Improving TB surveillance by transitioning to Case Based Web Based recording and reporting:**

Since implementation, RNTCP followed international guidelines for recording and reporting for Tuberculosis Control Programme with minor modifications. Epi-info based EPI-CENTRE software was being used for the purpose of electronic data transmission from district level upwards. Initially DOS version was in use and the programme shifted to windows version in 2007. However, the data available at district, state or national level is in aggregated form. So, with the objective to improve TB surveillance in the country, the programme has undertaken the initiative to develop a Case Based Web Based application named Nikshay. This is still in the early stage of development and implementation. Currently, the basic information of TB cases is being captured. Module for including TB notification by non-RNTCP health providers is already in place. The plan is to develop mechanisms under Nikshay to include treatment adherence data, MDR-TB management, referral transfer mechanisms, hand held devices, micropayment of DOT provides, financial and drug and logistics management by June 2013. The RNTCP also conducts Joint Monitoring Missions (JMM) at regular intervals of 3 years. The members of JMM are international experts invited from technical, financial, advocacy, patient representatives and program relevant areas. The objective of the JMM was to review the country's progress towards the TB-related MDGs, challenges and plans for TB control efforts, and to advise the GOI and partners on the pathway towards achieving universal access to TB care. The mission has provided inputs on strategic approaches and innovative mechanisms for achieving the key targets of 12th Five-Year plan i.e. an ambitious goal of universal access to quality assured TB care to all and expert guidance on how to develop, prioritize, and deploy the approaches. The JMM team has also assessed the GF funded program activities. A Common Review Mission (CRM) is constituted under NRHM to review the national health program. RNTCP is reviewed as part of the overall national health program.

As per the recommendations of various monitoring missions, RNTCP has conducted various studies to study the impact and aid effectiveness. The Economic Impact Study conducted in 2009 under the program has shown economic benefits and aid effectiveness. Tuberculosis control has consistently been ranked as among the most cost-effective health interventions available, second only to basic routine immunization. Though this project is typically a social development project with no direct financial returns, the indirect returns of the project are promising. Based on the studies of the economic impact of Revised National Tuberculosis Control Program (RNTCP) expansion in India in 2009, estimates indicate that on an average each Tuberculosis (TB) case incurs an economic burden of around US\$ 12,235 and a health burden of around 4.1 Disability Adjusted Life Years (DALYs). Similarly, a death from Tuberculosis (TB) in India incurs an average burden of around US\$ 67,305 and around 21.3 Disability Adjusted Life Years (DALYs). The expansion of RNTCP from 1997 – 2006 was estimated to have the following health and economic impact, relative to the absence of the program:

- 6.3 million TB patients diagnosed and treated, with 1.3 million deaths averted.
- Total health benefit of 29.2 million disability adjusted life years (DALYs),
- Total gain in economic well being from TB control of US\$88.1 billion
- Total public expenditure on TB control over this period amounted to US\$768 million, with the RNTCP accounting for US\$ 299 million and other health sector costs accounting for US\$469 million.
- 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.

Considering this, if the project would achieve its deliverables 2012-2017 of treating >8.2 million Tuberculosis (TB) patients with at least 88% success rate then an additional >1.3 million deaths (due to Project) due to TB could be averted and approximately 30 million DALYs saved.

RNTCP conducted a Joint Monitoring Mission in August 2012 and the findings of the JMM team have been very encouraging. The committee feels that India's RNTCP is a cause for great national pride. Over the last 5 years, the RNTCP has examined more than 36 million persons through sputum-smear microscopy and treated more than 7.5 million TB patients, saving more than 1 million lives. The RNTCP has firmly established decentralized diagnosis through 13,000 quality-assured microscopy centers embedded in the health system and has expanded community-based treatment to a network of more than 600,000 community treatment providers. On an average day, RNTCP examines 31,500 patients by sputum microscopy and initiates treatment for 6,000 TB patients

**c) Training:**

In RNTCP I series of training modules were developed for grass root level staffs like STS, MPW, LT, STLS etc. Under RNTCP II also sound training materials have been developed for all categories of staff. The training materials are modular in content to ensure standard quality training and to avoid possible subjectivity and bias of the trainers. List of Modules that have been developed under RNTCP are following:

- a. Training Module for Micro bacterium Tuberculosis Culture & DST- 2008
- b. Training module for Medical practitioners – 2010
- c. Training module for 14 intensified urban PPM sites on revised reporting and recording - 2008-09
- d. Training module for District Tuberculosis center –Drug stores 2008
- e. RNTCP training course for program Managers; Module 1-4 & module 5-9- 2008-09

As of December 11 79% of medical staffs and 79% of Para medical staffs have been trained on the relevant modules.

**d) Procurement:**

One of the most significant achievements of the project was to procure binocular microscopes and drugs at Central level for health facilities throughout the country. Under the World Bank project procurement was carried out at two levels, either at National level or at state/district level. Anti TB drugs for the entire country are being procured by the Central Government. The procurement of drugs at the National level was mainly affected following International Competitive Bidding procedures recommended by the World Bank. Anti TB drugs for treatment of adult and paediatric cases under DOTS were procured in two years (2006 & 2007) through National Shopping procedure. In RNTCP II second line drugs were also procured from Bank credit. In RNTCP II 1500 BM microscopes have been procured. The procurement of drugs both 1<sup>st</sup> line and 2<sup>nd</sup> line is as reflected in Annexure 1 and Annexure 2.

The programme helped in considerable infrastructure strengthening in the states by undertaking civil works at approximately 22 STDCs, 21 IRLs, 28 SDS, 53 DR TB centres 460 districts TB Centres and District drug stores , 9220 microscopy centres, 1853 TUs (World Bank areas only). Districts were enabled to purchase a computer, photocopier, fax machine etc. at the rate of one per district. Consultants and contractual staff procured under the project played a crucial role in programme implementation and monitoring and supervision.

**e) Advocacy, Communication & Social Mobilization**



- Professional Media Agency was engaged in August 2007 for developing, designing, production, and dissemination of IEC material including mass media activities
  - Developed three TV and radio spots for use on electronic media
  - Organized public event on World TB Day 2008
  - Organizing Capacity building workshops in few select states on effective use of communication material
- IEC Capacity Audit Conducted to assess the capacity in the states to plan and implement ACSM activities
- IEC Baseline Document developed (May 2007) which has the following crucial findings:
  - Except three states and UTs all other states (29/35) have IEC officers in place more than 90% of them have experience in communication and have undergone training. Yet majority of them expressed that they need more training and capacity building.
  - Out of the 10 large and 15 medium sized states, 50% of them felt that they were not confident for planning and implementing ACSM activities for all the four target groups (i.e. General public, patients and their families, practitioners, and opinion leaders): where as small states and UTs, except Sikkim had high level of confident of planning and implementing ACSM activities, especially for general public and for patients and their families.
- The process of engaging Communication Facilitators in the states has been slow as they lacked clarity on the roles and responsibilities of Communication Facilitators.
- About 50% of the eligible states (13/26) responded that a helping hand at the district level for ACSM activities will be useful.
  - Development and use of communication material hasn't been based on any need assessment. In fact questions pertaining to this were not responded and basis of calculation of quantities has been number of health facilities/population etc.
- Four National Level ACSM Capacity Building training workshops (six days each) held in collaboration with National Institute of Health and Family Welfare. The content of the training was decided on the findings of the IEC Capacity Audit Document. Segmentation of audiences, Advocacy and development Annual action were main focus areas of these workshops. Lot of emphasis was on relating each topic to the RNTCP field situation. PATH, one of the international agency, and partner of RNTCP participated in all four workshops as resource person.
- Communication material on website modified in line with the policy changes on diagnosis of smear positive pulmonary TB
- Pilot initiated in few states to refine the role of Communication Facilitators to focus on poor performing districts
- Questionnaire developed to collect information on effective use of communication facilitators in the states
- Discussion on partnership with other stakeholders to strengthen ACSM Component

At State and District levels following activities have happened:

- Decentralized ACSM planning and implementation.
- Fund utilization for ACSM improving at the state and district level. There are some districts that need to improve performance for developing ACSM activities that support TB care services.
- Village meetings are held, involving Panchayati Raj Institutions (PRIs – local elected bodies), to address social aspects of TB patient meetings & community meetings using cured patients to motivate those on treatment
- Felicitation of cured patients, community DOT providers for increasing treatment adherence
- Innovative approaches were piloted and documented at the state and district level, including Communication for Behavioral Impact (COMBI) in Kerala.

**f) Operations Research:**

Operational research under RNTCP aims to improve the quality, effectiveness, efficiency and accessibility (coverage) of the control efforts. Operational studies are generally:

- of low cost and limited staff time, because they should not deviate excessive resources from service delivery and disease reduction,
- of short duration, because the results should be available rapidly to decide on programme changes if necessary,
- based on simple standard protocols, to be repeated in different environments, and
- giving priority to test solutions to identified problems and to develop new implementation methods to improve the programme.

Some studies have contribute to the national experience and influence programme guidelines; others have addressed local issues or produce different results depending on the area, and had serve to develop interventions appropriate to specific populations or geographical areas.

**List of studies being undertaken by RNTCP:**

**National Level:**

A retrospective assessment of reasons and risk of default amongst Cat II patients was successfully undertaken by CTD. The results of the study showed important risk factors and reasons for default. The results of the study and the remedial actions to be taken have been communicated to the districts.

The following studies have been approved and funded by CTD and are presently underway:

1. Disease prevalence studies at 6 sites by the following institutes:
  - a. NTI Bangalore
  - b. MGIMS, Wardha
  - c. AIIMS, New Delhi
  - d. PGIMER, Chandigarh
  - e. JALMA, Agra
  - f. RMRCT, Jabalpur
2. Zonal ARTI survey being coordinated by NTI, Bangalore
3. A Study on Treatment of Genital Tuberculosis: A randomized controlled trial to compare the 6 months of Cat I treatment with 9 months of Cat I Treatment (extension for 3 months) in genital tuberculosis under RNTCP. (AIIMS, New Delhi)
4. A multi-centric study on treatment of abdominal tuberculosis (intestinal or peritoneal): A randomized controlled trial to compare the 6 months of Cat I treatment with 9 months of Cat I Treatment (extension for 3 months) in abdominal tuberculosis under RNTCP. (AIIMS, New Delhi)
5. Evaluation of the efficacy of thrice weekly DOTS regimen in TB pleural Effusion at six months. (AIIMS, New Delhi)
6. Utility of generic and disease specific health related quality of life instruments as outcome measures for tuberculosis patients treated under RNTCP at Chandigarh. (PGIMER, Chandigarh)
7. “Socioeconomic implications and incidence of default amongst patients put on DOTS, Himachal Pradesh” under RNTCP (IGMC, Shimla).
8. A study on the assessment of RNTCP strategy of FNAC diagnosis (at 2 weeks) and 6 months duration of treatment for peripheral tubercular lymphadenitis. (PGIMER. Chandigarh)

At the state level a total of 69 proposals have been reviewed by the Zonal OR committees since 2006 and 21 studies have been approved and funded. More than 107 postgraduate thesis have been approved during this period by the State OR Committees.

#### **g) TB-HIV Coordination Activities**

TB/HIV activity coordination started relative early in India in 2001, in the states of Maharashtra, Manipur, Nagaland, Karnataka, Tamil Nadu and Andhra Pradesh. The early activities were primarily joint training of health staff in TB-HIV and cross-referrals. Cross-referral in this context intensified case-finding at Integrated Counseling and Testing Centers (ICTC) with referral of TB suspects to RNTCP DMCs, and referral of TB patients with HIV risk factors from DMC to ICTC for voluntary HIV counseling and testing. These collaborative activities were extended to eight additional states of Delhi, Gujarat, Himachal Pradesh, Kerala, Orissa, Punjab, Rajasthan and West Bengal beginning in the year 2004. By the end of 2006, these TB-HIV collaborative activities were implemented in 14 states of the country.

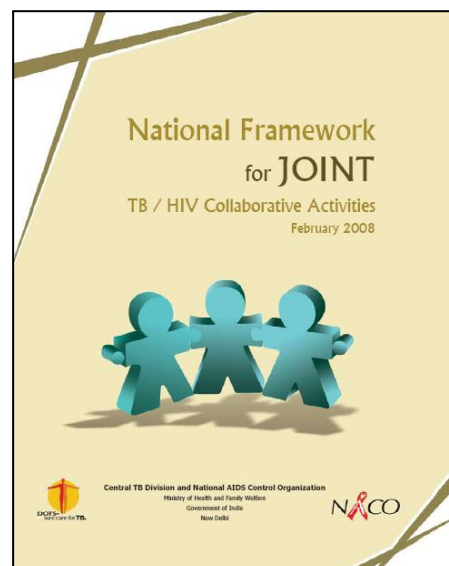
Two key pilot studies generated the evidence on the implementation of additional TB/HIV activities. First, in 2007 CTD and NACO pilot-tested the decentralized delivery of Cotrimoxazole preventive therapy (CPT) for HIV infected TB patients through RNTCP mechanisms. This pilot was undertaken in three districts with high prevalence of HIV in Andhra Pradesh. Evaluation of the pilot was undertaken by a team of experts from NACO, CTD and WHO in September, 2007. Based on that experience, CPT for HIV-infected TB patients was included into national policies.

Second, in 2008 a pilot study of provider-initiated HIV testing and counseling for TB patients was conducted in two high HIV prevalence districts with assistance from Tuberculosis Research Centre (TRC), Chennai and National Tuberculosis Institute (NTI) Bangalore. This study demonstrated that routine referral of TB patients for HIV testing could be successfully and efficiently implemented under the programme conditions without any discernable effect on TB case notification. In this study, the efficiency of linking HIV-infected TB patients to anti-retroviral treatment was also assessed. These studies highlighted the importance of high-quality counseling in helping patients receive all the necessary free care and treatment available for their continued wellbeing.

On the basis of these pilot study experiences and taking into account the variability in HIV epidemiology and HIV diagnostic and treatment service availability, a new national policy on TB/HIV collaboration has been developed. The first National Framework for TB/HIV Collaborative Activities was endorsed in November 2007, and updated in Feb 2008.

The **National Framework for TB/HIV collaborative activities** established that essential TB/HIV interventions were to be implemented nationwide. Those essential TB/HIV interventions for all states include:

- Establishment of mechanism of coordination in the form of coordination committees and Technical working groups both at the national as well as state level,
- Training of programme officials and field staff on TB/HIV.
- Intensified TB case findings at ICTCs, ART centres, and Care and support Centers.
- Risk-based referral of TB patients for voluntary HIV counseling and testing.
- Referral of HIV-infected TB patients to NACP for additional care and support, including antiretroviral treatment.



Those areas with higher HIV burdens were flagged for an “**Intensified TB/HIV Package**” of services. The Intensified TB/HIV package of services includes:

- Routine referral of all TB patients for HIV counseling and testing
- Provision of co-trimoxazole preventive therapy (CPT) to HIV-infected TB patients.
- Expanded recording and reporting, including recording HIV status of TB patients in the TB registers

Selection of states for the intensified TB/HIV package was based on HIV prevalence, absolute HIV burden, availability of decentralized HIV testing and treatment services, and programme capacity. During 2008, the Intensified TB/HIV packages of services started in the 9 HIV high prevalence states (Andhra Pradesh, Goa, Karnataka, Maharashtra, Manipur, Mizoram, Nagaland, Puducherry and Tamil Nadu.). Additional states were recently identified for the Intensified TB/HIV package (Gujarat and Delhi), bringing the total number of states to 11.

#### **External Quality Assurance:**

To ensure quality, external quality assurance of sputum microscopy is being introduced throughout the country. The protocol being implemented has taken into consideration the recommendations of the recently published international guidelines and has all components for ensuring quality -on site evaluation, panel testing and blinded crosschecking. The four National Reference Labs have been assigned states and they have started On-site evaluation visits to the Intermediate Reference Labs (IRLs), which are the state level labs. All the states have been visited either by NTI Bangalore or NRLs. Training of trainers of all states has been completed. All the 35 states/ UTs are implementing and reporting as per the protocol.

#### **h) Programmatic management of Drug resistant TB:**

WHO Global TB Report 2011, estimates that approximately 64,000 cases of MDR-TB emerge annually from the notified cases of pulmonary TB in India, based on the data available from population based drug resistance surveys carried out in 3 states of India that revealed the prevalence of MDR-TB to be ~3% among new TB cases and 12-17% among previously-treated TB cases. Isolated studies have reported XDR-TB in India. However, the extent and magnitude of this problem is yet to be determined. Preliminary results show that there is not yet any XDR-TB amongst new cases and ~0.5% amongst re-treatment cases. However when translated into numbers the M/XDR TB cases are significant and pose a serious challenge to TB epidemiology unless effectively managed

One of the major milestones in RNTCP II was the initiation of PMDT services in the country in the year 2007. The major activities that have happened in PMDT are following:

1. Quality diagnosis and treatment services under programmatic management of drug resistant TB were introduced since 2007.
2. PMDT services are available in all 35 states of the country across 380 districts covering a population of 588 million (49%) and are being rapidly scaled up.
3. 11/35 states have achieved 100% geographical coverage and the remaining states are expected to achieve complete geographical coverage by 2012-13
4. Anecdotal reports of TB that is resistant to all available anti-TB drugs highlights urgency to scale up RNTCP PMDT services for M/XDR TB nationwide.
5. All states are expected to move towards universal access to quality diagnosis and treatment of MDR TB patient by gradually extending the opportunity to diagnose early during the treatment course of TB patients.
6. PMDT guidelines refined and updated in June 2012 under guidance from National DOTS Plus committee.

7. To date, > 9000 MDR-TB patients have been initiated on standard treatment regimen for MDR TB under RNTCP, through 63 DR-TB centers (DOTS Plus sites). ~60% of these DR-TB centers function at Medical Colleges including some Private Medical Colleges.
8. Diagnostic services are available through 41 RNTCP certified quality assured laboratories to diagnose MDR TB. Out of these 33 laboratories are certified for solid culture & DST, 27 certified for rapid molecular diagnostic techniques and 10 are certified for liquid culture and DST. Six out of these certified laboratories are from Private and NGO sector.
9. Out of the cumulative total of 2625 MDR TB Cases registered for treatment 12-15 months earlier (latest 5 quarters 4Q09-4Q10), 1920 cases (73%) were reported to be alive and on treatment (with 1297 (49%) culture negative and 372 (14%) culture positive) at 12 months of treatment, while 358 (13%) died and 322 (12%) defaulted.
10. The treatment outcomes of MDR TB for the initial sites for the early 9 quarterly cohorts (3Q07-3Q09) have been reported. These patients were generally heavily treatment experienced, chronic cases, and so expectations on treatment outcomes were limited. Out of the cumulative total of 967 MDR TB Cases registered for treatment 31-33 months earlier (3Q07-3Q09), 493 cases (51%) have been successfully completed treatment while 175 cases (18%) died, 74 cases (8%) failed and 197 cases (20%) defaulted treatment. Substantial improvements in policies and procedures have been implemented to reduce treatment default. Research is underway to understand the unacceptable failure rates, but early results suggest poor outcomes have been strongly associated with pre-treatment ofloxacin resistance in this patient cohort. This analysis is being expanded to subsequent sites and cohorts to inform ongoing revision of programme policies and procedures.
11. Systematic feasibility study under guidance and monitoring of a National Steering Committee on CB-NAAT (Xpert-MTB-Rif) with ethical approval from the ethics committee of the National TB Institute, Bangalore has been initiated in India in 2012 in 18 sites across the country.
12. Further, with support of WHO and UNITAID, 9 CB NAAT laboratories (12 CB-NAAT (Xpert-MTB-Rif) machines with cartridges) are being extended to India through the EXPANDx TB Project to address the laboratory capacity gaps and boost the laboratory diagnostic capacity in additional 70 districts to test additional 30,600 MDR TB suspects. With this intervention, an additional 5300 Rif resistance cases expected to be put on treatment from the beneficiary districts.
13. As India moves into the next five year plan (2012-17), another 300 CB-NAAT machines and cartridges have been requested from WHO and UNITAID to support the rapid scale up of PMDT services in India.

The National PMDT Scale up Plan for 2011-2012, an operational plan, was developed by consolidating the state wise PMDT micro-plans developed during the series of meetings with 35 states organized by CTD at LRS Institute, New Delhi in early 2011. The plan was developed with the objective to articulate the operational strategy to achieve RNTCP vision for PMDT scale up to the states and align state plans with the resources expected to be available over time (second line drugs, and lab capacity) as per the national resources, such that the state plans are matched to drug supply and lab capacity at different points in time over 2 years, with implications for national training and appraisal needs and responsibilities understood by all. The timelines were set out in the plan by the states for scale up of services by districts (geographical expansion) and by gradually expanding MDR TB suspect criteria (towards universal access in various districts by phases) with careful consideration of all preparatory activities like civil work up-gradations, appointments and training of staff, procurement and plan for sample collection and transport and drug logistic management, trainings and appraisals. The plan was endorsed by the 7th National PMDT Committee meeting.

National PMDT scale-up plan 2011-12 has been documented and is hosted on the programme website. This plan was presented at the WHO SEARO Meeting of WHO country offices' focal points on Regional Response Plan for Programmatic Management of Drug Resistant TB in April '11 at Delhi for development.

Periodic intensive review of the progress made against the state PMDT scale up plans are being undertaken regularly by Central TB Division with all 35 states to identify bottlenecks faced by the states in scaling up services and address them through support from the Center in a timely manner.

**i) ARTI:** A nationwide tuberculin survey to estimate the Annual Risk of Tuberculosis Infection (ARTI) in different parts of India was conducted by NTI, Bangalore in 2009, with support from other institutions especially TRC, Chennai. Besides zonal differences, the ARTI was found to be higher in urban areas than in rural areas. This difference reflects the heterogeneity in such a vast country and population. A national ARTI of 1.1% has been derived from the zonal estimates. This study has provided robust data on the epidemiology of TB in India and will serve as a baseline data to assess the impact of RNTCP in the future. The ARTI seems to have come down from the earlier ARTI of 1.5 (2002), which is an early indicator of the efficacy of the DOTS strategy of RNTCP.

**j) PPM:** In India, the private sector is the first point of care in about 80% of episodes of ill health. This is true for TB patients as well. While most TB cases are ultimately treated by the RNTCP, most patients by then have already approached the private sector for TB diagnosis and treatment. Engaging the private sector (both for profit and not for profit entities) effectively is the single most important intervention required for RNTCP to achieve the overall goal of universal access and early detection.

The huge private sector in India comprises of a wide range of providers from private medical practitioners of many different systems of medicine, both modern and traditional including those having no formal training, and paramedics. Using the experiences gained from the collaborations with NGOs and the private sector in RNTCP 1, the Central TB Division published guidelines for the participation of the NGOs (in 2001) and private practitioners (in 2002). The guidelines for NGO/PP schemes have undergone revisions once in 2008 and recently the National Consultation for revision has been held with participation from various stakeholders. Currently 1,900 NGOs and 10,000 private providers are involved (under signed memorandum of understanding) with the TB programme in a variety of ways.

**These guideline are again under process of revision.**

**Again this has been done with the consultation of different stakeholders.**

As a result of PPM strategy, the efforts to involve all relevant health sectors became part of the routine activities of RNTCP districts across the country. However, the case detection rates have remained low in many districts, especially in large urban areas with inadequate public health infrastructure and a large private health sector.

**The current NGO/PP schemes include:**

- **ACSM scheme**
- **Sputum Collection scheme**
- **Transport scheme**
- **DMC scheme**
- **LT scheme**
- **Culture & DST scheme**
- **Adherence scheme**
- **Slum Scheme**
- **Tuberculosis Unit Scheme**
- **TB/HIV scheme**

As a response to this situation, the Central TB Division decided to pilot an “intensified PPM scaling-up project” in 14 urban areas of the country in 2003. The data from these sites show a contribution of various sectors to NSP case detection rate as Health Department 56%, government facility outside health department 9%, medical colleges 22%, private provider and NGOs 6% each in 2011. Analyses of the reports from the intensified PPM sites have shown a steady and gradual increase in the number of cases notified under RNTCP. In all the sites, the public health department of the government has remained the largest contributor to case detection. Medical Colleges, though fewer in number, have contributed a sizeable proportion of cases. The Public Private Mix advocacy kit (flipbooks, stickers, display boards, posters etc.) has been developed for facilitating interaction with Private Practitioners for community involvement. A training module for the Medical Practitioners has been especially designed by Central TB Division to update them on the technical and operational aspects of the programme.

#### **4. Performance Evaluation of the Borrower**

The assistance provided by the World Bank contributed substantially in starting the implementation of the DOTS strategy for TB Control in India. The benchmarking of performance and supervisory missions conducted by the Bank were very useful for programme evaluation and review of progress. Use of World Bank procurement procedures helped in ensuring fair prices and quality of procured items. However the two-stage bidding system contributed significant delays and the borrower has now sought to make it a one-stage bidding system for drug procurement. Excellent relationship existed between the Bank staff and the Central TB Division and this relationship continues to grow.

#### **5. Financial Performance**

The project had an initial outlay of USD 170 million for the period from October 2006 to September 2011. The credit was to finance USD170m. The project also got 2 extensions till September 2012 and ended on 30<sup>th</sup> Sept 2012. At the end of the project period RNTCP has received the reimbursement of all US\$170m.

The project has decentralized the financial management to the states and funds flow from CTD to STCS and from STCS to the DTCS. There is adequate capacity for financial management and maintenance of accounts at State level. The States have also been given requisite authority to manage the finances within the STCS and DTCSs. The flow of reporting is from the DTCS to STCS and from STCS to CTD. Annual financial statements and audit reports also originate from the district level to the STCS and are consolidated at STCS and then forwarded to CTD. The project had developed the financial guidelines for both the State and the District and the financial staff at TD has provided extensive training to the DTOs and accountants at State and District level on maintenance of financial records and preparation and reporting of financial statements. Modules of the internet and intranet based financial management system are being piloted in some states and districts before full scale implementation.

As of 30<sup>th</sup> September 2012, the project has made an expenditure of 99% of the approved credit. The reimbursable expenditure is Rs 458.34 Crores of an expected Rs 604.3 Crores. The category wise expenditures are given below:

#### **6. Assessment of Project outcomes**

The project has achieved most of the project targets which were mentioned in results framework. The baseline was of 2006 while the end line data is of September 2012. The result framework is placed as Annexure 3.

## **Evaluation of the Performance of Bank**

World Bank has provided support to the program not only on financial terms but also on technical terms. The Bank has done regular monitoring of the program through its various Joint Monitoring Missions. The bank was a part of various Joint Monitoring Missions of RNTCP. Apart from this in the development of National Strategic Plan of RNTCP for 12<sup>th</sup> FYP the Bank has played key role. The summary sheet on the challenges identified and recommendations given by bank during various missions are placed as Annexure 4.

### **7. Sustainability**

The Government of India (GOI) gives the highest priority to TB control and is committed to supporting the TB control activities for as long as it takes to achieve a situation where TB ceases to be a major public health problem in the country. There is commitment from highest echelons of authority that GOI would make necessary fund arrangements from domestic or other sources, after the end of the GFATM grant period. Considering the situation prevailing at that time, GOI would make available funds and resources from either domestic health allocation or could consider approaching bilateral agencies for credit/grants.

Under RNTCP funds are utilized at National, state and district levels. The Programme has well laid technical, financial and operational guidelines that are documented. The technical guidelines are as per the internationally recommended strategy. These guidelines ensure that funds are utilized efficiently and in a transparent manner.

TB programme is covered under the audit of the Comptroller and Auditor General (CAG) of India. CAG is the supreme audit institution of India that annually audits public accounts as per the constitution of India and international best practices. Offices of the Principal Directors of Audit are responsible for audit of the activities of the Federal Government, including Civil Ministries and Departments. Auditing standards have been published and give overall direction for auditing. The audit enhances accountability of the programme to the public representatives. The Government of India, in line with the objective of providing adequate health care for its citizens has been steadily increasing the allocations in health sector since commencement of the Five Year Plan. During 10th Five year plan Public health spending in India has been relatively low as a proportion of total GDP even when compared to other low and lower middle income countries, and that the public sector accounts for a very low share of total health spending. But the situation has improved during 11th five year plan period (2007-12). The allocation for the health sector has been substantially enhanced from INR 363780.00 crores in the 10th FYP to INR 1, 36,147.00 crores in 11th FYP. (1 crore equals 10 million).

### **Expenditure on Tuberculosis Control in India**

The Government of India is committed towards its funding to RNTCP. The total outlay for RNTCP during 10th FYP was 168 million US\$. In 11th FYP this was increased to 358 million US\$ while in 12th FYP the proposed budget for RNTCP is US\$ 950 million.

There is commitment towards the funding to RNTCP from both Government of India and donors. During The scale-up of the RNTCP has been primarily supported by funds from the Government of India including a Development Credit Agreement that was negotiated with the World Bank in 1997. These two sources have accounted for 67% of the RNTCP's total budget over 2002-2007. Apart from that, various donors like DFID has contributed towards drugs, UNITAID towards laboratory and USAID for various activities under the program. The GOI funding towards RNTCP has also increased in the consecutive Five Year Plans.



In recent years, a plateau in the number of cases put on treatment (around 1.5 million since 2008-09) is mirrored by a gradual increase in annual funding around from US\$ 65 million in 2007-08 to US\$ 85 million in 2011-12. The program's National Strategic Plan for 2012-17 proposes substantially increased funding levels, reaching around US\$ 260 million annually by 2016-17, in line with growth in the number of TB patients put on treatment (target of around 1.75 million by 2016-17).

The increase in RNTCP funding in absolute terms is in line with planned increases in overall central government health spending (see Table 1). Central government allocations to health are planned to increase dramatically in the 12th Plan. At the same time, the proportion allocated to RNTCP will also increase in relative terms, from 1.4% of the total during the 11th Plan to a proposed 1.5% in the 12th Plan. (This proportion, however, can perhaps be compared to TB burden, as the disease causes an estimated 2.8% of all deaths in India and 6.4% of deaths among the 15-49 age groups). In per capita terms, during the 12th Plan, average annual central government spending on TB control is proposed to be about US\$ 0.18, which represents a tripling in absolute terms from the 11th Plan average.

**Table 1. Central government health spending and RNTCP funding, 10th, 11th and 12th Five Year Plan**

Central Government health spending and RNTCP funding 10, 11 and 12 five year plan						
Five Year Plan	Years	US \$ Million			US \$ per capita per year	
		Total central Govt. Health Spending	RNTCP	RNTCP as % of total	Total central Govt. Health Spending	RNTCP
10	2002-2007	13,093	168	1.283 %	2.38	0.03
11	2007-2012	24,076	358	1.486 %	4.01	0.06
12	2012-2017	63,400	950	1.499 %	9.75	0.18

## 8. What Has Worked/Lessons Learned

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

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

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

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

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

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

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

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

## 9. Challenges

a) The major challenge was that during the course of implementation many of the expenditure which already were incurred were disallowed by bank and that resulted into the burden on the domestic budget.

b) The second challenge is that after dramatic and then steady increases in coverage, the annual number of cases identified by the program has reached a plateau in the past few years. RNTCP's reach needs to be increased, requiring greater resources as well as new strategies.

c) The third and related challenge is represented by the gap between the number of cases notified and the total estimated number of new cases. About a third of total estimated cases are not reached by the program, with these patients generally seeking care instead in the private sector. Even those who receive treatment from RNTCP usually will have gone to several private sector health service providers before seeking care from the program.

d) Another major challenge is thus the need to extend RNTCP support, such as quality standards and monitoring, anti-TB drugs, and subsidies, to patients who are diagnosed and treated in the private sector. The main reasons this is necessary relate to the financial barriers and burdens experienced by patients, particularly the poor, and to gaps in the quality of diagnosis and care. These quality gaps, driven by a variety of factors ranging from the use of ineffective diagnostic tests and treatment protocols to interrupted treatment due to financial barriers, are driving drug resistance, which is a third major challenge faced by the program (not represented in **Error! Reference source not found.**). WHO estimates that there are approximately 100,000 new cases of MDR-TB in India annually. Drug-resistant TB is complicated and expensive to diagnose and treat, requiring advanced diagnostics, specialized care, and a two-year course of treatment with costly and difficult-to-tolerate drugs.

## 10. Impact of the Programme

The World Bank in their supervision mission of April 2011 rated the implementation progress of the project as highly satisfactory and Achievement of Project Development Objectives as highly

satisfactory .The foremost objective of the project was to shift the focus of TB control in the country to the new internationally accepted paradigm for management of TB, namely DOTS. As on 30<sup>th</sup> Sept 2011, there is 100% DOTS coverage in World Bank project areas and in the entire country, about 8267lakhs population (projected population of 2005) has been covered under the DOTS strategy. As far as impact on Incidence of the disease in the country is concerned, the ARTI has reduced from previous estimate of 1.5% to 1.1% as measured in 2009. Program has planned do its own TB prevalence and incidence study. Mortality has also reduced considerably compared to the RNTCP 1. Death rates have been reduced 7-fold in DOTS areas versus non-DOTS areas. The benefit incurred in the program during 12<sup>th</sup> FYP is following:

<b>Indicator</b>	<b>11th FYP</b>	
	<b>Planned</b>	<b>Achieved</b>
No of TB suspects examined (millions)	29.65	35.5
Total number of patients to be put on treatment (millions)	6.3	7.55
New Smear Positive patients to be put on treatment (millions)	2.95	3.68
No of MDR TB patients to be put on treatment (000)	5	4.2
Success Rate in New Smear Positive patients in RNTCP (%)	≥85%	87%
Annual Risk of TB Infection (ARTI)	1.5% (2002-03)	1.1% (2007-10)
Prevalence of TB (millions)	4.1 (2005)	3.1 (2011)
Incidence of TB (millions)	2.4 (2005)	2.3 (2011)
Mortality (lakhs)	4.1 (2005)	3.2 (2011)

## **Annex 6. List of Supporting Documents**

### Government and Project Documents

Government of India (GOI), Ministry of Health and Family Welfare (MOHFW) (2006) *TB India 2006: RNTCP Status Report*, New Delhi, accessed at <http://www.tbcindia.nic.in/pdfs/Annual%20Report%20TB%202006.pdf>

Government of India (GOI), Ministry of Health and Family Welfare (MOHFW) (2007) *TB India 2007: RNTCP Status Report*, New Delhi, accessed at <http://www.tbcindia.nic.in/pdfs/TB%20India%202007.pdf>

Government of India (GOI), Press Information Bureau (2007) “Poverty Estimates for 2004-05,” New Delhi, accessed at <http://planningcommission.nic.in/news/prmar07.pdf>

Government of India (GOI), Ministry of Health and Family Welfare (MOHFW) (2012a) *TB India 2011: Revised National TB Control Program Annual Status Report*, New Delhi, accessed at <http://www.tbcindia.nic.in/pdfs/RNTCP%20TB%20India%202011.pdf>

Government of India (GOI), Ministry of Health and Family Welfare (MOHFW) (2012b) “TBC India: Performance Indicators,” website, accessed at <http://www.tbcindia.nic.in/perfor.html>

Government of India (GOI), Ministry of Health and Family Welfare (MOHFW) (2012c) *TB India 2012: Revised National TB Control Program Annual Status Report*, New Delhi, accessed at <http://tbcindia.nic.in/pdfs/TB%20India%202012-%20Annual%20Report.pdf>

Government of India (GOI), Planning Commission (2008) *Eleventh Five Year Plan 2007-12*, New Delhi, accessed at [http://planningcommission.nic.in/plans/planrel/fiveyr/11th/11\\_v2/11th\\_vol2.pdf](http://planningcommission.nic.in/plans/planrel/fiveyr/11th/11_v2/11th_vol2.pdf)

### World Bank Documents

World Bank (2004) “International Bank for Reconstruction and Development, International Development Association, Country Strategy for India,” Report No. 29374-IN, accessed at [http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2004/09/20/000160016\\_20040920102445/Rendered/PDF/293740REV.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2004/09/20/000160016_20040920102445/Rendered/PDF/293740REV.pdf)

World Bank (2006a) “Development Credit Agreement (Second National Tuberculosis Control Project) between India and International Development Association,” Credit No. 4228-IN, accessed at <http://documents.worldbank.org/curated/en/2006/10/7181014/credit-agreement-c4228-in-conformed>

World Bank (2006b) “Implementation Completion Report (IDA-2930 PPF1-P8940) on a Credit in the Amount of US\$ 96.7 Million to India for a Tuberculosis Control Project,” Report No. 34692, accessed at [http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2006/07/26/000012009\\_20060726101636/Rendered/PDF/346920rev0pdf.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2006/07/26/000012009_20060726101636/Rendered/PDF/346920rev0pdf.pdf)

World Bank (2006c) “Project Appraisal Document on a Proposed Credit for SDR 115.7 Million (US\$ 170.0 Million Equivalent) to the Government of India for the Second National Tuberculosis Control Program,” Report No. 32214, accessed at [http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2006/08/03/000160016\\_20060803115637/Rendered/PDF/32214.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2006/08/03/000160016_20060803115637/Rendered/PDF/32214.pdf)

World Bank (2007) “World Bank Statement on the Health Sector Projects in India,” Washington and New Delhi, accessed at <http://go.worldbank.org/YGSZIWB90>

World Bank (2012) *World Development Indicators*, accessed at <http://databank.worldbank.org/ddp/home.do>

World Bank (2006-2012), Second National Tuberculosis Control Project, Implementation Status Reports

World Bank (2006-2012), Second National Tuberculosis Control Project, Aide Memoires

#### World Health Organization (WHO) Reports

WHO (1997) “TB Patients and Private For-Profit Health Care Providers in India,” Report No. WHO/TB/97.223, Geneva, accessed at [http://whqlibdoc.who.int/hq/1997/WHO\\_TB\\_97.223.pdf](http://whqlibdoc.who.int/hq/1997/WHO_TB_97.223.pdf)

WHO (2003) “Joint Tuberculosis Programme Review, India, September 2003,” New Delhi, accessed at <http://tbcindia.nic.in/Pdfs/JMMFinalReport2003.pdf>

WHO (2006a) “Joint Tuberculosis Programme Review, India, 2006,” New Delhi, accessed at <http://www.tbcindia.nic.in/Pdfs/JMM-2006%20Report.pdf>

WHO (2006b) *WHO Report 2006 Global Tuberculosis Control: Surveillance, Planning, Financing*, Geneva, accessed at [http://libdoc.who.int/publications/2006/9241563141\\_eng.pdf](http://libdoc.who.int/publications/2006/9241563141_eng.pdf)

WHO and Stop TB Partnership (2006) *The Stop TB Strategy*, Geneva, accessed at <http://www.who.int/tb/strategy/en/>

WHO (2010) *A brief history of tuberculosis control in India*, Geneva, accessed at [http://whqlibdoc.who.int/publications/2010/9789241500159\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241500159_eng.pdf)

WHO (2011) *Global Tuberculosis Control 2011*, Geneva, accessed at [http://www.who.int/tb/publications/global\\_report/2011/en/](http://www.who.int/tb/publications/global_report/2011/en/)

WHO (2012a) Draft “Joint Monitoring Mission 2012: Revised National TB Control Programme”, New Delhi.

WHO (2012b) *Global Tuberculosis 2012*, Geneva, accessed at [http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/)

World Health Organization (WHO) and Stop TB Partnership (2011) *The Global Plan to Stop TB 2011-2015*, Geneva, accessed at <http://www.stoptb.org/global/plan/>

#### Other Sources

Ananthakrishnan R, Muniyandi M, Jeyaraj A, Palani G and Sathiyasekaran BWC (2012) “Expenditure Pattern for TB Treatment among Patients Registered in an Urban Government DOTS Program in Chennai City, South India,” *Tuberculosis Research and Treatment*, accessed at <http://www.hindawi.com/journals/trt/2012/747924/>

Chow J, Darley SR and Laxminarayan R (2007) “Cost-effectiveness of Disease Interventions in India,” Resources for the Future Discussion Paper 07-53, accessed at <http://www.rff.org/Publications/Pages/PublicationDetails.aspx?PublicationID=17520>

Goodchild M, Sahu S, Wares F, Dewan P, Shukla RS, Chauhan LS and Floyd K (2011) “A cost-benefit analysis of scaling up tuberculosis control in India,” *International Journal of Tuberculosis and Lung Disease* 15(3): 358-362.

Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, Jha P, Mills A and Musgrove P (eds.) (2006) *Disease Control Priorities in Developing Countries, Second Edition*, Oxford University Press and the World Bank, New York and Washington, accessed at <http://www.dcp2.org/pubs/DCP>

Jaroslawski S and Pai M (2012) “Why are inaccurate tuberculosis serological tests widely used in the Indian private healthcare sector? A root-cause analysis,” *Journal of Epidemiology and Global Health* 2(1): 39-50.

Kapoor SK, Raman AV, Sachdeva KS and Satyanarayana S (2012) “How did the TB patients reach DOTS services in Delhi? A study of patient treatment seeking behavior,” *PLoS ONE* 7(8) accessed at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0042458>

Laxminarayan R, Klein E, Dye C, Floyd K, Darley S and Adeyi O (2007) “Economic Benefit of Tuberculosis Control,” World Bank Human Development Network Policy Research Working Paper 4295, accessed at <http://documents.worldbank.org/curated/en/2007/08/8011024/economic-benefit-tuberculosis-control>

Nair D, George A and Chacko KT (1997) “Tuberculosis in Bombay: new insights from poor urban patients,” *Health Policy and Planning* 12(1): 77-85.

Oxlade O and Murray M (2012) “Tuberculosis and Poverty: Why Are the Poor at Greater Risk in India?” *PLoS ONE* 7(11), accessed at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0047533>

Udwadia ZF, Pinto LM and Uplekar MW (2010) “Tuberculosis Management by Private Practitioners in Mumbai, India: Has Anything Changed in Two Decades?” *PLoS ONE* 5(8) accessed at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0012023>

Uplekar M, Pathania V, Raviglione M (2001) Private practitioners and public health: weak links in tuberculosis control. *The Lancet* 358:912-916

Wells WA, Ge CF, Patel N, Oh T, Gardiner E and Kimerling ME (2011) “Size and Usage Patterns of Private TB Drug Markets in the High Burden Countries,” *PLoS ONE* 6(5), accessed at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0018964>

---