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Report No: 32214

PROJECT APPRAISAL DOCUMENT

ON A

PROPOSED CREDIT

OF SDR 115.7 MILLION
(US$170.0 MILLION EQUIVALENT)

TO THE

GOVERNMENT OF INDIA

FOR THE

SECOND NATIONAL TUBERCULOSIS CONTROL PROGRAM

July 15, 2006

Human Development Sector Unit
India Country Management Unit
South Asia Region

CURRENCY EQUIVALENTS

(Exchange Rate Effective September 30, 2005)

Currency Unit = Indian Rupees
INRs. 44.04 = US$1
US$1.46997 = SDR 1

FISCAL YEAR

April 1 – March 31

ABBREVIATIONS AND ACRONYMS

AG	Auditor General
AIIH&PH	All India Institute of Hygiene and Public Health, Calcutta
ARCS	Audit Reports Compliance System
ARTI	Annual Risk of TB Infection
ARV	Anti Retro-Virals
ASHA	Accredited Social Health Activist
BCC	Behavior Change Communication
CAAA	Controller of Aid Account and Audit
C&AG	Comptroller and Auditor General of India
CAS	Country Assistance Strategy
CBO	Community Based Organization
CIDA	Canadian International Development Agency
CMO	Chief Medical Officer
COPP	Certificate of Pharmaceutical Product
CPAR	Country Procurement Assessment Report
CSS	Centrally Sponsored Scheme
CTD	Central TB Division of MOHFW (see below)
DALY	Disability-Adjusted Life Years
DANIDA	Danish International Development Assistance
DC	Direct Contracting
DDG	Deputy Director General
DFID	UK Department for International Development
DGS&D	Directorate General of Supplies and Disposals
DIR	Detailed Implementation Review
DMC	Designated Microscopy Center
DOTS	Direct Observed Treatment Short-course
DOTS Plus	DOTS plus for multi drug resistant TB
DRS	Drug Resistance Surveillance
DST	Drug Susceptibility Testing
DTC	District TB Centre
DTO	District TB Officer
EOI	Letters of Expression of Interest
EPW	Empowered Procurement Wing of the MOHFW
EAG	Empowered Action Group states which includes Bihar, Chhattisgarh, Jharkhand,

	Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh and Uttaranchal
GAAP	Governance and Accountability Action Plan
GDF	Global Drug Facility
GDP	Gross Domestic Product
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GFR	General Financial Rules
GMSD	Government Medical Stores Depot
GoI	Government of India
GMP	Good Manufacturing Practices
HFWS	Health and Family Welfare Society
HIV/AIDS	Human Immuno Deficiency Virus/Acquired Immuno Deficiency Syndrome
ICB	International Competitive Bidding
IDA	International Development Association
IEC	Information, Education and Communication
INT	Department of Institutional Integrity, The World Bank
IMA	Indian Medical Association
IPC	Inter Personal Communication
IRL	Intermediate Reference Laboratories
I&E	Incentives and Enablers
KAP	Knowledge Attitudes and Practices
LRS	Lala Ram Swarup Institute of TB and Allied Diseases, Delhi
LTs	Laboratory Technicians
MC	Microscopy Center
MDG	Millennium Development Goals
MDR	Multi-drug Resistant TB
MOHFW	Ministry of Health and Family Welfare
NACO	National AIDS Control Organization
NCB	National Competitive Bidding
NGOs	Non-Governmental Organizations
NRHM	National Rural Health Mission
NTI	National Tuberculosis Institute, Bangalore
OR	Operational Research
PDO	Program Development Objective
PIP	Program Implementation Plan
PP	Private Practitioners
PPD	Purified Protein Derivative
PPM	Public-Private Mix
PRI	Panchayat Raj Institutions
QA	Quality Assurance
QCBS	Quality and Cost Based Selection
RCH	Reproduction and Child Health Project
RFP	Request for Proposal
RNTCP	Revised National TB Control Program (which provides DOTS)
RNTCP I	Revised National Tuberculosis Program I (1997 – 2005); this program was supported by the IDA assisted Tuberculosis Control Project
RNTCP II	Revised National Tuberculosis Program II (2005 – 2010)

SBD	Standard Bidding Documents
SC/ST	Scheduled Castes/Scheduled Tribes
SIA	State Implementing Agency
SIL	Specific Investment Loan
SOE	Statement of Expenditure
SPAR	State Procurement Assessment Report
STDC	State TB Training and Demonstration Center
STLS	Senior TB Laboratory Supervisor
STO	State TB Officer
STS	Senior Treatment Supervisor
SWAp	Sector Wide Approach
TB	Tuberculosis
TDP	Tribal Development Plan
TOR	Terms of Reference
TRC	Tuberculosis Research Center, Chennai
TU	Tuberculosis Unit
USAID	United States Agency for International Development
VCTC	Voluntary Counseling and Testing Centers for HIV/AIDS
WHO	World Health Organization

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INDIA

SECOND NATIONAL TUBERCULOSIS CONTROL PROGRAM

CONTENTS

SECOND NATIONAL TUBERCULOSIS CONTROL PROGRAM

PROJECT APPRAISAL DOCUMENT

SOUTH ASIA

SASHD

Date: July 28, 2006	Team Leader: Birte Holm Sorensen
Country Director: Michael F. Carter	Sectors: Health (100%)
Sector Manager/Director: Anabela Abreu/Julian F. Schweitzer	Themes: Other communicable diseases (P);Health system performance (P);Decentralization (S)
Project ID: P078539	Environmental screening category: Partial Assessment
Lending Instrument: Specific Investment Loan	Safeguard screening category: B Limited impact

Project Financing Data

[ ] Loan [X] Credit [ ] Grant [ ] Guarantee [ ] Other:

For Loans/Credits/Others:
Total Bank financing (US$m.): 170.0
Proposed terms: maturity of 35 years, including a grace period of 10 years.

Financing Plan (US$m)

Source	Local	Foreign	Total
BORROWER/RECIPIENT	29.8	12.7	42.5
GFATM DFID Drugs Phase II USAID GDF WHO Technical Assistance	90.6	38.9	129.5
IDA	119.0	51.0	170.0
Total Program Costs:	239.4	102.6	342.0

Borrower: INDIA
Department of Economic Affairs, Ministry of Finance
New Delhi
India
Tel: +91 11 23094413

Responsible Agency:
Ministry of Health and Family Welfare
India
Tel: +91 11 23063226

Estimated disbursements (Bank FY/US$m)							
FY	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	
Annual	12.00	28.7	29.0	35.3	38.6	26.4	
Cumulative	12.00	40.7	69.7	105.0	143.6	170.00	

Project implementation period: Start October 1, 2006 End: September 30, 2011
Expected effectiveness date: October 1, 2006
Expected closing date: March 31, 2012

Does the project depart from the CAS in content or other significant respects? ***Ref. PAD A.3***	[ ]Yes [X] No
Does the project require any exceptions from Bank policies? ***Ref. PAD D.7*** Have these been approved by Bank management? Is approval for any policy exception sought from the Board?	[ ]Yes [X] No [ ]Yes [ ] No [ ]Yes [X] No
Does the project include any critical risks rated "substantial" or "high"? ***Ref. PAD C.5***	[X]Yes [ ] No
Does the project meet the Regional criteria for readiness for implementation? ***Ref. PAD D.7***	[X]Yes [ ] No

Project development objective ***Ref. PAD B.2, Technical Annex 3***
(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 Directly Observed Treatment, short course (DOTS) has been under implementation for five or more years, the incidence of smear-positive Tuberculosis (TB) starts to decline.

Project description *[one-sentence summary of each component]* ***Ref. PAD B.3, Technical Annex 4***
Output one: Revised National Tuberculosis Control Program (RNTCP) services consolidated. This output aims at sustaining the quality of public TB services across the country. To have an impact on the incidence and mortality due to TB, quality services must be maintained for many years. The previous phase mainly focused on start-up to ensure provision of DOTS across the country. For sustained service quality in public service provision, special emphasis would now be given to improving the laboratory services, supervision and monitoring, continuous operations research, advocacy and health communication and strengthening of institutional capacity to implement the program.

Output two: RNTCP outreach to target special groups expanded. This output aims to maximize the inclusion of TB patients under DOTS. With expansion of DOTS to all districts in the country the program would now implement appropriate strategies to ensure that services reach (i) the poor, tribal people and other 'hard to reach groups'; (ii) patients who consult non-RNTCP health service providers; (iii) patients infected with HIV/AIDS; (iv) pediatric cases; and (v) multi drug resistant TB cases.

Which safeguard policies are triggered, if any? ***Ref. PAD D.6, Technical Annex 10***
Environmental Assessment, Indigenous Peoples

Significant, non-standard conditions, **if any**, for:

Ref. PAD C.6
Board presentation: None Loan/credit effectiveness: None
Covenants applicable to project implementation: The Government of India (GoI) shall cause the Ministry of Health and Family Welfare (MOHFW) to ensure that each project state and Project Executing Agency carry out their respective activities under the project in accordance with a Letter of Undertaking (LOU) satisfactory to the Association (IDA) to be signed by each project state and its respective State Implementing Agencies (SIA) i.e. expenditures from a given state would not be eligible for reimbursement from IDA unless the corresponding LOU has been signed. The GoI shall cause the MOHFW to ensure adequate management capability in Central TB Division (CTD); to review the number and composition of staff and the requirement for technical assistance annually; to revise the staffing norms and composition if found necessary during the mid term review; to maintain the Advocacy and Information Education Communication (IEC) Unit and an IEC Advisory Group within CTD, to maintain these structures throughout project implementation and to review annually the capacity for IEC at the CTD, the project states, and at the district levels; to maintain the Financial Management Unit and a Procurement Supply and Logistics Unit within CTD and maintain the units throughout project implementation; to maintain monitoring and evaluation systems for RNTCP II and ensure timely reports in an agreed format satisfactory to IDA for the six-monthly review missions. The GoI shall cause the audits of various Project Executing Agencies to be conducted in a timely manner in accordance with the terms of reference set out in the Finance and Accounts Manual and in the Procurement Manual for RNTCP II. The GoI shall cause Ministry of Health and Family Welfare (MOHFW) and the project states to enroll more medical colleges to actively support RNTCP II throughout project implementation; to ensure that all newly established laboratories for MDR-TB, public and private, are accredited to undertake Drug Susceptibility Testing (DST) before they are used for diagnosing Multi Drug Resistant TB; and to procure goods, works and services for the program in a timely manner, ensure that drugs are properly stored up to the end of the supply chain. The GoI shall cause the MOHFW and the project states to implement, in a manner satisfactory to IDA, the Tribal Development Plan and the interventions targeted towards other socially deprived groups set forth therein as well as the agreed Infection Management and Environmental Plan and ensure that the relevant manuals and guidelines are at all times consistently and satisfactorily applied. The GoI shall cause MOHFW to maintain the Empowered Procurement Wing, under terms of reference satisfactory to the Association, which is staffed with suitably qualified staff in sufficient numbers, and provided with adequate resources throughout the period of project implementation.

The GoI shall cause the MoHFW to implement the Governance and Accountability Action Plan (GAAP), refrain from taking any action which will prevent or interfere with the implementation of the GAAP, not waive, amend or abrogate the GAAP; and, provide a written report on progress achieved in the implementation of the GAAP, the first report dated December 31, 2006 and thereafter once every six months.

Based on the findings of the review on procurement capacity, on the quality and quantity of pharmaceuticals and medical goods, and on implementation of health sector projects financed by IDA, the GoI shall carry out revisions as necessary to strengthen the Governance and Accountability Action Plan (GAAP).

A. STRATEGIC CONTEXT AND RATIONALE

1. Country and Sector Issues

India is a low-income country with a gross national income per capita of US$620 (2004) and a population of 1.08 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.

Ill 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[1] (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 un-registered 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). The program was built upon an existing program and was first initiated in 1993 in five states. The success of this pilot, incorporating the internationally recognized Directly Observed Treatment Short course (DOTS) strategy, encouraged the GoI to expand the program which from March 2006 has made DOTS available in all districts of the country. The DOTS strategy is composed of the following elements: (i) the presence of political willingness to address the problem of TB adequately and to guarantee the means and resources necessary for its control; (ii) an appropriate way of diagnosis (sputum microscopy); (iii) availability of adequate stocks of good quality drugs; (iv) 'directly observed' adherence to effective combination treatment; and (v) proper ways of case registration, monitoring, and outcome evaluation.

[1] Mid-term appraisal of the 10th Five Year Plan (2002-2007), GoI

While there are inter-state and inter-district differences in the percentage of estimated cases put on treatment (the case detection rate), the average for the country had reached the global target of 70% by 2004. On an average, 85% of those patients put on treatment are cured. If the present levels of case detection and cure rates are maintained, India would be able to reduce the overall prevalence of TB by at least 5% every year. Yet, to reach the Millennium Development Goal (MDG) of halving the 1990 prevalence by 2015, the current program momentum must be maintained for the next ten to fifteen years and additional challenges overcome.

Strong central technical leadership has contributed to the success in scaling-up of DOTS service delivery but the long term consolidation and expansion of the program will need stronger institutional capacity at the state level, a more decentralized system and increased attention to social and management areas as well as targeted support from the center to under-performing states and districts.

A recent Social Assessment (SA) by GoI has confirmed that there are still special groups such as tribals, rural poor and urban slum populations who face difficulties in accessing TB treatment. Their knowledge of the symptoms of TB and availability of free treatment is limited and free public services are outside of their reach. Many seek treatment from non-RNTCP providers who are not well informed of DOTS and provide inadequate treatment at a high cost to the patient. Lack of knowledge about the importance of completing treatment often leads to treatment failure and drug resistance.

The Human Immuno Deficiency Virus (HIV) epidemic, which has already infected 5.1 million people in India, has created a new threat to TB control. India has the second largest number of persons living with HIV in the world. The probability that these persons are infected with TB depends on their age and may vary from 20-60% in the age group of 20-40 years. It is estimated that there is a 50-60% lifetime risk of developing TB for those who have both infections[2] (HIV-TB co-infection). A high HIV incidence may therefore lead to an increase in TB incidence even with an effective RNTCP.

Another challenge to TB control has emerged in the form of multi-drug resistant TB cases (MDR-TB) which are far more difficult and expensive to treat than drug susceptible (common) TB. These cases originate from inappropriate use of TB antibiotics (due to lack of compliance by the patient or lack of knowledge by the provider) and untreated, the drug resistant form is passed on to others through ordinary transmission. Fortunately, the available data shows that levels of MDR-TB remain relatively low, at around 3% among new patients and 12% in re-treatment cases. However, these relatively low percentage figures in the Indian context translate into large numbers of people who can transmit their drug resistant bacteria and who require effective treatment.

The RNTCP is a centrally sponsored scheme where the GoI provides all TB drugs, contractual services, Information Education Communication (IEC), vehicles, microscopes and other

2 Risk of development of tuberculosis in HIV-infected patients. Swaminathan S, Ramachandran R, Baskaran G, Paramasivan CN, Ramanathan U, Venkatesan P, Prabhakar R, Datta M. Tuberculosis Research Centre, Indian Council of Medical Research, Chetput, Chennai.

laboratory equipment, minor civil works, training and operating costs. The state contribution to the program is in the form of staff time, facilities, transport, supportive drugs and supplies. The state expenditure on TB control is not available but a rough estimate based on staff-time allocation in three states and a questionnaire filled by 15 states indicates that the GoI's contribution is in the margin of 35-65 % of the overall expenditure for TB control.

The RNTCP has received financial and technical assistance from a number of sources including Canadian International Development Agency (CIDA), Danish International Development Assistance (DANIDA), Department for International Development (DFID) of the United Kingdom, United States Agency for International Development (USAID), Global Fund for AIDS, Tuberculosis and Malaria (GFATM), Global Drug Facility (GDF), World Health Organization (WHO) and IDA.

2. Rationale for IDA involvement

IDA has supported the RNTCP since 1997 (TB Control Project, Credit No. 2936 IN, US$142 million; closed September 30, 2005). During this period the program has demonstrated remarkable results measured in case detection and cure rates for TB patients as well as expansion of coverage with DOTS treatment (for TB performance indicators see Annex 12). Since 1997, more than 5.6 million TB patients have been placed on DOTS. The program has entered a new phase of consolidation of the core RNTCP activities to ensure that all districts reach the global targets and expansion to ensure access of all TB patients to treatment. IDA support for this program would add value by bringing technical and institutional expertise as the program is facing the challenge of providing services to the most difficult areas of the country. Moreover, IDA is well placed to assist the government with ensuring that the assistance of all donors is well coordinated and fully in line with the government's program.

Several aspects of the program would facilitate increased coordination amongst donors and between the donors and the government. IDA and the other donors (GFATM, USAID, DFID, WHO and GDF) have agreed with the GoI on a shared results framework, and on the estimated costs and overall financing plan for the program. The assistance from all donors would be provided in the context of the program that has been agreed between GoI and IDA, and implementation by the states will also be guided by this agreed program. All states regardless of their source of program financing would be complying with a common set of financial management, procurement and program monitoring arrangements. Joint Review Missions for GoI and all donors were in principle agreed upon during negotiations (details in Annex 12).

It may also be noted that one of the health-related MDGs is to "halt and start reducing the incidence of TB by 2015". Since India is critical for achieving the global MDGs, the proposed program would re-affirm IDA's strong commitment to the global goals.

3. Higher level objectives to which the program contributes

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. India's prospects to achieve the MDG for combating TB depend on the success of the

program to sustain and deepen coverage throughout the country. This is noted in GoI's 10th Five Year Plan (2002-2007) as a priority and is also fully consistent with the Country Assistance Strategy (CAS) for India (July 2004).

B. PROGRAM DESCRIPTION

1. Lending instrument

The proposed lending instrument would be a Specific Investment Loan (SIL) with the funding disbursed in the form of program support (i.e. a sub-sector SWAp). A SIL would be suitable because: (i) it would allow for broad support to the maintenance of this program rather than narrowly financing a specific set of activities or geographical areas; (ii) it would allow the borrower to pursue other, parallel financing sources while ensuring that there is no financing gap; (iii) it would allow the borrower to develop and use its own indicators, monitoring and evaluation system, financial management and procurement arrangements regardless of funding source; (iv) it would help the borrower develop institutional capacity to plan, implement and monitor activities, expenditures and outcomes of the program; (v) it would reduce transaction costs for both the borrower and IDA; and (vi) it would promote coordination between the borrower and its partners.

The IDA credit would finance a time-slice for the period, FY2006 to FY2011 of the centrally sponsored RNTCP, excluding those program activities/expenditures that are funded by other donors and by the states. These other donors provide parallel support to specific inputs (technical support, drugs) or to all expenditures for specific states, with a limited time commitment, while IDA would pool funds with GoI and disburse up to an agreed 80% of the funding gap. The financing requirements are based on an estimate of other (grant) financing for the next five years.

2. Program development objectives, outcomes and key indicators

India had already reached the global targets of 70% case detection rate and 85% cure rate on a nationwide basis in areas where DOTS was being implemented in 2004. However, there are 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 new districts not yet having reached the global targets. On the other hand, there are many areas of the country where DOTS has now been implemented for five or more years, and the expectation would be that – if the program is functioning effectively – the incidence of smear-positive TB should start to decline in those areas. In accordance with these observations, the Program Development Objective (PDO) of the proposed operation is: (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 two key indicators to track progress towards the PDO (Annex 3) are as follows: (i) the number of districts that have achieved a detection rate of at least 70% and a cure rate of at least 85%; and (ii) the incidence of smear-positive TB in zones where DOTS has been implemented for five years or more begins to show a reduction.

The proposed operation would support the second phase of RNTCP, henceforth referred to as RNTCP II, which has been defined by the GoI in their Project Implementation Plan (PIP) dated May 31, 2005. This document has been prepared by CTD of the MOHFW, GoI, through extensive consultations with state and district representatives, representatives from the leading TB research institutions as well as IDA and other donor representatives during program preparation.

While emphasis in the previous phase of RNTCP was on introduction of DOTS in a uniform manner across the country, the RNTCP II will increasingly target the states and districts which have below average performance in the form of case detection rate below 70% and/or cure rate below 85% through additional technical and managerial support from the center. A provision is made for additional inputs to Empowered Action Group (EAG[3]) states with a special provision made for additional contractual posts in these states. In addition, the EAG states will be more closely monitored and supervised by the CTD. The North Eastern states with large tribal populations and geographically difficult areas will be provided an allocation which is 1.3 times the regular norm and special incentives will be made available for health workers who work in tribal communities. With DOTS available throughout the country, major emphasis will now be given to IEC both at national and state level with additional Communications Facilitators for every five districts engaged by the program.

The Government has recognized that although a strong public sector DOTS program is essential, it is not sufficient to reach all TB patients. A number of pilot activities therefore have addressed issues such as including non-public providers in RNTCP, providing services to urban slum populations, ensuring that HIV positive persons suspected of TB have access to diagnosis and treatment, and ensuring that multi drug resistant patients receive treatment. These activities will be scaled up in RNTCP II.

The challenges ahead for RNTCP II lie in (i) maintaining the current momentum of the program, of the strict clinical standards and of an effective IEC strategy throughout the country over a period of ten to fifteen years, especially as the larger, weaker states are fully included in the program; and (ii) expansion of DOTS availability to ensure that 'hard to reach' groups, patients who seek treatment from non-RNTCP providers, HIV positive and MDR patients have adequate access to effective TB treatment. These aspects are essential for achieving the long term goal of reducing TB incidence and will be addressed through this program.

The GoI has recently launched the National Rural Health Mission (NRHM), an initiative to improve the health status of the population in rural areas by promoting convergence of several centrally sponsored schemes including RNTCP. Several components of the NRHM, such as merging the different state and district health societies into one; making the Chief Medical Officer (CMO) responsible for overall program implementation at district level; supporting a local female volunteer, the Accredited Social Health Activist (ASHA) worker, in every village; and inclusion of Panchayat Raj Institutions and civil society groups in participatory health planning at local and district level are likely to strengthen the capacity of the states, especially the weaker states, and thereby facilitate implementation of the RNTCP.

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3 The EAG states include Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh and Uttaranchal

3. Program outputs and activities

To achieve the PDO, two broad outputs are required: (i) RNTCP services consolidated through enhancement of the quality of public DOTS provision; and (ii) TB services expanded to generally under-served populations. During the first year of this program, DOTS would have been introduced in all districts of the country. Focus would now be on achieving program consolidation throughout the country and inclusion of necessary additional components to expand and increase the program reach.

Output one: RNTCP services consolidated. This output aims at sustaining the quality of public TB services across the country by placing special emphasis on the improvement of laboratory services, supervision and monitoring, continuous operations research, advocacy and health communication, and strengthening of institutional capacity to implement the program.

Quality of laboratory services would be consolidated through (i) establishment of a network of intermediate reference laboratories (IRL) at the state level to allow intensified supervision of laboratory activities at district level; (ii) introduction of a comprehensive laboratory quality assurance (QA) mechanism based on regular supervision of staff at all levels, proficiency testing with slide panels and blind cross-checking of slide samples from all diagnostic centers; (iii) ensuring the routine reporting of QA results to state and central levels to allow targeted interventions for quality improvement.

To improve supervision and monitoring the RNTCP II would strengthen the system of supervision at all levels of the program. Every year a few randomly selected districts would be visited by a team from CTD and data validated. State TB officers would regularly supervise the districts and likewise select a number of districts every year for in-depth supervision and validation of data. District TB officers would travel for 15 days every month to supervise laboratory and other field staff as well as the DOTS providers. This is one of the first DOTS programs worldwide to use a comprehensive, computerized Management Information System for data collection and transmission; this system would be on-line for all districts early in the program period. To monitor the impact of the RNTCP on the incidence of tuberculosis, Annual Risk of TB Infection (ARTI) surveys will be taken up in 2008; results from zones where DOTS has been implemented for more than five years would provide the first evidence of program impact on TB incidence. The program would continue to employ contractual staff for field level supervision i.e. the Senior Treatment Supervisors (STS) and the Senior TB Laboratory Supervisors (STLS) but increase the number of staff in low performing areas.

Operational research to generate an appropriate and continuous flow of information would receive priority attention in order to make TB control in India more effective. The RNTCP would communicate the research agenda widely and engage individuals/organizations to undertake research. Priority topics would include strengthening service delivery to and demand for services from marginalized groups and HIV/TB co-infected persons, further development of Public Private Mix (PPM) models, and new areas such as pediatric DOTS and DOTS Plus[4].

[4] DOTS Plus is the acronym for treatment of multi-drug resistant TB

Information, Education and Information (IEC) would be strengthened to: (i) create awareness of TB symptoms and demand for free DOTS services, with the drugs provided in patient-wise boxes[5], among the public and the health providers; (ii) advocate for policy, administrative and community-level commitment to TB control in India; (iii) enhance patient-provider communication and counseling to help ensure patient compliance and patient-friendly service. A *process* rather than *products* orientation would promote interpersonal interactive communication and needs-based planning using a three-step package (formative research, strategy development and monitoring). The CTD would provide leadership, manage the national level media and advocacy sub-component, and oversee capacity building in the states. Detailed state and district IEC plans would ensure contextual relevance and wide reach of information. Additional contractual staff to facilitate communication would be provided for every five districts and special attention would be paid to social issues such as stigma and gender, hearing the voices of beneficiaries, and reaching marginalized and vulnerable groups and patients living with HIV.

Appropriate institutional capacity would be ensured at all levels to maintain program quality. It would include: (i) strengthening CTD through the provision of equipment and adequate physical facilities, and by having units and officers in charge of supervision and monitoring, human resource management and development, financial management, procurement, advocacy and health communication, and epidemiology/surveillance to better address weaker areas; (ii) strengthening managerial capacity at state level and implementation capacity at district level through hiring of additional contractual staff; (iii) technical assistance to support CTD's efforts to further decentralize the program's activities in a phased manner and encourage states to take ownership, and assigning additional WHO consultants to large and poorly performing states; (iv) support to states' efforts to provide quality training to all staff involved in the program, as well as DOTS providers; and (v) assistance to public and private medical colleges to provide training on DOTS implementation and monitoring to the faculty, to support existing state level TB task forces in defining their roles and plans of action, and to support the continued creation of active task forces in medical colleges.

Output two: RNTCP outreach to target special groups expanded. This output aims to maximize the inclusion of TB patients under DOTS. With the expansion of DOTS to all districts in the country, the program would now implement appropriate strategies to ensure that services reach (i) the poor, tribal people and other 'hard to reach groups'; (ii) patients who consult non-RNTCP health service providers; (iii) patients infected with HIV/AIDS; (iv) pediatric cases; and (v) multi-drug resistant TB cases.

Despite country wide coverage of the RNTCP, the poor, tribal and other 'hard to reach' groups still do not adequately avail of its services. A Social Assessment has been undertaken to prepare an overview of who is not being reached in the current program and provide insights into how the program can better ensure that their needs are addressed. Based on this assessment, on a Tribal Plan, and on documentation of the numerous positive experiences with accommodating the needs of special groups around the country, each state would implement these activities as appropriate to the conditions of their state. Special incentives will be provided to health staff

5 Patient wise boxes: cardboard boxes containing the full regimen of TB drugs for treatment of one patient – currently only used for adult DOTS.

working in difficult and tribal areas and additional financial and managerial support extended to below average performing areas.

The first point of contact for patients is most often the private providers (the term private providers, here, refers to the large range of providers who are not part of the Ministry or Directorates of Health and Family Welfare of the central or state governments). The program would seek to identify and successfully treat, under the RNTCP, as many of the presently unregistered and undetected cases as possible and promote the involvement of private providers in the RNTCP and in DOTS provision. Continuing with the current efforts that appear to be yielding results, RNTCP II would provide additional support in the form of training for non-public providers. It would also provide additional technical assistance in the states to: (i) draw from the experiences of current Non Governmental Organizations (NGOs) and Private Practitioner (PP) schemes and revise them, if necessary; (ii) prepare a framework for phased expansion of PPM, develop tools for implementation and indicators to monitor progress; and (iii) undertake operational research to assess the effect of PPM related interventions on case detection, treatment success, equity in access and financial protection for the poor.

Under the RNTCP II, the aim of HIV/TB coordination would be to ensure optimal synergy between the two programs at both state and district levels for prevention and control of both diseases. This would be accomplished primarily through joint planning, sensitization, health communication and training in both programs, ongoing HIV surveillance among TB patients, and intensified TB case-finding among people living with HIV/AIDS. Training in both programs would include management of TB in HIV patients, including those on anti-retroviral drugs, and implementation of infection control to prevent the spread of TB in HIV/AIDS clinical care facilities. Activities would be targeted to all states and districts with a high HIV/AIDS prevalence. In addition, the number of state level HIV/TB coordinators would be increased from the current six to fourteen to ensure coverage of all states with a high HIV prevalence.

Standardized drug regimens for the treatment of pediatric cases in 'patient-wise' boxes would be introduced along with ensuring the availability of the necessary diagnostic facilities for pediatric cases and appropriate staff training. The existing recording/reporting system would be modified to allow adequate evaluation of case-finding and treatment outcomes for pediatric cases.

To address the problem of Multi Drug Resistance (MDR), laboratory capacity at state level for the performance of sputum culture and drug sensitivity testing would be established in a phased manner. This would include routine surveillance systems for levels of drug resistance against anti-TB drugs, clinical centers at the state level for the treatment of MDR cases, and gradual expansion of access to drug resistance testing and treatment of MDR-TB for cases who fail treatment under the RNTCP category two drug regimens. Due to the high cost of second line drugs, DOTS Plus, and rigorous compliance requirements, facilities would be carefully selected based on their demonstrated ability to implement DOTS and to comply with strict quality assurance requirements.

4. Lessons learned and reflected in the program design

The program design was informed by 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.

RNTCP I:

- *Need to continue additional core Human Resources*: experience from RNTCP I showed that provision of contractual support staff, especially for supervision, at the states, districts and sub-districts, and ensuring mobility of staff is a core element for the success of the program. The technical support provided through a large network of WHO-contracted local consultants also proved very valuable.
- *Need for upfront assessment of minimum standards of implementation:* the preparation and field testing of policies and guidelines and a system of appraisal of each district before the start of service delivery has ensured that a minimum standard was met before starting DOTS. A similar approach would be used for scaling up the PPM, HIV/TB coordination, DOTS Plus and other initiatives to expand services to all TB patients.
- Need to address procurement issues upfront to ensure uninterrupted supply of TB drugs of adequate quality: drugs have been continuously available in the field although there have been considerable delays in the procurement process. With additional procurement and logistic management capacity in the CTD, the additional capacity building and oversight provided through the Empowered Procurement Wing (see page 11) and the introduction of the Governance and Accountability Framework (see Annex 11), it is expected that these delays will be substantially reduced.
- Need to build capacity at state level before granting authority for implementation: an attempt to decentralize the procurement of TB drugs was made during RNTCP I; since no states were able to procure the drugs, this will remain the responsibility of the CTD in RNTCP II.
- Need to strengthen Public Private Partnerships: delivery of RNTCP services through a mix of public-private providers has resulted in increased case detection. In view of the rapid growth of private sector provision of health care in India, their involvement is essential to ensure that all TB patients receive quality DOTS. With a strong public sector DOTS program established throughout the country, the PPM can now be more aggressively expanded.

Other HNP projects:

- It has become increasingly evident that the management of centrally sponsored schemes needs to be decentralized to the states. There will be significant efforts during RNTCP II to strengthen program ownership and capacity at the state and district levels; TB drug procurement will however remain a central function to ensure that quality drugs are available on time.
- During the implementation of the RCH I project, serious deficiencies were encountered in procurement, including procurement processes. The MOHFW has shown strong commitment to address these issues comprehensively. Agreed actions to counter these risks are detailed in Annexes 8 and 11.
- Experience from IDA support to the National Leprosy Elimination Program has confirmed the effectiveness of a good advocacy and health communication strategy to increase political and community awareness, reduce stigma, and strengthen the demand for quality services.

International best practice in TB control:

- Between 1991 and 2000, prevalence of tuberculosis was reduced significantly in areas of China by the use of short-course chemotherapy using WHO guidelines and supported by IDA. It was estimated that in 2000, in a population of more than half a billion people, there were 280,000 fewer sputum positive cases than there would otherwise have been.
- The RNTCP closely follows the operational and technical guidelines for DOTS recommended by the WHO and other organizations such as the International Union against TB and Lung Diseases, Stop TB and the United States Center for Disease Control. This approach will be continued with the introduction of DOTS Plus.

5. Alternatives considered and reasons for rejection

First, financing of a set of specific interventions or geographical areas was considered but rejected. It would not have leveraged IDA financing into a partnership where a program with common goals across states was ensured regardless of financing source. It would also not have contributed to capacity building and development of common procedures for all states in the country. Second, performance-based financing from center to state was discussed but rejected. Since TB is a communicable disease, its control is of national, in addition to, state concern: infectious patients in any given state would infect residents of other states when they traveled within the country. Rather than reducing financing to below average performing states, additional inputs in the form of technical and management support would be provided. Since this is the consolidation phase of a highly successful program, other alternatives were not considered.

C. IMPLEMENTATION

1. Partnership arrangements

The borrower has in the past received assistance from a number of bilateral and multilateral partners, who financed activities in individual states or a number of districts within states and for a limited time period. Some of this assistance is now being phased out and the borrower is increasingly seeking assistance which is complementary to and in support of their own program. GFATM has committed support until 2009 and additional support up to 2011 may be applied for. WHO has three year planning circles and fully commits consultant support on an annual basis depending on funds availability, but is expecting to continue its present support until at least 2011; USAID supports all the RNTCP activities in one state but will complete this support by 2008. DFID will provide drugs through the GDF to ensure a buffer stock of TB drugs[6] as well as support consultants contracted by WHO. The GoI is coordinating this support to ensure that it is complementary to the overall program financed from IDA and GoI funds and that only one set of systems and procedures are used for program performance and financial management. Specific aspects of the program that would facilitate increased coordination amongst the donors and between the donors and the government are mentioned in Section A.2.

[6] Support already committed is indicated in annex 5, table 1

2. Institutional and implementation arrangements

Institutional Arrangements. The program has been successfully managed for several years by the CTD, headed by the Deputy Director General for TB as the National Program Director, under the leadership of the Director General Health Services who reports to the Health Minister (see organogram in Annex 6). Under RNTCP II, this arrangement would continue with the Joint Secretary from the administrative arm of the MOHFW overseeing the financial and administrative areas. The CTD has five regular officers, one TB specialist and a number of support staff. Experienced technical staff manages all aspects of the program, and also receive significant technical and administrative support from WHO consultants. For RNTCP II five units have been established to manage supervision, monitoring and surveillance, human resources development, advocacy and IEC, procurement supply and logistics, and finance. During project implementation, additional staff may be hired with skills and specialties that complement existing staff.

The CTD would be responsible for facilitating and monitoring state-level planning, establishing technical standards and providing technical and financial oversight, coordinating central procurement and training, and leading the monitoring and evaluation. The CTD Finance Unit would be responsible for financial management activities while the CTD Procurement, Supply and Logistics Unit would be responsible for all drugs procurement and all other large procurement. These two units will include consultants, contracted by WHO. The Procurement, Supply and Logistics Unit would benefit from the general capacity enhancement being undertaken by MOHFW and would receive supervision and oversight from the newly established Empowered Procurement Wing (EPW) of the MOHFW which is intended to professionalize the procurement of health sector goods and services. The wing will ensure better competition and transparency in procurement of health sector goods, drugs and services in India, for delivering quality products in time. The EPW would also support the development and implementation of new policies and actions which will enhance procurement practice and supply chain management. Three national institutions[7] support CTD by carrying out basic and operational research, performing quality control functions, developing training materials and providing training to State TB Officers (STO) and trainers from the State TB Training and Demonstration Centers (STDCs).

At the state level, the Director of Medical Services and the Director of National Programs have had the overall responsibility of overseeing TB program implementation. During RNTCP II, day-to-day implementation responsibility, however, will increasingly be with the STO, who will be the responsible authority for all TB control activities in the state. The STO will be assisted by a team of professional and administrative staff, and by WHO consultants who will provide technical support. State TB Cells will undertake all program related activities such as preparing state plans and budgets based on the consolidation of district plans, allocating funds received from CTD to districts based on their annual plans, training various levels of staff, managing logistical and supply requirements, undertaking minor procurement, ensuring that districts comply with program guidelines and directives, preparing technical and financial reports, and timely reporting. In RNTCP II there would be increasing flexibility in the financial norms to

7 Tuberculosis Research Center, Chennai, National Tuberculosis Institute, Bangalore, and Lala Ram Swarup Institute of TB and Allied Diseases, Delhi

allow states to reallocate budget allocations among line items and move towards zero based budgeting. All states would assume greater responsibility for advocacy and health communication strategies and implementation, and would actively promote local level advocacy and health communication innovations.

The District TB Centre (DTC) has been the nodal point for TB control activities in the district and also functions as a specialized referral center. It is headed by a District TB Officer (DTO), working under the direction of the Chief Medical Officer (CMO). Tuberculosis Units (TU) are sub-district units responsible for providing microscopy services. Responsibility for ensuring a successful TB control program at the local level falls on the large number and wide range of DOTS providers.

In any given district, DOTS implementation was initiated only after successful appraisal by the CTD. In the initial stages representatives from CTD shared the responsibility for directing the program and ensuring compliance with national guidelines with the DTO. Under RNTCP II, such responsibility will increasingly fall on the DTO who has recently been charged with preparing annual plans based on the specific requirements of the district.

To facilitate the new functions at the state and district levels noted above, there is now a need to strengthen the capacity of the central, state and district structures to keep up with the changed demands for program management. RNTCP II therefore aims to strengthen CTD's management capacity, and states' and districts' management and program implementation capacity with additional contractual staff, as the need arises, and a more appropriate skills mix to meet the projected increase in services and address weaknesses in the non-clinical components of the program. In particular, the CTD would seek agreement from the state governments to ensure that STO and DTO positions are filled with medical staff, preferably with background and experience in community health, public health, community health administration, social and preventive medicine, health administration, or health management, and that these officers remain in their position for at least three years. The institutional arrangements for procurement are discussed in Section D.3.

The RNTCP is expected to integrate easily with and benefit from the NRHM in two areas that will directly affect it: (i) transfer of funds through a single society at the state and district levels (see below); and (ii) incorporate 'ASHAs' as DOTS providers at the village level.

3. Monitoring and evaluation of outcomes/results

The RNTCP has in place a robust recording and reporting system which monitors the overall program regardless of financing source. The system is based on quarterly and annual cohorts of TB patients registered for treatment. It allows for systematic cohort analysis of case detection, sputum conversion and treatment outcomes. To further strengthen the surveillance system, the treatment cards, laboratory registers, TB registers and quarterly reporting formats have been modified, and a few additional records have been added to document referrals for treatment after diagnosis. RNTCP began using these new and revised reporting formats in the second quarter of 2005. At the national level, a quarterly and annual performance report is generated with state and district performance indicators, and placed on the program website (www.tbcindia.org).

One of the key components of a monitoring strategy is a set of monitoring indicators. These indicators are already in place and have been further expanded to cover all activities related to the RNTCP at different levels extending from the national to the DOTS Centre level and covering political and administrative commitments, human resources, diagnosis, drugs and treatment. There are also indicators related to recording and reporting, supervision, financial management and health communication. These indicators include all the important input, process, outcome and impact indicators. They have been developed to assist the program managers to identify areas of both strength and weakness in program implementation and bottlenecks in service delivery (Annex 3).

The RNTCP surveillance system collects routine information to measure treatment success and case detection. ARTI studies and existing data from the Tuberculosis Research Center, Chennai would be used to measure reductions in incidence, prevalence and deaths. This information would be validated periodically to ensure the program has the desired long term effect on the TB epidemiology in the country.

During joint Donor Review missions, the program would be monitored based on the overall results framework; data is available for the entire country in the quarterly report posted on the CTD website, and would be supported by financial management and procurement reports. While some donors would make field visits to the specific areas they support, others would monitor states/districts with below average performance and/or issues which require additional attention. A joint Aide Memoire would highlight progress of the overall program and include specific issues for the states under review as well as technical issues which may require additional technical assistance, supervision or review. (Details of the supervision strategy are in Annex 12).

4. Sustainability

Political Sustainability. The RNTCP has demonstrated its value and enjoys strong backing for continued financing from GoI; the program forms an integral part of India's 10th five-year plan and India is an active member of the Global Stop TB movement. During this phase of the program, focus would be on advocacy to ensure long term political commitment of the state governments. The program would add to state and district ownership through its advocacy and institutional development activities. There is a clear political understanding of the threats posed by an HIV/AIDS epidemic to TB control and the need for close coordination between the two programs. Political sustainability must thus be rated as good.

Institutional Sustainability. Program activities are undertaken by regular state government health staff with the exception of a few cadres (the IEC officer, the STS and the STLS) and a few contracted staff in cases of vacancies or special needs. The GoI's contribution is a supplement to that of the States, who provide physical facilities, assign personnel and cover the costs of office and other supplies. All activities are undertaken through the use of government rules and procedures. The WHO consultants play an essential role in program planning and management at central, state and district levels. The GoI is committed to ensure this technical resource regardless of external funding. In view of all this, the prospects for institutional sustainability are considered good.

RNTCP II would seek to encourage states with high case detection and cure rates and continuous good program outcomes to progressively take leadership of the RNTCP, while CTD would more closely monitor and support states with below average performance.

Financial Sustainability is discussed in Section D.1.

5. Critical risks and Possible Controversial Aspects

Risk	Risk Mitigation Measure	Risk* Rating
To program development objective		
Program stops being considered a priority public health program by decision-makers; donors stop their financing of the program	Continuous dialogue with Government; increased budgetary allocations since 2000; demonstrated success of RNTCP I through independent evaluations and dissemination of results; and continued marketing of the program's successes; the close link between HIV and TB and the international concern for the growing epidemic of both diseases. All these points contribute to a low risk rating for decreasing political support and financing from both GoI and other donors	N
Systemic weakness within the government public health system and 'program fatigue' undermine efficiency and state ownership	Continued and targeted technical support from WHO consultants, particularly in low performing states; targeted supervision in low performing states; institutional strengthening of state's capacity to implement the program including measures to ensure that STOs and DTOs stay in office for at least 2-3 years	M
To outputs		
Lack of capacity within CTD to provide leadership in IEC, draw in outside expertise, and to systematically promote state level ownership of communication strategies, hampers the IEC input to the program	Identify outside talent to provide input to the IEC Advisory Group. TORs for outside agency (agencies) will ensure that gaps in expertise are met and the best talent in India is harnessed. Develop mechanisms for providing technical assistance to the IEC unit in CTD and State TB Cells. Develop mechanisms to synthesize lessons learnt from RNTCP I IEC experiences, and maximise potential to share successful pilots within CTD and across states.	M
Limited response by state authorities to the staffing and monitoring requirements of RNTCP II	Develop a more focused advocacy and health communication strategy which targets political and administrative leaders and promotes and disseminates the benefits of the RNTCP to the states; promote the participation of other actors, such as NGOs and the private sector	M
Insufficient demand for RNTCP II services	Raise awareness of services and create demand through targeted communication. Strengthen community level partnerships to reduce stigma and provide support for uptake of services	M
HIV epidemic expands rapidly leading to large escalation in active TB disease overwhelming the RNTCP budget and resources	At the national level and state level there is an agreed plan for joint HIV/TB action to expand case detection of TB among HIV positive patients; an aggressive Behavior Change Communication (BCC) is planned by both the RNTCP and the National AIDS Control Organization (NACO)	M
Lack of interest of private and public providers in using DOTS for treatment of TB patients	Develop health communication strategy targeted to these groups; and devise incentive schemes to encourage adoption of DOTs as the preferred treatment for TB	S
If the 30% cases not detected are from special sub-groups of society, then TB incidence will remain high in those sub-groups even if the overall incidence is falling	Ensure special schemes for and monitoring of tribal, poor and other vulnerable population groups	S
A decision has been taken by the	The MOHFW has confirmed that the separate project financial	M

MOHFW to merge the individual project implementing entities (Societies) in the state and districts. The process of merger could impact the timelines in funds flowing to the TB program.	management arrangement would continue. IDA will be actively engaged in the merger process to ensure that the funds flow and other financial management arrangements are suitably addressed during the merger process.	
A large number of districts (600) and states/territories (35) will be required to account for and report on the expenditure under the program. Similarly audit reports of the districts would need to be consolidated by each state society. There is a possibility of inconsistency in the format of reporting in the financial statements and in the audit opinion. Also delay in submission of timely audited financial statements is a common occurrence in centrally sponsored programs	The program has guidelines for state and district societies which incorporate the basic requirements of financial management. This is being strengthened in RNTCP II with a proper financial management manual. A separate Financial Management Cell has been created in the CTD to monitor the performance of the states on a regular basis.	M
Lack of suitably qualified finance staff with the necessary skill set and experience in the state societies may hamper the flow of finance information (FMR and audit reports) as well as a lack of guidance to the district accountants.	The remuneration of the state finance consultants is proposed to be increased in RNTCP II, which will enable better qualified staff to be engaged and retained. Training of finance staff is being built into the program. In addition, specific job descriptions have been defined for the state and district accountants.	M
During the implementation of the RCH I project, serious deficiencies were encountered in procurement including the application of GMP certification	A comprehensive Governance and Accountability Action plan (Annex 11) was agreed with GoI. Specifically the plan proposes to: • improve GMP certification process for pharmaceuticals. • Increase competition and mitigate collusion. • Strengthen procurement implementation and contract monitoring. • Handle procurement complaints. • Disclose information and promote oversight by civil society.	S
Overall risk rating		S

(*) Risk rating with mitigation: H (high), S (substantial), M (moderate), N (negligible)

6. Loan/Credit Conditions and Covenants

- The GoI shall cause the MOHFW to ensure that each project state and Project Executing Agency carry out their respective activities under the project in accordance with a Letter of Undertaking (LOU) satisfactory to IDA to be signed by each project state and its respective State Implementing Agency (SIA), i.e. expenditures from a given state would not be eligible for reimbursement from IDA unless the corresponding LOU has been signed.
- The GoI shall cause the MOHFW to ensure adequate management capability in CTD; to review the number and composition of staff and the requirement for technical assistance annually; to revise the staffing norms and composition if found necessary during the mid term review; to establish an Advocacy and IEC Unit within CTD and an IEC Advisory Group, and to maintain these structures throughout project implementation and to review annually the capacity for IEC at the CTD, the project states, and at the district levels; to establish a Financial Management Unit and a Procurement Supply and Logistics Unit within CTD and maintain the units throughout project implementation; to maintain monitoring and evaluation systems for RNTCP II and ensure timely reports in an agreed format satisfactory to IDA for the six-monthly review missions.
- The GoI shall cause the audits of various Project Executing Agencies to be conducted in a timely manner in accordance with the terms of reference set out in the Finance and Accounts Manual and in the Procurement Manual for RNTCP II.
- The GoI shall cause MOHFW and the project states to enroll more medical colleges to actively support RNTCP II throughout project implementation; to ensure that all newly established laboratories for MDR-TB, public and private, are accredited to undertake DST before they are used for diagnosing MDR TB; and to procure goods, works and services for the program in a timely manner, ensure that drugs are properly stored up to the end of the supply chain.
- The GoI shall cause the MOHFW and the project states to implement, in a manner satisfactory to IDA, the Tribal Development Plan and the interventions targeted towards other socially deprived groups set forth therein as well as the agreed Infection Management and Environmental Plan and ensure that the relevant manuals and guidelines are at all times consistently and satisfactorily applied.
- The GoI shall cause MOHFW to maintain the Empowered Procurement Wing, under terms of reference satisfactory to the Association, which is staffed with suitably qualified staff in sufficient numbers, and provided with adequate resources throughout the period of project implementation.
- The GoI shall cause the MOHFW to implement the Governance and Accountability Action Plan (GAAP), refrain from taking any action which will prevent or interfere with the implementation of the GAAP, not waive, amend or abrogate the GAAP; and, provide a written report on progress achieved in the implementation of the GAAP, the first report dated December 31, 2006 and thereafter once every six months.
- Based on the findings of the review on procurement capacity, on the quality and quantity of pharmaceuticals and medical goods, and on implementation of health sector projects financed by IDA, the GoI shall carry out revisions as necessary to strengthen the Governance and Accountability Action Plan (GAAP).

D. APPRAISAL SUMMARY

1. Economic and financial analyses

TB is a significant public health challenge in the world and especially in India, which has more people with active TB than any other country. Country wide, TB is the second most important cause of death. Due to its contagious nature, where one untreated TB patient may infect more than ten new people in one year, there are substantial externalities associated with the disease; its prevention and early treatment is therefore essential. It is also a good public investment as it is estimated that over the next five year period, the program would result in a gain of twelve million Disability-Adjusted Life Years (DALY) at a cost of US$ 34 per DALY reduced (base case). Even if the increasing number of HIV positive persons should reduce the benefit of the RNTCP by 50% (relative to the base case), the cost per DALY gained would be US$ 69, still a good public investment.

Assuming that public spending of 0.9 % of GDP for health and real GDP growth of 6% per year are maintained, the total cost of the RNTCP could account for between 1.0-1.3 % of total government health expenditure between 2005 and 2010. Assuming there are efficiency gains and a reduction in incidence of TB by 2017, the total cost of the RNTCP could account for between 0.5% - 0.6 % of total government health expenditure. Given very strong commitment to combating TB by GoI, recent achievements of the RNTCP, its inclusion in the NRHM and the program focus on institutional advocacy, it is likely that the government would continue adequately to fund the RNTCP in the long term.

2. Technical

The program would implement TB control strategies following the operational and technical guidelines recommended by the WHO and other organizations such as the International Union against TB and Lung Diseases, the STOP TB office of the WHO and the United States Center for Disease Control. The merits of the DOTS strategy (see page 1 for details of DOTS strategy) are evidence based, drawing on a number of trials performed under different circumstances and in different countries. Six months of "short course" combination chemotherapy is highly effective and would cure more than 90% of new TB patients provided drugs are of good quality, adherence to treatment is good, and that drug resistant TB is not highly prevalent.

DOTS Plus is the acronym for treatment of Multi-Drug Resistant TB. It includes: (i) development of DOTS Plus centers at state level in states with facilities for quality assured drug sensitivity testing; (ii) a protocol and monitoring system for case holding with daily patient supervision; (iii) a routine of regular sputum microscopy and sputum culture for monitoring effectiveness of treatment; (iv) clinical services and medical know-how for handling of adverse reactions; (v) use of a standardized regimen for all cases; (vi) uninterrupted delivery of 2nd line TB drugs for DOTS Plus; and (vi) limited duration of hospitalization and treatment completion under supervised ambulatory services.

The program targets for TB control are to achieve a detection rate of at least 70% of all new sputum smear positive cases and to cure not less than 85% of these. These targets are recommended by WHO as necessary to achieve a long term reduction in the annual number of new infectious cases. With such consistent achievement, and excluding the negative effect of an HIV/AIDS epidemic, the annual number of new infectious cases is likely to be reduced by 50% over a 12-13 year span. For more details of the epidemiology of TB in India and the DOTS strategy see Annexes 1 and 4.

3. Fiduciary

Financial Management. The basic financial management structure is in place and has improved considerably in the last two years of implementation of the recently closed Tuberculosis Control Project. The system of obtaining quarterly financial reports by program activity is in place, functioning reasonably well, and would facilitate report based disbursement instead of the traditional statement of expenditure based disbursement. In the RNTCP II, the program would strengthen its financial management capacity (planning, budgeting, accounting and reporting) including provision of additional finance staff in nine larger states and periodic monitoring visits by the CTD finance staff to the states and districts. The program will provide one consolidated report on audits for all the states and one audit report for the expenditure incurred in the CTD. Details of the financial management and disbursement arrangements can be found in Annex 7.

Flow of Funds. The CTD undertakes planning and budgeting for TB control in India. Based on the approved plan, the GoI makes allocations for TB control in every Five Year Plan. The amounts for each year are planned and allocated in the annual GoI's budget and CTD can spend only within each annual capped allocation.

To ensure continuous funding from the CTD down to each state and district, a system of funding through societies has been adopted. Each state government receives funds for TB control from the GoI via its State TB Control Society. The MOHFW has decided that all the individual program specific state and district societies should be merged into one implementing entity at the state and district level under the umbrella of the NRHM. The MOHFW has however agreed that the financial management arrangements of the project (separate financial reporting, finance staff and audit arrangements) would continue. In addition, IDA would continue to be proactively engaged with the MOHFW in facilitating merger process from a financial management perspective. It may be noted that the societies of Uttaranchal and West Bengal were merged two years ago and implementation of RNTCP in these states through a single society has not faced problems due to this merger. The financial management unit in the CTD, which is independent of the state and district societies, would carry out a management audit of the states on a selected basis. In addition the state accountant would be made an integral part of the district review process. The program prepares an annual report. In order to increase transparency the contents of the annual reports have been agreed between IDA and the CTD (see Annex 7). In addition the States would also prepare similar annual reports.

Procurement. TB II anticipates procurement of civil works, pharmaceuticals, goods, equipment and other miscellaneous items and consultancy services. As an interim arrangement until such

time as the Bank and the Government agree otherwise[8], procurement of all ICB and LIB contracts, contracts estimated to cost more than US$ 100,000 (for goods and works under NCB and consulting services for firms) and individual consultants above US$ 50,000 will be carried-out by a qualified procurement agent. This agent will be competitively selected through Quality and Cost Based Selection (QCBS) satisfactory to the Bank or through sole sourcing in case of a UN Agency. The procurement agent will follow the World Bank Procedures and Guidelines of May 2004. Pending the appointment of the procurement agent, agreed urgent procurement could be carried out on behalf of MoHFW by/through an entity, or UN agency under TORs and arrangements satisfactory to the Association. Procurement Support Agencies (PSA) will not be used until the Association and GOI agree to their use. Procurement of goods, works and services below the above mentioned thresholds will be conducted by CTD and the States, following the Procurement Rules and Procedures indicated in the CTD Procurement Manual. The Borrower may also procure pharmaceuticals and medical supplies directly from UN agencies with prior approval of the Bank.

The Association carried out a comprehensive assessment of existing procurement policies and procedures in respect of CTD at the central level and on a sample basis for the three states of Assam, Maharashtra, and Uttar Pradesh, to identify areas for strengthening of the State Procurement Systems, to allow their use for procurement under the program. These states, with the agreement of the CTD and the IDA, were selected as sample states ranging from low to high-performing states. Based on the findings of the Country Procurement Assessment Report (CPAR), State Procurement Assessment Reports (SPARs), and the assessment of the above mentioned three states in respect of CTD, procurement risk is considered to be substantial as indicated in section C.5.

The MOHFW will strengthen the already established EPW to improve efficiency in the procurement of health sector goods and services. The procurement activities of the Department of Health and Family Welfare will be overseen by this wing. The EPW will ensure better competition and transparency in procurement of health sector goods, drugs and services in India, and it will be responsible for delivering quality products in time. It will also support the development and implementation of new policies and actions which will enhance procurement practice and supply chain management.

Keeping in view the experience gained and lessons learnt in the previous RCH project, issues relating to improving Good Manufacturing Practice (GMP) certification process, increasing competition and mitigating collusion, strengthening procurement implementation and contract monitoring, handling procurement complaints, and disclosing information and promoting oversight by the civil society have been discussed with MOHFW at a senior level. The actions agreed to achieve improvements along these five dimensions are described in the Governance and Accountability Action Plan (Annex 11). The GOI shall, based on the findings of the review

[8] The intention is to shift procurement implementation to relevant Indian institutions, including the PSAs, as soon as the Bank and GOI agree that they have the requisite capacity. The determination of features and duration of the transition towards full reliance on these institutions would need to be based on the outcome of the Detailed Implementation Review (DIR), the procurement review by the EPW consultants, the report on quality and quantity of pharmaceuticals and medical goods, and progress in implementation of the GAAP.

on procurement capacity, on the quality and quantity of pharmaceuticals and medical goods, and on implementation of health sector projects financed by IDA, carry out revisions as necessary to further strengthen the Governance and Accountability Action Plan (GAAP).

Detailed procurement arrangements for the project are given in Annex 8

4. Social

The highest burden of TB is borne by the disadvantaged groups of society. These "hard to reach" populations include the poor (both urban and rural), tribal communities and women. Experiences from the ongoing Tuberculosis Control Project and the Social Assessment undertaken by the MOHFW have provided insights[9] into the constraints faced by these groups, based on which improved institutional and implementation arrangements have been designed for RNTCP II. This would help address the social aspects of TB and increase access of "hard to reach populations" to treatment by bridging information, access and provider gaps; and it would help the disadvantaged groups overcome socio-economic and cultural barriers. The program would continuously refine its strategies based on better identification of disadvantaged populations, success with different enablers deployed, public-private partnerships, and emerging research findings and experiential learning in this area.

A separate Tribal Development Plan (TDP) has been prepared based on primary data, review of available experience, and consultations with tribal communities including women, NGOs and other development institutions, civil society representatives and health workers. The TDP addresses major issues related to physical access of tribal populations to TB diagnosis and treatment. IEC would be adapted to the social and cultural context of the tribal populations to increase their awareness and change their treatment seeking behavior. Community participation will be promoted and enablers and incentives will be introduced for the public and private health care providers to work in the tribal areas. The states will adapt the actions included in the national PIP to their specific context and prepare detailed implementation plans.

5. Environment

The program is classified as a Category B, given that the environmental issues are well understood, documented, manageable and site-specific. The primary issue is that of management of clinical and infectious waste materials (primarily needles, sputum cups and slides) given the infectious, communicable and opportunistic nature of the disease involved under the scope of the program. Under the ongoing Tuberculosis Control Project, the CTD developed a manual for laboratory technicians, which incorporates basic elements of infection control, including waste treatment and disposal. It has been recognized that these guidelines need strengthening and the CTD has undertaken an assessment of a representative sample of TB clinics to assess existing environmental practices. This assessment provides an understanding of implementation gaps and additional measures, including training and evaluation, required to ensure that the quality of services are enhanced under RNTCP II. An Infection Control and Infectious Waste Management Plan has been finalized after consultation with relevant stakeholders. Whereas such training is part of general training of health care staff in the states, this Plan focuses on revision of existing training modules and of the Manual for Laboratory Technicians; training of appropriate health

[9] Details in annex 10

care workers; appropriate facilities and awareness activities to ensure sustained behavioral change and continued compliance with the Biomedical Rules of the GoI. Additional elements to be reviewed would include procurement of recyclable and/or environmentally-friendly equipment and laboratory consumables and involvement of the private sector for out-sourcing activities such as transportation, treatment and disposal of infectious waste.

6. Safeguard policies

Environmental Classification B; Safeguard Classification: S2

Safeguard Policies Triggered by the Program	Yes	No
Environmental Assessment (OP/BP/GP 4.01)	[Y]	[ ]
Natural Habitats (OP/BP 4.04)	[ ]	[N]
Pest Management (OP 4.09)	[ ]	[N]
Cultural Property (OPN 11.03, being revised as OP 4.11)	[ ]	[N]
Involuntary Resettlement (OP/BP 4.12)	[ ]	[N]
Indigenous Peoples (OD 4.20, being revised as OP 4.10)	[Y]	[ ]
Forests (OP/BP 4.36)	[ ]	[N]
Safety of Dams (OP/BP 4.37)	[ ]	[N]
Projects in Disputed Areas (OP/BP/GP 7.60)*	[ ]	[N]
Projects on International Waterways (OP/BP/GP 7.50)	[ ]	[N]

7. Policy Exceptions and Readiness

There are no policy exceptions required for the program. Safeguard clearances have been obtained. The program is ready for implementation as evidenced by the following: (i) the RNTCP II Program Implementation Plan has been prepared and found to be of sound quality; (ii) the procurement plans for ICB contracts have been developed and shared with IDA; (iii) the Infection Control and Waste Management Plan and the Tribal Development Plan have been finalized, cleared by IDA and disclosed to the public by the borrower; (iv) adequate allocations for the program have been included in the GoI's 2005/06 budget; and (v) indicators for results monitoring have been specified and are already being collected routinely.

* By supporting the proposed project, the Bank does not intend to prejudice the final determination of the parties' claims on the disputed areas

Annex 1: Country and Sector or Program Background
INDIA: Second National Tuberculosis Control Program

Background and Epidemiology of TB in India

1.1. India is the country with the greatest burden of TB worldwide in terms of annual case numbers. It is also the country where the most dramatic advances have been made in DOTS expansion during recent years. India's RNTCP was introduced on a pilot scale in 1993 and, after a period of testing, was formally launched by the government in 1997. By mid-1998, the program had expanded to serve some 20 million people. A phase of rapid expansion followed from late 1998, so that by 2004, 850 million people lived in areas where DOTS was provided. The program reached 100% coverage in March 2006.

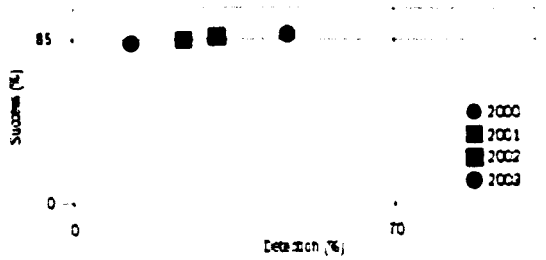
Table 1: Key epidemiological indicators

2005 data		***TRENDS***	***2000***	***2001***	***2002***	***2003***	***2004***	***2005***
Population	*1,08 mill.*	*DOTS coverage*	30	45	52	67	84	91
Global rank (by est. number of cases)	*1*	*Notification rate (all cases/100 000 pop)*	111	105	101	101	105	117
Incidence (all cases/100 000 pop/year)	*168*	*Notification rate (new ss+/100 000 pop)*	34	37	38	41	43	46
Incidence (all new ss+/100 000 pop/tear)	*75*	*Detection of all cases (%)*	65	63	60	60	62	64
Prevalence (all cases/100 000 pop)	*277*	*Case detection rate (new ss+, %)*	46	50	50	54	60	66
TB mortality (all cases/100 000 pop/year)	*35*	*DOTS case detection rate (new ss+, %)*	12	24	31	47	57	61
TB cases HIV (adults 15-49y. %)	*5.2*	*DOTS case detection rate (new ss+)/coverage(%)*	42	53	60	69	72	66
New cases multi-drug resistant (%)	*3.4*	*DOTS treatment success (new ss+, %)*	84	85	87	86	86	86-

1.2. Previous estimates of smear-positive incidence have been revised on the basis of a three-year national tuberculin survey that was completed during 2003. Based on these revised estimates, 46% of all new smear-positive cases in the country were detected by the RNTCP in 2003, compared with 31% in 2002. In 2002 case detection was 68% in the areas already covered by the DOTS program, nearly reaching the global target for case detection of 70%. In 2004 India reached the global targets of 70% of case detection and 85% of cure rates for areas which were covered with DOTS. However, in the first quarter of 2006, after the inclusion of all districts (including those not yet covered by DOTS) the national average has dropped to 64%. This increase in cases detected represents nearly half (44%) of the increase in cases detected by DOTS programs worldwide. India has made a larger contribution than any other country to the acceleration in global case-finding observed since 2000.

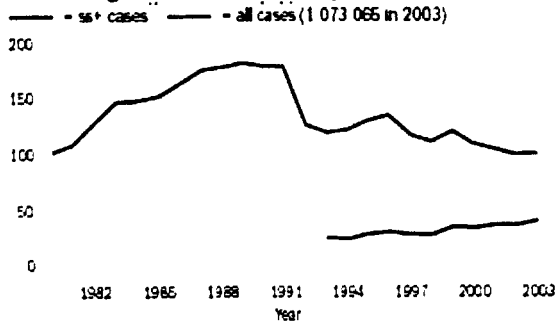
1.3. The reported treatment success has also increased over the past three years, reaching 87% in 2002. This figure exceeds the global target of 85%. It is even more remarkable if one considers that this success has been achieved during a period of rapid expansion of the DOTS strategy.

Figure 1: Progress towards global targets for TB control



1.4. In contrast to the upward trend in case notifications seen in the RNTCP, the notification rate of all TB cases from all sources in India, has been gradually falling since 1992. It is likely that this downward trend reflects improvements in diagnosis (eliminating false-positives) rather than a real decrease in incidence. National data for the years up to 2003 do not yet provide evidence that the RNTCP has reduced prevalence, although it is clear that there are significantly fewer deaths among cases notified, with an estimated 18 deaths averted per 100 patients treated under DOTS. Since there is a time lag between increased case finding and cure and epidemiological impact in terms of reductions in prevalence and incidence, a decrease of these indicators on a national scale is not expected for the coming few years. However, in areas where the program has been operating for several years (such as the "model DOTS project" being carried out by the Tuberculosis Research Centre in Chennai) studies are currently underway to determine the overall epidemiological impact of DOTS implementation.

Figure 2: Trends in notification rates



1.5. An estimated 5.2 million people are infected with HIV in India. HIV is likely to have a significant impact on the TB epidemic in the six states where the prevalence of HIV is greater than 1%, namely, Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland and Tamil Nadu. The RNTCP and NACO have estimated that in India as a whole, HIV would have led to an additional 9 million cases of TB and 7 million deaths between 1990 and 2020 without the efforts of the RNTCP. The prevalence of HIV in TB patients has been measured in a number of tertiary care hospital settings and co-infection levels of up to 25% have been reported in 2001. However, the results from such studies in special settings cannot be regarded as representative of the HIV levels in TB patients nationally and co-infection rates of up to 60% are possible. In 2005, HIV surveillance of TB patients started in four districts in the six high-prevalence states, using a more representative sampling methodology, the results of which are currently being analyzed. WHO estimates the HIV prevalence in TB patients in India to be 5.2% (Global TB Report, WHO, 2006).

State and District Imbalances

1.6. The RNTCP publishes a quarterly performance report which provides information on district-wise RNTCP implementation status. This report provides data on districts and states where performance is below average-either below 85% case holding or below 70% case detection or both-thereby allowing central level managers to identify states and districts where performance is sub-optimal and state and district level managers to take corrective actions. At district level, similar data is available for the sub-district level. By comparing these reports to existing poverty and tribal maps of India, RNTCP performance in poor states and districts and in tribal areas would be measured and appropriate action taken.

India's 10th Five Year Plan

1.7. India's 10th Five Year Plan recognizes the need for long term support to DOTS for TB control. It acknowledges the inherent problems associated with ensuring compliance in long term treatment and suggests the involvement of all health service providers as well as the Panchayat Raj Institutions to ensure that all patients receive optimal treatment. It further supports better communication to the general public about the availability of services and operational research to improve program performance.

Annex 2: Major Related Projects Financed by IDA and/or other Agencies

INDIA: Second National Tuberculosis Control Program

World Bank Financed Projects (ratings as of May 23, 2005):

Sector	Project	Credit Number	Latest Supervision (ISR) and Completion Ratings		OED Ratings
			Development Objectives (DO)	*Implementation Objectives (IP)*	
Bank-financed Ongoing	Rajasthan Health Systems Development Project	38670	MS	MU	
	UP Health Systems Development Project	33380	MU	S	
	Disease Surveillance	39520	MS	MS	
	Food & Drugs Capacity Building Project	37770	S	S	
	Tamil Nadu Health Systems Project	40180	MS	MU	
Closed	Health 1 (MCH)	2300	S	S	MS
	Second TN Nutrition	21580	S	S	MS
	Population Training (VII)	31990	S	S	S
	ICDS 1 (Orissa & Andhra)	32530	S	S	U
	AIDS Prevention	23500	S	HS	S
	National Leprosy Project	25280	S	S	S
	Population VIII	23940	HS	S	S
	Blindness Control	26110	S	S	HS
	Family Welfare Project	26300	S	S	MS
	AP 1st Referral Health	26630	HS	S	HS
	ICDS II (Bihar & MP)	24700	S	S	U
	State Health Systems II	28330	HS	S	S
	Reproductive Health I	N0181	S	S	U
	Leprosy II	34820	S	S	S
	Tuberculosis Control	29360	S	S	
	Orissa Health System	N0410	MS	MS	
	Malaria Control	29640	S	S	
	Women & Child Development	N0420	MS	MS	
	2nd National HIV/AIDS Control	32420	S	MS	
	Maharashtra Health Systems Project	31490	MS	MS	
	Immunization Strengthening Project	33401	MS	S	

IP/D ratings: HS (Highly Satisfactory); S (Satisfactory), U (Unsatisfactory) HU (Highly Unsatisfactory); MS (Moderately Satisfactory); MU (Moderately Unsatisfactory).

Other Development Agencies:

Name of Agency	Name of Project	Status
UNFPA	Integrated Population and Development Project	Completed
UNICEF	Border District Cluster Project	Ongoing
UNICEF	Women's Right to Life and Health project	Ongoing
European Union	Health and Family Welfare Sector Investment Project	Ongoing

Annex 3: Results Framework and Monitoring

INDIA: Second National Tuberculosis Control Program

Program Development Objective	Outcome Indicators	Use of Outcome Information
All districts have reached the global targets of 70% case detection rate and 85% cure rate; zones that have been implementing DOTS for 5 + years begin to show reduction in incidence of smear+ TB	No. of districts reaching global targets; Zonal figures for ARTI	This information will allow for policy review in case performance is below expectations. Program quality and strategy to be reviewed if ARTI is not reduced in zones where DOTS has been implemented for >five years
Outputs	**Output Indicators**	**Use of Results Monitoring**
Sub-Output 1.1: Quality service provision consolidated within all districts in the country	• No. of States where global targets are met; • Population of administrative areas with DOTS coverage/total country population	This will allow central and State managers to take corrective action in below average performing areas
Sub-Output 1.2: Raise awareness about TB and DOTS treatment among the public and health care providers.	• Increase in TB suspects examined per 100,000 population • Increase in the level of awareness about TB diagnosis and DOTS treatment among practitioners • Increase in awareness of target groups being reached with information that DOTS is the correct treatment, and is available free in patient-wise boxes • Increase in State and district level capacity to plan and execute IEC activities	This will show effectiveness of the IEC strategy and will serve to review the strategy if necessary
Sub-output 1.3: Ensure the quality of RNTCP smear microscopy	• % of RNTCP designated microscopy centers (MC) with major errors in the random blinded rechecking process	This will identify MCs which require additional technical assistance and training of the lab technicians.
Sub-output 1.4: Ensure capacity at all levels for long term sustainability of TB control activities	• % of actual expenditure compared to planned budget in a financial year • % of States with full time and trained State TB Officer during the year	Technical and managerial support from center to State and from State to district can be targeted to under performing areas based on regular management information
Output 2: RNTCP outreach to target special groups expanded		
Sub-output 2.1: Quality DOTS services delivered to poor and difficult to reach groups	• Performance level achieved in pre-determined set of predominantly tribal and/or poor districts will achieve 70% case detection and 85% cure rate	This will identify locations which may require additional management input
Sub-Output 2.2: DOTS treatment is provided by an increasing number of non-public health providers	• Number of NGOs participating in RNTCP • Number of non-public health care providers involved in RNTCP • Treatment outcomes for the different provider groups in the 14 cities with intensified PPM activities	Data will be used to adjust policies on PPM
Sub-output 2.3: Adequate coordination ensured between HIV/AIDS and TB activities in the 14 States included in the	• Number of persons suspected to have TB disease and referred from VCT services	Corrective action taken when performance is below average/expectation

NACP-RNTCP TB/HIV action plan	• Number of persons diagnosed with TB, having been referred from VCT services, and placed on DOTS	
Sub-Output 2.4: DOTS treatment expanded to Children	• Number of children under 15 years of age receiving DOTS; • Patients on DOTS under 15 years of age/all patients on DOTS	Quarterly reports will identify areas where the ratio is below average/ expectations; these areas will receive training to improve diagnosis of children and receive additional management inputs
Sub-Output 2.5: DOTS Plus introduced in a phased manner across the country	• Number of quality assured Intermediate Reference Laboratories (IRLs) available to undertake drug sensitivity testing (DST) under RNTCP • Number of DOTS Plus sites initiated • Number of Category II failures receiving a drug sensitivity test/total number of Category II failures reported in respective State(s) with an RNTCP DOTS Plus site • Number multi-drug resistant TB (MDR) cases started on DOTS Plus • Number of patients who have successfully completed DOTS Plus/number of MDR patients put on DOTS Plus treatment	DOTS Plus reporting system will identify areas with lower than expected performance where corrective action can be taken or treatment revised

Arrangements for Results Monitoring

Outcome Indicators	Baseline	Target Values					Data Collection and Reporting		
		YR1	YR2	YR3	YR4	YR5	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
ARTI in zones where DOTS has been implemented for > five years	1.5%	Not applicable		1.34%			Every five years	ARTI studies with national and zonal data	CTD
No of districts which have reached the global targets for cure rate and case detection rates	111	200	300	350	400	450	Quarterly	National quarterly and annual performance reports	CTD
Results Indicators for each Objective and Output									
No. of states which have reached the global targets for cure rate and case detection rate	8	10	15	20	25	28	Quarterly, annually	National quarterly and annual performance reports	CTD/ State TB Cells (STCs)
No. of Zones which have reached the global targets for cure rate and case detection rate	0	1	2	3	4	4	Quarterly, annually	National quarterly and annual performance reports	CTD/ State TB Cells (STCs)
Population of administrative areas with direct observed treatment short courses (DOTS) coverage/ total country population	87%	90%	100%	100%	100%	100%	Quarterly, annually	National quarterly and annual performance report	CTD/STCs
Increase in TB suspects examined per 100,000 population	138/annual	Increasing trend →→→→→→→→→→→→→→→→→→→→					annually	Quarterly reports KAP study report Formative research Targeted qualitative assessments; Internal evaluation reports;	CTD/STCs
Increase in the level of awareness about TB diagnosis and DOTS treatment amongst practitioners	KAP 2005	Increasing trend →→→→→→→→→→→→→→→→→→→→							
Increased awareness in target groups being reached with information that DOTS is the correct treatment, it is available free in patient-wise boxes	KAP 2005								
Increase in state and district level capacity to plan and execute IEC activities	Baseline survey to be conducted in 2005								
Performance level achieved in pre-determined set of predominantly tribal and/or poor districts will achieve 70% case detection and 85% cure rate	Districts to be identified in 2005	≥50%	≥50%	≥60%	≥70%	≥70%	Quarterly, annually	District quarterly and annual reports	Selected districts/STCs/CTD
		≥85%	≥85%	≥85%	≥85%	≥85%	Quarterly, annually		

Number of NGOs participating in RNTCP	1000	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	District quarterly and annual reports	STCs/CTD
Number of non-public health care providers involved in RNTCP	5000	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	District quarterly and annual reports	STCs/CTD
Treatment outcomes from the different provider groups in the 14 cities with intensified PPM activities	Base line established 2005/6	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	Quarterly and annual reports from the 14 cities	CTD
Number of persons suspected to have TB disease, and referred from VCT services	Base line established 2005/6	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	District quarterly and annual reports	14 STCs/CTD
Number of persons diagnosed with TB disease having been referred from VCT services	Base line established 2005/6	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	District quarterly and annual reports	14 STCs/CTD
Number of persons diagnosed with TB disease, having been referred from VCT services, who are placed on DOTS	Base line established 2005/6	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	District quarterly and annual reports	14 STCs/CTD
No. of children under 15 years of age receiving DOTS	Base line established 2005/6	Increasing trend →→→→→→→→→→→→→→					Quarterly, annually	National and quarterly reports	CDT
Patients on DOTS under 15 years of age/all patients on DOTS	Base line established 2005/6	5%	6%	6%	7%	7%	Quarterly, annually	National quarterly and annual reports	CTD
Number of quality assured IRLs available to undertake DST under RNTCP	0	8	15	21	24	24	Annually	NRL annual reports	NRLs/CTD
Number of DOTS Plus sites initiated	0	0	2	9*	16*	21*	Annually	National level annual report	CTD
Number of Category II failures receiving a drug sensitivity test/Total number of Category II failures reported in respective state(s) with an RNTCP DOTS Plus site	0	-	50%	60%	65%	70%	Annually	DOTS Plus reporting system and National level annual report	DOTS Plus sites/CTD
Number of MDR-TB cases started on DOTS Plus treatment	0	0	100	450	1250	2350	Annually	DOTS Plus reporting system and National level annual report	DOTS Plus sites/CTD
Number of MDR-TB patients who have successfully completed DOTS Plus treatment/number of MDR-TB patients put on DOTS Plus treatment	0	-	-	-	≥65%	≥70%	Annually	DOTS Plus reporting system and National level annual report	DOTS Plus sites/CTD

*the new monitoring format will provide these baseline data for 2005/2006

Annex 4: Detailed Program Description

INDIA: Second National Tuberculosis Control Program

4.1 Along with a number of other countries with a high TB burden, India has adopted the DOTS strategy as a way to reduce morbidity, mortality and eventually the prevalence and incidence of TB, and to prevent the occurrence of a considerable problem of multi-drug resistant TB cases.

4.2 The DOTS strategy summarizes a series of elements: (i) the presence of political willingness to address the problem of TB adequately and to guarantee the means and resources necessary for its control; (ii) an appropriate way of diagnosis (sputum microscopy); (iii) availability of adequate stocks of good quality drugs; (iv) 'directly observed' adherence to effective combination treatment; and (v) proper ways of case registration, monitoring, and outcome evaluation. The merits of the DOTS strategy are evidence based, drawing on a number of trials performed under different circumstances and in different countries. Six months of "short course" combination chemotherapy is highly effective and would cure more than 90% of new TB patients provided adherence to treatment is good, and that drug resistant TB is not highly prevalent.

4.3 India has scaled up availability of DOTS across the country with remarkable speed and at the same time introduced a strict system of appraisal before allowing a state/district to start treatment. It is recognized that while the focus during the past was on establishing a safe system for DOTS delivery, the thrust of the program must now be on consolidation of the public sector DOTS program and expansion to ensure that DOTS is available to all TB patients while ensuring adequate institutional capacity to manage the program.

Output One: RNTCP Services Consolidated

4.4 Key tasks for consolidating the quality of the RNTCP include ensuring reliable sputum microscopy services, supervision and monitoring and continuous operations research as well as institutional strengthening and human resource management and development. Now that designated microscopy centers are in place and laboratory technicians have been trained, the future challenge is to ensure good quality laboratory services. Phased strengthening of the IRL at state level would support the implementation of an effective external laboratory quality assurance mechanism. The RNTCP has published a new set of national quality assurance guidelines, which are already being implemented. This new QA system is based partly on a system of "on the spot" checking of microscopy slides by the STLS and partly on blinded cross-checking of samples of randomly selected slides prepared in the designated microscopy centers. The planned IRL would prepare slides for proficiency reading at the district centers by the STLS, and the quality of the IRL would in turn be tested and supervised by the three national reference laboratories. Conflicting microscopy results would be further examined and poorly performing laboratories or staff selected for targeted supervision and re-training. Regular reports from all states would be forwarded to the national reference laboratories and the CTD. This new system is fully in line with recently published WHO guidelines for the establishment of laboratory QA systems. A key feature of the laboratory QA strategy by the RNTCP is that it will cover both RNTCP and non-RNTCP facilities designated for TB diagnosis.

4.5 The IRLs at state level would also be upgraded to perform drug resistance surveys (DRS). The IRL of most states would be located in the existing STDCs that would be refurbished and equipped for their new activities. Poorly performing and unsupervised TB treatment is known to generate drug resistant TB. An objective of the DOTS program is to control and reduce the risk of drug resistant TB cases; therefore the outcome of well designed and representative surveys will be a crucial program performance parameter, together with detection and cure rates. Quality assured culture and drug sensitivity testing at the state level will also be a pre-requisite for the future availability of treatment of MDR TB. This new QA system and the expanded laboratory services and infrastructure will be evaluated for efficiency, adequacy, appropriateness and cost-effectiveness at mid-term.

4.6 The RNTCP has a robust recording and reporting system for the supervision, monitoring and evaluation of program input, process, outputs, outcome, and also of impact. A strategy document for supervision and monitoring has now been finalized and would be used to register and monitor the key program performance indicators in terms of diagnosed patients with TB and their treatment outcome. A series of useful management input, outputs and program implementation indicators would also be monitored regularly and analyzed quarterly. Feedback on outcome data will be provided from district, state and central level; supervisory visits, review meetings at different levels and periodic in-depth evaluations (both internal and external) will be undertaken. The system uses the standardized recording and reporting system of the DOTS strategy (laboratory and treatment register, case-finding, smear-conversion and treatment outcome reports). RNTCP II would continue to use this reporting system based on quarterly and annual cohorts of TB patients. This system allows the direct evaluation of progress towards the program objectives of 85% cure and 70% case detection of new smear positive pulmonary TB cases by age and gender.

4.7 RNTCP II would continue to use electronic quarterly data collection and transmission at all managerial levels (DTO, STO, and CTD). This allows the rapid evaluation of data and easy calculation of additional output indicators derived from raw data on laboratory results, case detection and treatment. While the standard DOTS reporting system would continue to provide information on program outcomes, e.g. case-detection and cure rates, the RNTCP system allows individual monitoring of activities, thus allowing managers at all levels to identify specific poorly performing program components in implementation sites.

4.8 To evaluate the impact of the RNTCP on the incidence of tuberculosis, ARTI surveys would be repeated every 3-5 years. The first national ARTI was completed in 2003, followed by a number of state level ARTI surveys. Estimation of the prevalence and deaths due to tuberculosis in the country would be done through a separate study or indirect estimation from existing information, according to the WHO guidelines.

4.9 The RNTCP II would continue to support and expand the use of operational research in order to generate an appropriate and continuous flow of information to make TB control in India more effective. It would seek to more widely communicate the research agenda, application processes, enroll more individuals and organizations, i.e. Medical Colleges and Social Science

Research Institutions in undertaking research, and streamline the research development, approval and funding processes.

4.10 The continuing use of private health facilities as the first point of contact for the majority of TB patients, points to the need for stepping up efforts to involve the private sector in the RNTCP II. Additional operational research would be conducted in the RNTCP II to explore ways to reduce the economic burden (direct and indirect) of accessing TB care; to strengthen service delivery to marginalized groups such as the poor, the homeless and migrants; new areas for research would also be included such as pediatric DOTS, DOTS Plus, and testing new linkages between HIV/TB.

4.11 Information, Education and Communication (IEC) would be strengthened to enhance the effectiveness of the expanded RNTCP. With diagnostic and treatment facilities established throughout India, the IEC strategy would simultaneously address three objectives: (i) raise awareness among the public about TB and the availability of free treatment in patient-wise boxes, and practitioners about correct TB diagnosis, treatment and referral to RNTCP services; (ii) advocate for political, administrative and community-level commitment to TB control in India; and (iii) enhance patient-provider communication and counseling to help ensure patient compliance with the treatment regimen and establish the reputation of a patient-friendly service. Lessons learned from achievements, pilots, and studies during the ongoing TB Control Project would provide a basis for the IEC strategy.

4.12 The IEC strategy would be guided by three principles: (i) A *process* rather than *products* orientation, with a three-step IEC planning process (formative research, strategy development and monitoring) and special attention to communication as an interactive process; (ii) decentralization to ensure contextual relevance and wide reach of information; and (iii) attention to social issues such as special problems of vulnerable groups, stigma and gender.

4.13 Overall leadership would emanate from the center to promote a core IEC strategic framework, ensure synergy with national level media campaigns, and facilitate cross-fertilization of experiences. Greater emphasis, however, would be on decentralization of IEC planning. Detailed audience segmentation at state and district levels would identify localized communication needs (objectives), players/audiences (target groups), and communication tools (channels, activities and materials). District level innovations would be actively encouraged to reach all target groups through the most appropriate communication tools.

4.14 Special IEC strategies would address hard-to-reach groups such as tribal populations, marginal populations in urban slums and other vulnerable sections of the community and would aim to ensure that the voices of beneficiaries are heard in program planning. Joint HIV/TB IEC materials would be developed and co-ordination with the PPM component would ensure relevant IEC for non-public providers.

4.15 Awareness among the public and policy makers/opinion leaders would be raised through a combination of mass media and grass roots interactive approaches. The value of interpersonal channels have been recognized: satisfied cured patients become good advocates; verbal information by a trusted local source is persuasive; community meetings are effective in

addressing social issues, barriers to TB treatment and promoting social mobilization; face-to-face contact can strengthen cooperation with private providers and convince policy makers and administrators to support the program. Interpersonal channels are further useful in spreading the word in areas remote from the reach of mass media. Mass media plays a role in disseminating information widely, raising general awareness of TB and the efficacy and free availability of DOTS, and promoting the profile and visibility of the program among influential groups. The mass media campaign would be managed from the center with software made available to the states for further dissemination and adaptation. District level media would include local TV cable channels, radio and non-electronic media such as popular folk media and street plays.

4.16 Provider-patient communication and counseling skills are important at all levels of the program to bridge the gap between providers and beneficiaries, and to establish supportive relationships so that patients complete treatment. The module on Improving Interpersonal Communication (IPC) Skills in RNTCP training would be reviewed and the quality of IPC training would be assessed.

4.17 All IEC sub-components would be analyzed qualitatively to assess the needs, correct and refine the program as it evolves and to help in gauging program success. Process indicators for monitoring state and district capacity to formulate and implement IEC plans will be developed during the first year and used for monitoring the decentralization of IEC. A mid-term impact assessment would review the impact of the media plan.

4.18 Capacity within the IEC Unit in CTD would be enhanced by the establishment of an IEC Advisory Group for infusion of ideas and experience. Members would be specialists with practical experience in the different aspects of IEC, field staff who have worked with the program, experts in various sub-components of the IEC strategy from national or state institutes. A mechanism for providing IEC technical assistance to CTD and State TB Cells would be developed. Communication research, planning and implementation would be outsourced to an IEC agency or consortium specializing in social communication strategies, media planning and implementation, advocacy, event management, social mobilization, interpersonal skills assessment and training and state level capacity building. State level IEC capacity would be enhanced and the role of the IEC officer supported. A new level of IEC functionary, Communication Facilitators, one per 4-5 districts, would link state and district level initiatives.

4.19 Efforts would be made to ensure appropriate institutional capacity at all levels to maintain program quality, given the current coverage and continuing expansion under the RNTCP II. CTD would be strengthened by having five units and officers in charge to lead each one: supervision and monitoring; human resource management and development; advocacy and health communication; finance; and procurement. This would be done to better address already identified weaker areas. Also, CTD would receive technical assistance to further decentralize the program's activities in a phased manner and continue to encourage states to take ownership of the program activities, and assign additional WHO consultants to large and poor performing states. States' and districts' implementation capacity would be strengthened through hiring of contractual staff and, supported by CTD and WHO consultants, would provide quality training to all staff involved in the program, as well as DOTS providers. Public and private medical colleges would be encouraged to revise their curricula to include DOTS as the prescribed

treatment for TB, to provide training on DOTS to the faculty, to support existing task forces in defining their role and plan of action, and will be supported in the continued creation of active task forces in each college.

4.20 MOHFW has established an Empowered Procurement Wing with appropriate technical expertise in pharmaceuticals, biomedical equipment, quality assurance and supply logistics. This unit would monitor the procurement process, including the procurement conducted by CTD. The EPW will ensure better competition and transparency in procurement of health sector goods, drugs and services and delivery of quality products in time. MOHFW would also encourage the states to strengthen their procurement at state and district level and prepare an action plan for building general state capacities for improving procurement and supply chain management including providing technical support to the districts. As an interim arrangement until such time as the Bank and the Government agree otherwise[10], procurement of all ICB and LIB contracts, contracts estimated to cost more than US$ 100,000 (for goods and works under NCB and consulting services for firms) and individual consultants above US$ 50,000 will be carried-out by a qualified procurement agent. This agent will be competitively selected through Quality and Cost Based Selection (QCBS) satisfactory to the Bank or through sole sourcing in case of a UN Agency. The procurement agent will follow the World Bank Procedures and Guidelines of May 2004.

4.21 Enhancing implementation capacity. The TB program's fast increase in coverage and expansion of services would stretch management and implementation capacity at all levels beyond their limits. While the clinical aspects of the program are continuously being addressed to ensure quality services, the management and social aspects of the program have been relegated. During the program's consolidation phase, CTD will focus on these aspects as well. Joint periodic reviews would analyze the institutional requirements and define the additional number and qualifications of human resources required. The GoI would carry out rehabilitation/ upgrading of existing CTD offices to accommodate existing and future new staff in appropriate and less congested offices. Existing office equipment would be upgraded and new equipment purchased. At the state level, financing would be provided to STOs to contract human resources when necessary, upgrade their office space and equipment, and contract services performed by STDCs in those states that lack one. At the district level, because of the critical importance of District TB Centers (DTCs) and Tuberculosis Units (TUs) for program management success, strengthening of these administrative units would be strongly supported through provision of additional full time human resources, continuous technical assistance in program planning and budgeting, management, implementation, supervision and monitoring in the district, and provision of adequate financial resources to supervise and carry out quality control functions at local levels.

4.22 Developing a long-term decentralization plan. Important efforts begun under the ongoing TB Control Project would continue and CTD would: (i) develop a plan to, first, redeploy WHO

10 The intention is to shift procurement implementation to relevant Indian institutions, including the PSAs, as soon as the Bank and GOI agree that they have the requisite capacity. The determination of features and duration of the transition towards full reliance on these institutions would need to be based on the outcome of the Detailed Implementation Review (DIR), the procurement review by the EPW consultants, the report on quality and quantity of pharmaceuticals and medical goods, and progress in implementation of the GAAP.

technical support from the better performing states to poor performing states, and, second, initiate actions aiming at phasing out WHO technical assistance by 2015. This plan would be discussed during the program's mid-term review; (ii) strengthen states/districts planning, budgeting and implementation capacity in all areas of the program; and (iii) support the development of alternative models in selected districts in difficult to reach areas. During the mid-term review, the plan and these aspects of the program would be reviewed in detail.

4.23 Providing quality training. The ongoing TB Control Project correctly focused its efforts on training of medical and laboratory personnel and also provided training to managers at all levels. Under the RNTCP II, support would continue for periodic quality training and retraining of medical, laboratory and managerial staff, and additional efforts would be made to train staff working in the social science areas at all levels. Funds would be provided to districts and states for computer training, and other specific training to benefit RNTCP that is not being provided within the existing human resource development plan.

4.24 Promoting DOTS treatment in Medical Colleges. Under the ongoing TB Control Project, a significant number of public and private medical colleges have opened DOTS centers and created task forces to promote TB treatment under DOTS. More efforts are required in this area to ensure that medical colleges' faculty and curriculum fully support the program adopting DOTS as the treatment of choice for TB, and ensuring that all faculty are knowledgeable in this area. Support would be provided to medical colleges to train faculty and staff, improve their microscopy facilities, and define the role of their TB task forces.

Output Two: RNTCP Outreach to Target Special Groups Expanded

4.25 With the expansion of DOTS to the entire country, the program would now focus on ensuring that all TB patients, wherever and whoever they are, have access to these services.

4.26 As a first step, RNTCP II would define and identify population groups that have or may have difficulties in accessing services provided by RNTCP. This would be undertaken at the state and district levels as a special task which would include further analysis on information coming in routinely to determine pointers to the problems of access according to level of poverty and social setting, geography, age, sex, delays in diagnosis and/or treatment, defaults, transfers, failures and deaths. Findings from social and operational research and qualitative studies already available would also be considered. This information would be complemented with data available from other national programs for poverty reduction and disease control. International literature would also provide useful guidance in this respect.

4.27 Next, ways to improve access to hard to reach groups would be documented by studying some of the working approaches that may be currently in place and used successfully by some of the RNTCP units, NGOs, corporate sector units, PPM projects and medical college initiatives. Again, international experience could provide useful lessons. Special reference must be made to a large body of literature available on use of incentives and enablers in TB control. Diverse enablers such as vouchers, transport pass facilities, and financial subsidies as well as direct financial incentives have been found useful in diverse settings. Their applicability in the Indian settings would be determined through focused intervention research on target populations.

4.28 Gathering a knowledge and evidence base from working approaches and intervention research should help define both hard to reach groups and ways to reach them through varied approaches. This would then be shared with program personnel, NGO representatives, academia, researchers and international experts with the specific purpose of developing schemes that could be promoted to the public and private sector organizations.

4.29 In a country with a vast network of diverse health care providers, a logical way to ensure that those who need TB care receive proper DOTS would be through a Public-Private Mix (PPM) approach, i.e. linking all relevant public and private providers to the RNTCP. An effective PPM would help improve access to care and help detect more cases; reduce diagnostic delay and disease transmission; minimize inappropriate treatment and emergence of drug-resistant TB as well as reduce the financial burden on poor patients.

4.30 The RNTCP has adopted and successfully piloted the PPM approach in its first phase. Effective expansion would require significant inputs and investments. The RNTCP has formulated schemes and guidelines to attract NGOs and PPs to collaborate. These schemes are expected to offer support as well as financial incentives to collaborating NGOs and PPs. Some experience has been gained about the uptake and effectiveness of these schemes. The RNTCP would carry out further analysis and, on that basis, make appropriate revisions to the current schemes. It would be advisable to defer revision of PP schemes to enable incorporation of lessons learned from the fourteen city PPM pilot scale up project referred to below.

4.31 Special attention paid to medical colleges (public and private), a component of the public-private mix approach, seems to be producing results. Special task forces at the national and state levels have been established to steer involvement of medical colleges. Of the 213 medical colleges (public and private) 206 have already been reported to be part of the initiative. These efforts would be sustained in RNTCP II.

4.32 The initiatives undertaken by the Indian Medical Association (IMA) and the reciprocal support and encouragement that the RNTCP has offered, would continue. IMA's current statewide project in Kerala, where members are trained and motivated to collaborate with the RNTCP, augurs well for their involvement in national efforts to control TB

4.33 Mere production and distribution of schemes and guidelines are unlikely to attract diverse care providers into DOTS implementation. In recognition of this, the proactive PPM approach to reach out to diverse care providers and instituting collaboration with them, currently being tried out in 14 cities, is noteworthy. This is being facilitated by a dedicated RNTCP-PPM consultant for each city supported by two field supervisors. By the end of next year, experience from this initiative would define strategies to engage different types of providers; identify tools to facilitate collaborations; design sensitization and training materials for both RNTCP staff and other providers and identify modifications required for the surveillance and monitoring system. The knowledge gained from the pilot scale up of PPM would be effectively used for phased expansion and eventually PPM would become an integral part of the RNTCP.

4.34 Effective partnership with other health care providers would require change of mindset as well as current practices of both the RNTCP staff and their counterparts. The input therefore would be directed to both sides and not reduced only to some form of training by the RNTCP to other care providers. In view of the successes achieved by the RNTCP, there appears to be a general willingness on the part of other care providers to collaborate. The question of whether first to get on board corporate, private, voluntary and public institutions which cater to large number of TB cases or the individual providers where chest-symptomatic patients tend to report would be addressed through well designed operational research.

4.35 Towards the end of the 14 city PPM project focused on urban areas, sufficient collective experience would have been gained in engaging diverse health care providers in rural areas through the extent of the uptake of various NGO and PP schemes, of their output and of any constraints in their implementation. This knowledge base should help in the development of a framework for nationwide and systematic implementation of PPM through highlighting distinctions between urban and rural areas

4.36 The implementation of the specially designed PPM surveillance system would continue even after the termination of the 14 city project. These would be preserved as sentinel sites to monitor evolution of strategic PPM interventions, determine and extrapolate provider-wise contribution to case detection and treatment success and experiment innovative strategies if and when indicated. If the PPM monitoring system being used in the 14 cities currently proves to be too demanding and is going to add significantly to training and supervision, countrywide implementation of this system would not be advisable.

4.37 Development of a national PPM framework and strategies to involve diverse care providers would be followed by adequate hands-on support for its local implementation in diverse state-settings. For this purpose, the RNTCP-PPM consultants would be withdrawn from cities where adequate local capacity should have been built. They would then be assigned to states to guide the implementation of the suggested framework through and with the available RNTCP staff and consultants. The use of an interface in addressing the inertia to collaborate and tackling the teething problems of working together has been documented to be effective. The RNTCP-PPM consultants would not only act as an interface initially but would also help identify and institute local interface mechanisms to sustain collaboration.

4.38 Recognizing the importance of TB/HIV co-infection, the CTD in collaboration with the National HIV/AIDS Control Organization, developed a joint Action Plan for TB/HIV in 2001. In the ongoing TB Control Project, this joint action plan was initiated in the six high HIV prevalence states - Andhra Pradesh, Tamil Nadu, Karnataka, Maharashtra, Manipur and Nagaland and in this extension year has been extended to an additional eight states - Delhi, Gujarat, Himachal Pradesh, Kerala, Orissa, Punjab, Rajasthan and West Bengal. Joint activities have included sensitization of key policymakers to address the importance of TB/HIV coordination, service delivery and cross-referral, training for clinical service providers involved in both TB and HIV, involvement of NGOs and private practitioners, IEC, joint monitoring and evaluation and a specific training and infection control guideline development and dissemination to prevent the spread of TB in facilities caring for HIV-infected persons.

4.39 The primary mechanism to improve TB case detection among potentially HIV infected persons was by screening, voluntary counseling, and testing clients for cough of greater than, or equal to three weeks duration. These patients with cough were formally referred to microscopy centers. In the ongoing TB Control Project, cross referrals were established in 242 Voluntary Counseling and Testing Centers (VCTC) and these referrals contributed to 2.8% of the TB caseload in the six high HIV prevalence states. In addition, advocacy and health communication materials containing the message that TB is curable through quality free treatment were widely distributed to VCTCs and AIDS care centers.

4.40 State level joint co-ordination committees were also established in these six high HIV prevalence states and in Maharashtra, district level co-ordination committees are now also in operation. In 2004, HIV surveillance among TB patients was conducted by NACO in collaboration with the RNTCP in one district of each of the four high HIV prevalent states of Maharashtra, Tamil Nadu, Andhra Pradesh and Karnataka. The RNTCP II would build upon the same strategy for HIV/TB joint action but will expand collaborative activities to a total of eighteen states throughout the country and include components that incorporate the specific TB treatment needs of patients receiving anti-retrovirals as well as operational research to examine new ways of administering DOTS through ARV centers.

4.41 Guidelines have now been developed for pediatric TB, treatment boxes have been designed according to weight groups of children and tenders prepared for the production of boxes. The guidelines for pediatric TB have been developed by the RNTCP in collaboration with the Indian Academy of Pediatrics (available online from the RNTCP website at *www.tbcindia.org*). Diagnosis of TB in children is notoriously difficult. Only rarely do children with TB develop sputum smear positive pulmonary TB, although their lungs often are affected by tuberculosis. Thus microscopy of sputum is not an adequate tool for diagnosis of TB in children. Extra-pulmonary forms of TB are also more frequent in children than in adults. Suspected cases of pediatric TB should normally receive a chest x-ray. A purified protein derivative (PPD) skin test can also be helpful although a positive test result requires careful interpretation in areas where TB Immunization vaccination is common (such as India). Because of the relative difficulty of diagnosing pediatric TB, and the difficulty in management of loose anti-TB drugs in pediatric dosages, pediatric TB tends to be a 'neglected' area in the National TB Control Programs. Since the DOTS strategy is now well established in India, the program is ready to address this issue. The very welcome introduction of treatment boxes for children with TB, introduced in March 2006, addresses a long felt need and is an important innovation - a first time ever in any national TB control program.

4.42 For the purpose of diagnosing pulmonary and extra pulmonary TB in children, PPD for the skin test is required to be supplied to the districts by the RNTCP. Staff already trained under the RNTCP, would be given additional training on the diagnostic and treatment guidelines, utilization of patient-wise boxes (cardboard boxes containing the full regimen of TB drugs for treatment of one patient–currently only used for adult DOTS) for pediatric patients, and revised recording and reporting formats. As the training material for the initial RNTCP training has been revised to include the details of the new pediatric guidelines and the revised records and reports, regular and newly appointed health staff will be taught all aspects of the new pediatric management guidelines.

4.43 Multi drug resistant TB is thought to be a limited problem in India, with small studies indicating a prevalence of MDR TB of 3% of all new infectious TB cases. MDR TB is resistant to normal DOTS treatment regimens. However, MDR TB is transmissible and poor treatment practices will invariably add to the problem, which must be addressed both on human and financial grounds. Currently, treatment of MDR TB takes place in some medical colleges and private facilities without any approved protocols, no secured line of an uninterrupted drug supply, and without any quality assurance of the culture and drug resistance testing. The risk is imminent that these practices will result in development of TB which is also resistant to 2nd line TB drugs, the last chance of cure for an MDR TB case. It is therefore important and very timely for the DOTS program to now consider MDR as an urgent "standard of care issue" by the RNTCP.

4.44 The provision of treatment for MDR cases through the RNTCP would further increase the acceptance of the RNTCP by the community of clinical doctors and TB specialists, for whom the lack of 2nd line drugs for MDR cases has been a frequent issue of concern and complaint. It would also address the human rights issue of the current practice of denying additional treatment for those who have had one re-treatment opportunity but have failed to become cured. At present these patients can be offered no further treatment.

4.45 DOTS Plus is the acronym for this new program, which includes the following elements: (i) development of DOTS Plus centers at state level in states with facilities for quality assured drug sensitivity testing; (ii) a protocol and monitoring system for case holding with daily patient supervision; (iii) a routine of regular sputum microscopy and sputum culture for monitoring effectiveness of treatment; (iv) clinical services and medical know-how for handling of adverse reactions; (v) use of a standardized regimen for all cases; (vi) uninterrupted delivery of 2nd.line TB dugs for DOTS Plus; and (vi) limited duration of hospitalization and treatment completion under supervised ambulatory services.

4.46 There is international agreement that the best prevention of a growing problem of MDR TB is a strong DOTS system with high detection and cure rates combined with DOTS Plus facilities for the treatment failures in need of this special, difficult and expensive treatment option. A meeting in April 2005 with national TB experts, the CTD and international experts discussed and agreed on the strategic steps to be taken, the development of guidelines for selection of patients, case treatment regimens, and principles and practical details of case holding. A special system would be developed for registering and monitoring the MDR TB patients and their treatment outcomes, including follow up for 1-2 years after treatment completion.

4.47 DOTS Plus is particularly complicated by the fact that treatment is very long (24 months). Treatment compliance is a challenge compounded by frequent, severe adverse drug reactions. Drugs are extremely expensive (approximately US$1,600 versus US$9 for a normal course of DOTS). Solutions will have to be identified for uninterrupted drug procurement and supply, treatment sites must be identified and staff trained. The focus would be on failed re-treatment regimens (Category 2 failures) since approximately half of those are presumed to have MDR TB. For these patients DOTS Plus treatment will be the only possible cure, which will

also mean prevention of further transmission of MDR TB. DOTS Plus would only gradually be introduced and would cover no more than 4,000-5,000 patients within the first five years at 24 treatment sites. The planning and implementation of the component will take place with a close contact to and involvement of international DOTS Plus experts. Eventually, the annual demand for DOTS Plus treatment is estimated at 5,000-10,000 persons not including any backlog of MDR cases. Thus, beyond the next five years, drug costs alone for DOTS Plus may amount to more than 30% of the total RNTCP drug budget.

Annex 5: Program Costs

INDIA: Second National Tuberculosis Control Program

Table 1: Total Estimated Program Expenditure Financing Plan (In US$ Million)

	2006/07*	2007/08	2008/09	2009/10	2010/11	2011/12*	Total
Total Program Expenditure**	**32.4**	**67**	**67.2**	**68.5**	**68.9**	**37.9**	**342**
GFATM	6.3	18.2	19.2	12	6.9	3.2	65.9
DFID Drugs Phase II	7.9	8.1	8.6	9.2	10.5	0	44.3
USAID	1.8	1.9	0	0	0	0	3.7
WHO Technical Assistance	1.4	2.9	3.1	3.2	3.3	1.7	15.6
Total expected financial support	17.1	31.1	30.9	24.4	20.7	4.90	129.5
Gap/Requirement	15	35.9	36.3	44.1	48.2	33	212.5
GoI contribution (20%)	3.0	7.2	7.3	8.8	9.6	6.6	42.5
Proposed IDA Credit (up to 80%)	**12**	**28.7**	**29.0**	**35.3**	**38.6**	**26.4**	**170.0**

* Only six months covered by Indian financial year

**Includes only national financing requirements; state contribution is not available and therefore not included

Note: differences due to rounding

Table 2: Estimated Program Costs

Program Cost	Local US$ million	Foreign US$ million	Total US$ million
Borrower	29.8	12.7	42.5
Other Donors	90.6	38.9	129.5
IDA	119.0	51.0	170.0
Total Program Costs	239.4	102.6	342.0
	-	-	-

Physical and price contingencies are included

Table 3. RNTCP II Detailed Costs

Country Budget for RNTCP (includes GFATM, DFID drugs, USAID, GDF, GoI and WB Credit)								
								INR Lakhs ('00000)
Categories	2006-'07	2007-'08	2008-'09	2009-'10	2010-'11	2011-'12	Total	%
Investment Costs								
Civil Works	112	278	193	197	198	49	1027	0.70%
Lab Equipment	94	207	212	165	165	81	924	0.63%
Office Equipment	25	56	43	44	44	24	237	0.16%
Vehicles	110	216	190	194	195	98	1004	0.68%
Drugs	2844	8236	8432	8613	8639	6035	42798	29.14%
HRD/Training	647	1134	1184	1206	1220	640	6031	4.11%
Medical Colleges	323	566	586	606	619	319	3018	2.05%
IEC	944	1768	1712	1741	1768	748	8682	5.91%
Contractual Services	3990	7174	7271	7423	7489	3905	37251	25.36%
Consultancy Services and Research Studies	178	757	367	374	375	107	2159	1.47%
NGO & Private Sector	860	1530	1559	1588	1595	753	7885	5.37%
Sub Total	***10,127***	***21,922***	***21,749***	***22,151***	***22,307***	***12,760***	***111,016***	75.58%
Recurrent cost								
Printing	561	1135	1098	1117	1141	564	5617	3.82%
Lab materials	904	1608	1707	1738	1744	875	8576	5.84%
Counselling Charges	148	260	280	295	286	97	1365	0.93%
Vehicle Operation	368	655	675	697	683	370	3449	2.35%
Vehicle hiring	644	1146	1165	1197	1172	547	5871	4.00%
Office operations	1016	1807	1836	1861	1848	920	9287	6.32%
Equipment Maintenance	187	332	342	348	339	157	1705	1.16%
Sub Total	***3,827***	***6,942***	***7,103***	***7,253***	***7,214***	***3,529***	***35,870***	24.42%
Total Country Budget Rs Lakhs	13,955	28,864	28,852	29,404	29,520	16,290	146,886	100.00%
Overall Budget In USD Million	31.0	64.1	64.1	65.3	65.6	36.2	326.4	
WHO TA USD Million	1.4	2.9	3.1	3.2	3.3	1.7	15.6	
Grand Total USD Million	32.4	67.0	67.2	68.5	68.9	37.9	342.0	
USD1 =INR 45 Price and physical contingencies included								

Annex 6: Implementation Arrangements

INDIA: Second National Tuberculosis Control Program

Partnership Arrangements

6.1 The RNTCP has been supported through parallel funding by the DANIDA, DFID, GDF, GFATM, USAID and WHO. DANIDA provided US$21.0 million to support RNTCP in the State of Orissa ending late 2005. USAID is providing grant assistance of US$6.6 million over 5 years (up to 2007) to cover the entire 21 million population of Haryana. DFID has provided US$26.0 million to cover the entire state of Andhra Pradesh, with the support ending in September 2005. For the next five years their support will include provision of TB drugs through GDF and consultant support through WHO (US$44 million). The GDF is already providing anti-TB drugs for the state of Orissa, and for an additional 200 million population as a commodity grant valued at over US$2.0 million per year up to the end of 2005. The GFATM is presently committed to providing an estimated US$56.0 million to: (i) cover a population of 56 million in the 3 states of Chhattisgarh, Jharkhand and Uttaranchal from the GFATM *Round 1* (up to 2006); (ii) cover a population of 110 million in Bihar and Uttar Pradesh from *Round 2* (up to 2009); and (iii) cover Andhra Pradesh and Orissa from *Round 4* once DANIDA and DFID support ends (up to 2010). A GoI proposal to obtain GFATM financing for the program under *Round 6* may come up during the program period. WHO provides technical support to the RNTCP, via a country-wide network of medical consultants based from central to district level. WHO works on 3-year planning circles but expects this assistance to continue at the present level until at least 2011. Donors may use different procurement arrangements for their 'in kind' support to the program (such as TB drugs and technical assistance); however all states would use the same results framework, program monitoring, financial management and procurement procedures regardless of source of financing. Donors would monitor the program jointly with GoI during annual joint reviews.

Program Implementation.

6.2 The RNTCP is a program of national impact; as such it requires a strong coordination and management structure, at the central and state levels and an effective strategy to ensure that the district level has the technical and financial support and flexibility to implement the program successfully. The program's rapid expansion during the past three years has not been accompanied by a proportional increase in staff at the central and state levels, outstripping the managerial capacity required for ensuring high quality of expansion and implementation. A phased implementation of adjustments in institutional arrangements to strengthen management and to further decentralize would be supported by the program to ensure a smooth transition from RNTCP I into the RNTCP II.

6.3 **Central Level Management.** The program has been successfully managed for many years by CTD, headed by the Deputy Director General for TB, as the National Program Director, under the leadership of the Director General, Health Services who reports to the Health Minister. Under RNTCP II, this arrangement would continue and the Joint Secretary from the administrative arm of MOHFW would oversee the financial and administrative areas. CTD is responsible for TB policy formulation, providing technical and operational guidance to the states,

program monitoring and evaluation, definition of operational research priorities, and overall quality control. It also has the responsibility for the transfer of funds to State Health and Family Welfare Societies, procurement of anti-TB drugs, mobilization of funds, and coordination with the National AIDS Program. At present, WHO provides significant technical support that is expected to continue during the next five years of program implementation.

6.4 **National Institutions.** The National TB Institute (NTI) in Bangalore, the Tuberculosis Research Center (TRC) in Chennai, the Lala Ram Swarup Institute of TB and Allied Diseases (LRS) in Delhi support CTD's quality control functions, carry out basic and operational research, develop training materials, and provide training to the STOs and trainers from the SDTCs.

6.5 **State Level Management.** The Director of Medical Services and the Director of National Programs are responsible for overseeing TB program implementation. Day to day implementation responsibility lies primarily with the STO, who is supported by a Deputy STO (in larger states), a medical officer, an accountant, an IEC Officer, and administrative staff. Their responsibilities include: ensuring district compliance with eligibility criteria for participating in the program; overseeing the functioning of the DTCs; coordinating TB activities with other health institutions; identifying and correcting bottlenecks in implementation; overseeing implementation of staff training plans; and ensuring quality control and appropriate recording for monitoring of project outcomes. State TB Cells are also responsible for monitoring of the program throughout the state, including metropolitan cities, and for ensuring the integration of the program throughout the health system.

6.6 States have the responsibility to provide adequate space and human resources for the STDCs that have three units: (i) an IRL; (ii) a supervision and monitoring unit; and (iii) a training unit that supports the program through training, program monitoring, and operational research activities. Some states have already established STDCs; states that have not yet established them are expected to obtain these services from public/private institutions in the state that are found to provide quality services.

6.7 Medical colleges play an important role in the TB program and many have established DOTS centers and created task forces to address TB issues. Under the RNTCP II, more medical colleges would be expected to actively support the program.

6.8 **District and Local Level Management.** The DTC is the key administrative unit responsible for implementation of the TB program (municipal corporations in large metropolitan areas). It is headed by a DTO, assisted by a medical officer, a statistical assistant, a lab technician, a treatment organizer and other paramedical staff. The districts have one microscopy center (DMC) per 100,000 population (one per 50,000 population in hilly, difficult, or tribal areas). The DTC is the nodal point for TB control activities in the district and also functions as a specialized referral center. The districts also have TUs that include STSs and STLSs, who do not always work full-time on TB program implementation (there is one TU per 500,000 population overall, and one per 250,000 population in hilly, difficult, or tribal areas). A TU medical officer has overall responsibility for implementation, monitoring and supervision of TB control activities in its designated geographical area, for maintaining TB registers, and preparing

quarterly reports. DOTS Centers consisting of public, NGO, community volunteers, or private providers function at the community level.

Implementation arrangements

6.9 Under the RNTCP I, CTD proved to have satisfactory management capacity and to meet IDA's fiduciary requirements[11]. It has a comprehensive management information system, satisfactory reporting system, procedures for budget control, internal control and financial reporting, and a system that supports accounting processes and transactions. Notwithstanding the above, the RNTCP II aims to address identified weaknesses in management and non-clinical areas of the program, and develop strategies to advance the advocacy and health communication, expand HIV/TB coordination, introduce treatment of pediatric TB, and initiate a program to address drug resistant TB cases.

6.10 Due to the rapid expansion of the program, there is a need for institutional strengthening at central and state levels. The center would be strengthened through the hiring of additional staff, including non-clinical staff, provision of equipment and adequate physical facilities. CTD would have units in the areas of advocacy and health communication, human resource management and development, finance, supervision and monitoring, and procurement and logistics. Additional staff to supplement the existing teams would also be contracted. WHO will continue to provide technical support to CTD, and to the states and the districts. It has also provided additional consultants to support large and poorly performing states.

6.11. States would receive support from CTD and WHO technical assistance to begin implementation of need-based planning, budgeting and implementation. State public and non-public institutions are providing quality training to all levels of RNTCP staff and DOT providers. Also, agreement would be sought from the state governments to ensure that: (i) STO and DTO positions are filled with medical staff with background and experience in community health, public health, community health administration, social and preventive medicine, health administration, or health management, and that these officers remain in their position for at least 3 years; and (ii) medical and laboratory personnel working in the program remain in their posts for at least two years. CTD would ensure that District Health Societies, responsible for financial resource management, allow transfer of 100% of funds between budget heads in a given fiscal year.

6.12 Medical colleges in the states would also receive support to incorporate DOTS as the treatment of choice for TB, and resources to provide training to their faculty.

6.13 The specific arrangements for Financial Management are detailed in Annex 7 and for Procurement in Annex 8.

6.14 **Strengthening of non-clinical areas of the RNTCP.** These areas include advocacy and health communication, hard to reach groups and other social issues, and promotion of the involvement of private providers.

11 See Annex 8 for a detailed description of the procurement arrangements

6.15 Advocacy and IEC strengthening would start with the establishment of an Advocacy and IEC Unit within CTD to be responsible for strategic planning, relationships with contracted agencies, and strengthening state capacity in this area. The Unit would oversee the implementation of the communication strategy. Opportunities would be explored to strengthen staff capacity through international institutional linkages facilitated through bilateral support.

6.16 The State TB Cell would be responsible for state level IEC, with an IEC officer dedicated to RNTCP work. Further training of IEC officers would aim to maximize their potential. Institutional IEC capacity in each state would be assessed and resources available within the government and private sector would be identified. The network of WHO consultants who provide technical support to the program includes a number of consultants who have a public health background, field experience of health communication in community settings, and an interest in strategic planning for IEC. Options on how to tap this talent as an advisory resource would be explored.

6.17 Districts would play an active role in developing plans for IEC activities with sufficient flexibility to allow for local initiatives and variations. Each district would establish networks of local communicators according to available talent and interest, maximizing horizontal linkages with other programs and organizations to tap varied experience in community level health promotion.

6.18 Different ways to improve access to "hard to reach" groups would be defined by studying some of the working approaches that are currently in place and used successfully by some of the RNTCP units, NGOs, corporate sector, PPM projects and medical college initiatives, as well as international experience. Incentives and enablers in TB control would be considered (i.e. transport passes, and financial subsidies as well as direct financial incentives which have been found useful in diverse settings). Their applicability in the Indian settings would be determined through focused intervention research within target populations. The results would then be shared with program personnel, NGO representatives, academia, researchers and international experts with the specific purpose of developing schemes that could be promoted to the public and private sector organizations.

6.19 To promote the involvement of private providers, there is a proactive approach currently being tried in 14 cities to reach out to diverse care providers and instituting collaboration with them. This work is being facilitated by a dedicated RNTCP PPM consultant for each city supported by two field supervisors. Careful documentation of the processes and outcomes of this pilot scale up would be undertaken. By the end of 2006, information collected from this initiative would be used to define strategies to engage different types of providers--public and private, to identify tools to facilitate collaborations, to design sensitization and training materials for both RNTCP staff and other providers, and to identify modifications required for the surveillance and monitoring system. All this would contribute to undertake countrywide expansion during and beyond the RNTCP II.

6.20 To enhance coordination between HIV/AIDS and TB activities, the RNTCP and NACO have developed a joint plan of action to ensure synergy between the two programs at the different levels. Implementation of this plan at the national level would be the responsibility of

the RNTCP HIV/AIDS coordinator and the NACO HIV/TB coordinator, under the supervision of the respective national program directors. Under the RNTCP II, an additional eleven HIV/TB coordinators would be contracted to implement the joint action plan in the additional eleven States where joint activities were initiated in early 2005. After the coordinators are trained on HIV/TB, they would assist in implementing joint activities at the state and district levels.

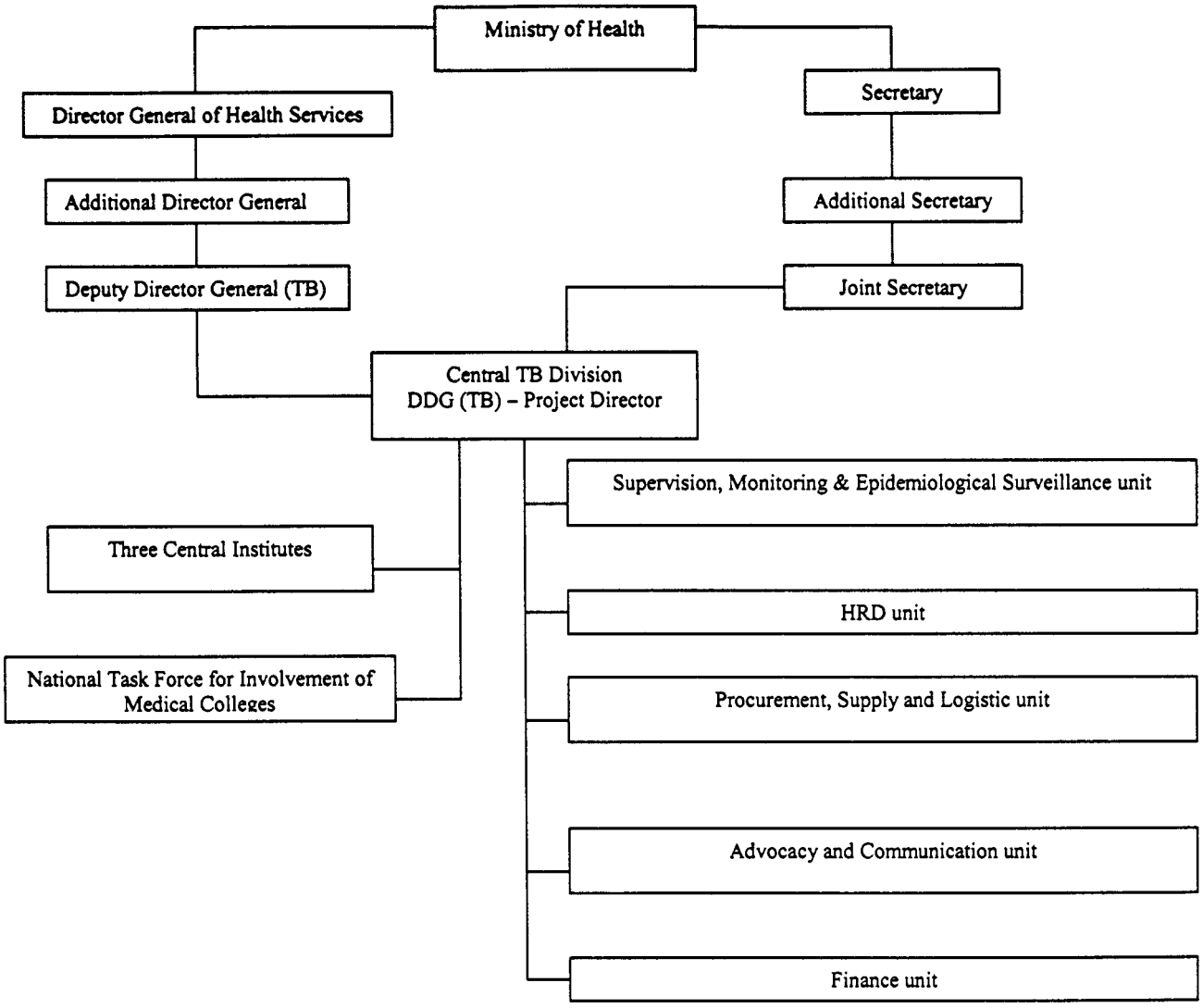
6.21 Implementation of integrated health communication would be shared by NACO and the RNTCP. The printing of HIV/TB reporting formats would be the responsibility of NACO in the six GFATM states and the RNTCP in the other states. The RNTCP envisions further expansion of the HIV/TB collaborative activities to a total of eighteen states using similar implementation arrangements. Joint quarterly coordination review meetings between both national programs would continue under RTNCP II. The same mechanism would be used at the state and district levels, with the establishment of state and district joint coordination committees. These committees would meet quarterly to review progress and facilitate effective implementation of the joint national action plan.

6.22 For the treatment of Pediatric TB, specific guidelines were developed under the RNTCP I following several consultations with national and international experts during 2003-2004. Following the model for adult cases, boxes with drug regimens containing pediatric dosages have been developed. The countrywide introduction of the new drug boxes, differentiated by color, is anticipated for 2006. The RNTCP reporting forms have already been modified to allow a detailed analysis of case finding and treatment outcomes in pediatric cases. RNTCP training materials are now based on the new forms. All new staff would be trained with the material, while already trained staff would receive refresher training to get acquainted with the new pediatric drug boxes and the modified reporting system.

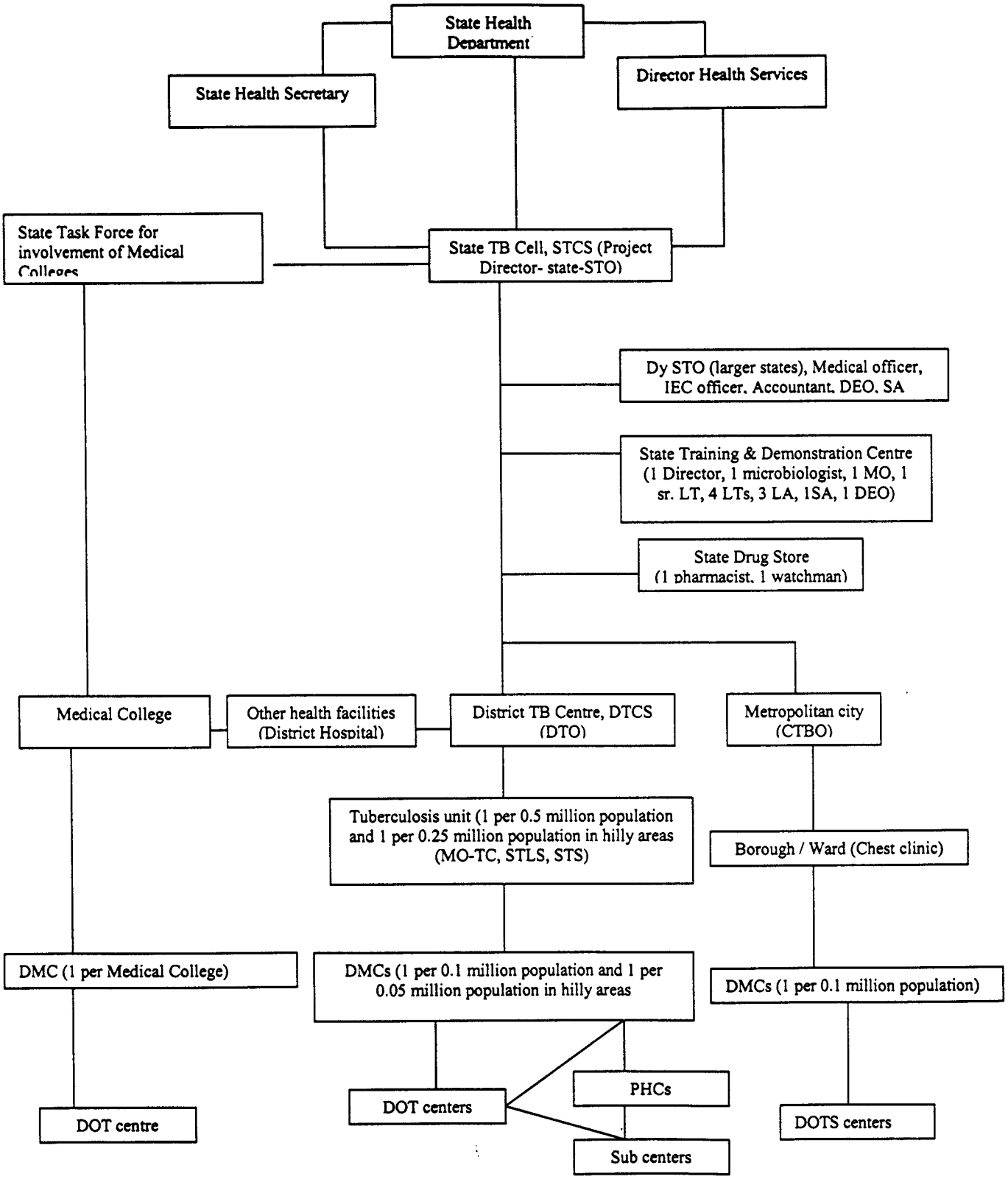
6.23 Details of the proposed strategy to implement DOTS Plus were discussed during a national DOTS Plus Committee meeting in April 2005, after which national guidelines for the treatment of MDR cases are being prepared. TRC Chennai is working with the STDCs initially in Gujarat and Maharashtra to accredit them for quality assured DST. This capacity in other states will gradually be developed so that by the end of the RNTCP II, a network of IRLs capable of doing quality assured DST will be available throughout the country. RNTCP is also exploring the availability of drug sensitivity testing facilities at medical colleges and private laboratories.

6.24 The GoI recently launched the NRHM with the goal to improve the availability of and access to quality health care by people, especially for those residing in poor states and in rural areas, the poor, women, and children. The program will integrate easily with the NRHM in two areas that will directly affect it: (i) transfer of funds through a single health society at the state and district levels; and (ii) incorporate "ASHAs" (female health volunteers) as DOT providers at the village level.

Institutional Organogram for Revised National Tuberculosis Control Program



RNTCP Institutional Organogram for the States



Annex 7: Financial Management and Disbursement Arrangements

INDIA: Second National Tuberculosis Control Program

7.1 The program has a satisfactory financial management system to adequately account for and report on the program expenditures incurred by the program. The support provided by DFID through WHO and the WHO assistance will be accounted for separately by these two agencies through annual reports.

Country issues

7.2 Generic country level issues and specific resolutions under the program:

GoI's existing accounting system concentrates mainly on book keeping and transactional control over expenditures and there is little in the way of a concept of financial management information being used for decision making. Also GoI considers all releases as expenditure.

A separate program financial management system has been designed for the program under the ongoing Tuberculosis Control Project, which enables the generation of reliable financial reports for enabling timely managerial decision making.

Quality and timeliness of audit reports: as the audit of the CTD will be conducted by the Comptroller and Auditor General (C&AG), India for the expenditure incurred by the CTD.

It has been agreed with the MOHFW and C&AG's offices that the program financial statements generated by the program for the expenditure incurred at the CTD would be audited in accordance with the TOR agreed to with IDA and consented to by the C&AG's office.

The audit of the state societies at the states and districts would be carried out by independent chartered accountants firms empanelled with the C&AG and one consolidated report for each state will be received. The CTD will consolidate all such reports and provide one consolidated report on audits.

The (merged) state and district societies are required to prepare financial statements which will be audited by an independent chartered accountant firm. CTD will also maintain books of account based on which a statement of sources and applications of funds will be prepared for the expenses incurred at the CTD.

The following country issue, with respect to non-availability of the program financial statements, does not apply in this program:

The issue of availability of funds on a timely basis to the program implementing entity does not apply to this program as the funds to meet the expenditure at the states will be remitted directly to the State TB Control Societies/State Health Societies.

Strengths

7.3 The program has the following strengths in the area of financial management:

- The finance cell in the CTD is fully staffed with 4 consultants who are well versed with the GoI financial regulations as well as IDA requirements.
- An updated draft Finance Manual has been prepared which details the budgeting and planning processes, accounting policies, procedures and internal control processes financial reporting and audit arrangements.

Weaknesses

7.4 In centrally sponsored programs the flow of funds from the center to the states and the District is not normally linked to meeting financial reporting targets (i.e. timely submission of SOEs, FMRs and Audit Reports). It has been agreed and included in the Finance Manual that the flow of funds will be linked to adherence to financial reporting conditions.

Implementing Entity

7.5 The program will be coordinated by the MOHFW. The CTD is responsible for overall implementation of the program including its financial management. The Joint Secretary, MOHFW (Administrative Head) and the Deputy Director General, (TB) (Technical Head) would have overall responsibility for the proposed program. One of the four Deputy TB Program Managers of the CTD is responsible for financial management aspects.

7.6 At the state and district levels, State and District TB Societies are already in existence and have been implementing the program for a number of years. The officer in-charge of the State TB Society is responsible for financial management of the program within the state, state level procurement, annual work plans, management and technical support to the districts and annual progress review in the state.

7.7 The MOHFW has decided that all the individual program specific state and district societies should be merged into one implementing entity at the state and district level under the umbrella of the NRHM. The MOHFW has however agreed, that the financial management arrangements of the TB project (separate financial reporting, finance staff and audit arrangements) would continue. In addition, IDA would continue to be proactively engaged with the MOHFW in facilitating merger process from a financial management perspective. It may be noted that the State Societies of Uttaranchal and West Bengal were merged two years ago and implementation of RNTCP in these states through a single society has not faced problems due to the merger.

Finance Staffing and Training

7.8 In addition to the Finance Unit of the CTD, headed by a Deputy Program Manager, the state level accountants are already in place. In nine large states a provision for additional staff to

support the existing accountant will be made under RNTCP II. A training plan, which is detailed in the PIP, aims at providing dissemination of the finance manual to the finance staff.

Budgeting and Fund Flow Arrangement

7.9 The funding of the RNTCP II would be through the budget of the MOHFW. RNTCP has a separate budget head (minor head) at the national level; this account would be operated by the CTD. The annual budget of the program would be allocated as per National PIP. The budget would be allocated to each state based on state annual work plans and the utilization of funds released. As this is a centrally sponsored scheme, funds would be made available to the state societies on a full grant basis.

7.10 Funds required to implement the program will be released by GoI to the state societies normally in two installments based on the annual work plan and expenditure incurred. The state society in turn would release necessary funds to district level societies based on their work-plans and requirements. Release of second installment funds from the central to the state level would be incumbent on the receipt of the audit and utilization certificates. No further release of funds would be made to the concerned units from central/state level until audit and utilization certificates are received.

Books of Accounts and Accounting Policies and Procedures

7.11 The program costs incurred at the CTD and costs incurred by the Central Procurement Agent, IEC consultants and training would be recorded in the books of the CTD at MOHFW in accordance with procedures and policies prescribed in the General Financial Rules (GFR). The accounting policies and procedures and the formats for existing financial reports for the GoI are captured in the various accounting forms ('Books of Forms'), cash book, the reports and the GFR. These guidelines also lay down the internal control procedures and the formats of the reports and books of accounts.

7.12 As the GoI follows a Cash Accounting System, all funds transferred to the states and to the central level implementing units are recorded as expenditure in the books of the GoI. For the purpose of the program however, the Accounting Policies as documented below will be followed.

Level	Activity	Mainstream GoI	For Program
Central Ministry	Centralized Procurement including ICB, Training, Monitoring and Evaluation and IEC.	Carried out by designated procurement agents and IEC consultants who receive advances from the CTD; training which is carried out by NTI and LRS and other administrative costs of CTD. The books of account for this are maintained by the Chief Controller of Accounts (CCA). Advances to the procurement agencies are recorded as expenses (Non plan)	The CTD (Finance Cell) will monitor advances/ settlement to the various central procurement agents and training institutes. For the purpose of financial reporting to IDA only the actual expenditure as reported by the various agents and institutes will be recognized as expenditure and the balance

		and transferred to Plan expenditure once the procurement process is completed i.e. proof of delivery is provided by the agents. The advances to the training institutes and for IEC are recorded as expenditure when funds are released and Utilization Certificates are required to be provided by such agencies.	will be recognized as advance.
State Society	All program incremental activities	Fund releases to state societies are also recorded as expenditure in GoI's books with a requirement that the Utilization Certificate (UC) be submitted within 9 months from the end of the financial year.	The actual expenditure incurred and reported by the state and district societies (based on accounting policies prescribed in the Financial Management Manual) will be the basis both for reporting and for the financial statements

7.13 A Financial Management System, based on a manual system (with support by way of Excel spreadsheets) is already in use by the program. Expenses would be recorded on a cash basis and would broadly follow the program activities for ease in reporting to various stakeholders. Standard books of accounts on a double entry basis (cash and bank books, journals, fixed assets register, ledgers, work registers, contractor registers etc.) will be maintained under the program by the state and district societies. A Finance Manual laying down the financial policies and procedures, periodic and annual reporting formats including financial statements, flow of information and methodology of compilation, budgeting and flow of funds, format of books of accounts, chart of accounts, information systems, disbursement arrangements, internal control mechanisms, and external audit for the program has been prepared for guiding the program personnel.

Information Systems

7.14 Only manual books of account are proposed for the program in view of the low level of capacity at the districts and varying skill sets from state to state. Most of the states and districts send their financial reports electronically to the CTD.

External Audit

7.15 The requirements for external audit are:

- One audit report in respect of CTD (including program financial statement- sources and uses of funds) audited by C&AG, who shall be acceptable to IDA as an independent auditor, under terms of reference agreed with IDA; and

- One consolidated audit report (including program financial statements) for each state. This consolidation at the state level will be based on the individual audit reports received from the district societies. The audit will be carried in out in line with the terms of

reference (both for the stand alone audit of the district and state society and the consolidation) approved by IDA. Based on the state audited financial statements, the CTD will consolidate and provide a consolidated report on audits.

7.16 One auditor will be appointed for each state. This auditor will have the responsibility for audit of the state society and all the district societies in the state and also the consolidation of all the individual audit reports. This will serve the purpose of achieving uniformity and consistency in financial statements and audit opinions across the state. In larger states, joint auditors will be appointed.

7.17 In addition, an audit report for the special account held at GoI would also be submitted. The annual program financial statement to IDA would include: (i) a summary of funds received (showing funds received from the IDA, and a Summary of Expenditures shown under the main program activities); and (ii) a Balance Sheet showing accumulated funds of the program, bank balances, other assets of the program, and liabilities, if any (only in case of the state and district societies). The audit of the program accounts would also include an assessment of the adequacy of the accounting and internal control systems, the ability to maintain adequate documentation for transactions, the eligibility of incurred expenditures for IDA financing and reconciliation of claims with audited expenditure as per financial statements. The annual program financial statements duly audited would be submitted within six months of the close of GoI's fiscal year. Thus the following audit reports will be monitored in the Audit Reports Compliance System (ARCS):

Implementing Agency	**Audit**	**Auditors**
CTD, MOHFW (1 audit report)	Program Audit for central level activities	Comptroller & Auditor General of India
Consolidated report on audits of all state societies (1 audit report)	Program Audit for state level activities	Private Chartered Accountants
DEA / GoI	Special Account	Comptroller and Auditor General of India

Internal Audit

7.18 As the program is widely spread (being implemented in all districts of the country) it will not be possible to have a meaningful and comprehensive internal audit. The CTD carries out an intensive review of two districts per quarter in which financial management is also reviewed. Similar reviews are also required to be carried out by the states. It was agreed that in addition to the existing review, a management audit would be carried out by the financial management unit of the CTD and the state finance officer would be included as an integral member of the review carried out by the states. A financial management checklist has also been developed against which six monthly reviews would be conducted by the state society accountant and also by supervision teams from the CTD and IDA. This checklist has been made an integral part of the Financial Manual.

Disbursement and Payment Arrangements

7.19 It is proposed that IDA will finance up to 80% of the gap between funding by all bilateral/multilateral agencies and the total expenditures incurred by the program rather than specific percentage for each activity. The activities in some states and the central procurement of drugs related to those states (currently Haryana, Jharkhand, Chhattisgarh, Uttaranchal, Andhra Pradesh, Orissa and some districts in Uttar Pradesh and Bihar) are financed by GFATM/ USAID. The CTD has a separate budget head for the GFATM/USAID funds and funds are released into a separate bank account and separate books of account are maintained to avoid duplication. For central procurement also separate contracts are made for the procurement. These states would however be eligible for financing from IDA credit as and when the GFATM/USAID/DANIDA grants close. It may be mentioned that while there are more than one development partner and pooling of funds is not envisaged, the financial management arrangements have been made uniform for all the states regardless of financing source.

7.20 It is proposed to disburse the IDA credit on a six monthly basis against a consolidated expenditure report by activity –interim financial statements- , and any excess or deficit in between the expenditure report and consolidated audited financial statements would be adjusted in the subsequent disbursement.

Disbursement Schedule

Expenditure Period	Expenditure Report	Disbursement	Audit Report	Adjustment
October 2006 to March 2007	June 30, 2007	July, 2007	Sept. 2007	Jan. 2008
April 2007 to Sept 2007	Dec. 31, 2007	Jan. 2008	Sept. 2008	Jan. 2009
October 2007 to March 2008	June 30, 2008	July, 2008	Sept. 2008	Jan. 2009
April 2008 to Sept 2008	Dec. 31, 2008	Jan. 2009	Sept. 2009	Jan. 2010
October 2009 to March 2009	June 30, 2009	July, 2009	Sept. 2009	Jan. 2010
April 2009 to Sept 2009	Dec. 31, 2009	Jan. 2010	Sept. 2010	Jan. 2011
October 2009 to March 2010	June 30, 2010	July, 2010	Sept. 2010	Jan. 2011
April 2010 to Sept 2010	Dec. 31, 2010	Jan. 2011	Sept. 2011	Jan. 2012
October 2010 to March 2011	June 30, 2011	July. 2011	Sept. 2011	Jan. 2012
April 2011 to Sept. 2011	Dec. 31, 2011	March 2012	Sept. 2012	Jan. 2013 *

* This year the excess, if any, will have to be refunded by the GoI.

Other Disbursement Features:

- Disbursement would be subject to receipt of the consolidated report of audits due by September each year. If this report is not received by January of the following year, no further disbursement would be made until the report is received. The GoI would however still be required to submit the Financial Monitoring Reports (FMRs) on the due dates, i.e. November and May each year.

- If the audit reports indicate higher levels of eligible expenditure as compared to the FMRs for the same period, the excess will be added to the next report based disbursement; and

- When the audit reports indicate lower levels of eligible expenditure against the relevant FMRs, an adjustment will be made to the next disbursement by way of a reduction.

Financial Reporting and Monitoring of Program Expenditures

7.21 The FMR formats (expenditure reports) are being mainstreamed with the program internal reporting. The reporting from the districts to the states will be on a monthly/ quarterly basis and from the states to the CTD on a quarterly basis. IDA will receive half yearly progress reports from the CTD which will also be a basis for disbursement. The output/activity reports will be monitored separately by way of monitoring and logistics reports. The FMRs will include a comparison of budgeted and actual expenditures and analysis of major variances. These financial reports will also form the basis/format of the annual financial statements to be prepared by the state/district societies and the CTD. The financial reporting will be done on a semi annual basis by way of FMRs (for the period ending September and March e very year) and will be submitted by May 31 and November 30 of each year to IDA.

Advance for GoI: an advance will be provided to the project representing six months of expenditure. The initial advance is expected to be approximately US$15 million.

Retroactive financing: no retroactive financing is envisaged under this project.

Public Disclosure

7.22 The CTD prepares an annual report which is put up on their website; the report for 2006 is already available. The following financial information will be included in the annual report: information on release of funds under the program, actual expenditure, audit reports and utilization certificates. In addition the states will also prepare an annual report in an acceptable format. The annual reports prepared by the states will be introduced in a phased manner.

Supervision Plan

7.23 The program would require in depth supervision in the initial year, especially for ensuring successful implementation of the state level financial management and fund flow arrangements. Mid term review would be conducted after two and a half years of the program to comprehensively review the financial management performance of the program.

Annex 8: Procurement Arrangements

INDIA: Second National Tuberculosis Control Program

General

8.1 The Central TB Division, Ministry of Health and Family Welfare (CTD) in consultation with IDA has prepared a "Procurement Manual" for Revised National TB Control Program (RNTCP II) for guidance of the procuring agencies at all levels under the project. This manual gives details of various methods of procurement agreed for the program along with steps and thresholds to be followed under each method. This manual will be issued to the states for carrying out procurement under the project and will apply to all procurement done by the CTD, states or districts. Procurement thresholds for International Competitive Bidding (ICB), National Competitive Bidding (NCB), Direct Contracting (DC), Shopping for works and goods and Hiring of Consultants Services agreed with CTD are mentioned below. Goods and Works following ICB procedures, contracts valued more than US$ 100,000 for NCB/LIB and consulting services (i) above US$ 100,000 for firms; and (ii) above US$ 50,000 for individual consultants will follow the World Banks' procurement/consultant guidelines respectively. All other methods would follow procurement procedures stipulated in the CTD Procurement Manual

	ICB	NCB[12]	Shopping[13]	DC[14]
Works	> US$2.0 million equivalent*	US$50,000 to US$2.00 million equivalent*	< US$50,000 equivalent	US$10,000 equivalent or less

*Most works will be procured following shopping and direct contracting. Procurement of works under NCB and ICB is not expected. However, should the need for larger value works contracts arise, the above thresholds will apply for NCB/ICB.

Goods/ Equipment	> US$1.00 million equivalent	> US$50,000 up to US$1.00 million equivalent	< US$50,000 equivalent	< US$10,000 equivalent

12 For NCB up to US$ 100,000CTD Procurement Manual will be followed.
13 For this method of procurement, CTD Procurement Manual will be followed.
14 For this method of procurement, CTD Procurement Manual will be followed.

Consultancy Services	Quality and Cost Based Selection (for selection of Firms) estimated to cost > US$ 500,000 equivalent : international shortlist. estimated to cost US$ 500,000 equivalent or less : short list may comprise national consultants only. Single Source/Least Cost Selection: - With firms when cost is estimated at < US$50,000 equivalent per contract; and - Individual Consultants, irrespective of value.

8.2 Invitation for Bids (IFB) for Works, Goods and Equipment for all ICB contracts and advertisement for calling of Letters of Expression of Interest (EOI) for short listing of consultants for services costing more than US$200,000 equivalent will be published widely including in UNDB and dgMarket.

Procurement of Civil Works

8.3 No major construction work is envisaged in the project. Most of the civil work involves repairs, modifications, additions and alterations to the existing buildings such as the laboratories in rural and urban peripheral health institutions, drug storage areas at sub-district, district and state level, microscopy centers, district TB Center and upgradation of laboratories and training facilities in the State TB Training and Demonstration Centers (STDCs). Since all the civil works are of small value, these will be procured under shopping procedures or in special circumstances by Direct Contracting by the state societies and/ or by the district societies.

8.4 Works estimated to cost less than US$15,000 equivalent may also be procured by Panchayat Raj Institutions (PRIs). Wherever works are executed by PRIs, the states would ensure that these institutions are able to obtain contributions from the community and that adequate arrangements for supply of standardized designs, preparation of estimates, supervision of construction, maintenance of quality control, and rendering appropriate accounts are either in existence or the states would provide necessary technical/managerial assistance through NGOs or individual experts.

8.5 Since the value of each civil works contract is generally small, there are no civil works expected to fall in the category of NCB/ICB. Total approximate cost of procurement of civil works indicated by CTD is US$2 million.

Procurement of Goods

8.6 The program includes procurement of binocular microscopes for microscopy centers, culture and sensitivity equipment for the STDCs, office equipment such as computers, fax machines, photocopiers, scanners, LCD projectors etc., vehicles (four and two wheelers), anti-

TB drugs in combi-packs as well as lose drugs and laboratory materials, printing of treatment cards, patient identity card, TB register, training modules and other forms/formats.

8.7 Procurement of goods/equipment may be undertaken at the state/district level following Shopping procedures and in exceptional cases by Direct Contracting. Total estimated value of procurement of goods/equipment/vehicles etc. is expected to be US$63 million approximately.

8.8 Goods/equipment under the project will be procured following ICB, NCB, LIB, Shopping (NS), and Direct Contracting (DC). In exceptional cases, where (i) there are only a limited number of suppliers of the particular goods or services or (ii) demand is urgent in nature or (iii) exceptional reasons exist justifying departure from advertised open tender, Limited Tender System, which is nothing but NCB without advertisement and by inviting bids from qualified suppliers as per the MOHFW list and other known suppliers, can also be adopted, up to the procurement threshold applicable to NCB. Rate contracts of the Directorate General of Supplies and Disposals (DGS&D) shall also be an appropriate method of procurement under Shopping i.e. under US$ 50,000. State governments' rate contracts may be taken as one of the quotations under shopping. For NCB for Works /Goods /Equipment /Drugs, CTD is planning to adopt Government of India (GoI's) Task Force bidding documents as modified from time to time. These documents have been approved by the Bank and have been used for several years for all Bank financed procurement.

8.9 MOHFW has agreed to appoint a qualified agent to conduct a review of the quality and quantity of pharmaceuticals and medical goods supplied under Bank financed health sector projects. The findings of this review will be used to improve quality of pharmaceuticals and medical goods to be procured by MOHFW under Bank supported projects.

Good Manufacturing Practice (GMP) certificate as per WHO certification scheme for procurement of pharmaceuticals and vaccines:

8.10 Good Manufacturing Practices (GMP) certificates will be issued as per the procedures described in the GAAP in Annex 11.

8.11 The World Bank will support procurement of pharmaceuticals or medical supplies under NCB and shopping only after the recommendations of the Bank DIR are incorporated into the GAAP and the concerns regarding revised Schedule M have been addressed in a way that is satisfactory to the Bank.

Selection of Consultants

8.12 Consultant services include training of staff, specialized training for financial management, IEC, HIV-TB coordination, inter-personal communication, private sector participation, management information system (MIS), review meetings for monitoring and training, hiring of procurement agency and any other agency including for drug quality monitoring, for IEC (media plan for TV, Radio and Press, advocacy, awareness, sensitization of health providers, wall paintings, banners, hoardings and kiosks etc.), hiring of contractual staff for medical colleges and staff at central, state, district, sub-district and peripheral levels, hiring of

services of NGOs and private sector, and of consultants to conduct research and studies relevant to improve implementation of the program. Total estimated cost of consultancy services is US$139 million approximately.

8.13 For hiring of consultant services, the method of selection would be - Quality and Cost Based Selection (QCBS), Single Source, least cost and selection of Individuals. All consultant services costing more than US $ 100,000 equivalent each for firms would be procured following Quality and Cost Based Selection (QCBS) and individual consultants costing more than US$ 50,000 equivalent each would be procured in accordance with the World Bank's "Guidelines: Selection and Employment of Consultants by World Bank Borrowers" dated May 2004 and World Bank's standard request for proposals (RFP). Consultant contracts costing less than US$ 100,000, Single Source selection of firms below US$ 50,000 and selection of Individuals below US$ 50,000 equivalent shall be awarded as per the procedures prescribed in the CTD Procurement Manual.

Assessment of the Agency's Capacity to Implement Procurement

8.14 The Constitution of India (Seventh Schedule) lists specific subjects in which the Union Government or the State Government alone can make laws and concurrent subjects in which both the Union and State Government can make laws. Procurement under contracts falls in the concurrent list.

8.15 Procurement of Goods/Works and Services by CTD and the State Government is regulated by the General Financial Rules of the Government (GFR), Indian Contract Act 1872 as amended to-date, Sales of Goods Act and, in special cases, by the Essential Commodities Act.

8.16 A task force to improve public procurement rules has been set up with the CPAR as one of the inputs. Revised General Financial Rules (GFR) have already been issued. Specific issues relative to the health sector and directly relevant for the project are intended to be addressed through the Governance and Accountability Action Plan (GAAP), CTD procurement manual and the CTD action plan.

8.17 All states and union territories will be participating in the RNTCP II. A review of existing procurement policies and procedures was carried out through a consulting firm in respect of CTD at the central level and on a sample basis for the three states of Assam, Maharashtra, and Uttar Pradesh, selected with the agreement of CTD, to identify areas for strengthening of the State Procurement Systems, to allow their use for procurement under the program.

8.18 Based on the findings of the CPAR, the SPARs, the assessment carried out in preparation of the RCH Project II and the assessment of the above mentioned three states, procurement risk is considered to be substantial.

8.19 The areas for strengthening have been identified in the report of the procurement capacity assessment of the CTD and the three states, and these have been reflected in the GAAP. The GAAP focuses on the following five key areas: improving Good Manufacturing Practice (GMP)

certification process, increasing competition and mitigating collusion, strengthening procurement implementation and contract monitoring, handling procurement complaints, and disclosing information and promoting oversight by the civil society. The GAAP shall be further strengthened as necessary, based on the risks identified and the recommendations of the RCH-I review, the Detailed Implementation Review [DIR], the procurement review by international consultants supporting EPW, and the report on the assessment of quality and quantity of pharmaceuticals and medical goods under the Bank supported projects.

8.20 MOHFW has established an Empowered Procurement Wing (EPW) with appropriate technical expertise in pharmaceuticals, biomedical equipment, quality assurance and supply logistics, to professionalize the procurement of health sector goods and services. The procurement activities of both Health and Family Welfare Departments including the CTD will be overseen by this wing. The EPW will ensure better competition and transparency in procurement of health sector goods, drugs and services in India, for delivering quality products in time. It would also support the development and implementation of new policies and actions which will enhance procurement practices and supply chain management. After strengthening the capacities at the central level, the MOHFW would support the states in strengthening their procurement and supply chain management. A consultancy assignment is being commissioned by MOHFW with support from DFID to review the supply chain logistics for the health sector and recommend improvement. The Bank will undertake the Detailed Implementation Review (DIR) of procurement as per the agreed terms of reference to identify bottlenecks and help CTD to resolve them.

8.21 As an interim arrangement until such time as the Bank and the Government agree otherwise, all ICB procurement, contracts estimated to cost more than US$ 100,000 for (i) goods and works under NCB; and (ii) consultancy services for firms, and individual consultants costing more than US$ 50,000 will be carried out by a qualified procurement agent or alternatively an appropriate UN Agency sole sourced to perform this function. The procurement agent will be selected through Quality and Cost Based Selection (QCBS) following the World Bank Consultant Guidelines. The procurement agent (commercial or UN Agency including GDF) will follow the World Bank Procedures and Guidelines of May 2004. However, UN Agencies and GDF acting as suppliers will follow their own procedures. The intention is to shift procurement implementation to relevant Indian institutions, including the PSAs, as soon as the Bank and GOI agree that they have the requisite capacity. The determination of features and duration of the transition towards full reliance on these institutions would need to be based on the outcome of the Detailed Implementation Review (DIR), the procurement review by the EPW consultants, the report on quality and quantity of pharmaceuticals and medical goods, and progress in implementation of the GAAP. Procurement of goods, works and services below the aforementioned thresholds will be conducted by CTD – at the central level under the oversight of the qualified consultant hired by MOHFW to support capacity development - and the states, following the CTD Procurement Manual.

8.22 Pending the appointment of the procurement agent, agreed urgent procurement during the interim period could be carried out by/through an entity under TORs and arrangements satisfactory to the Association. Procurement Support Agencies will not be used except as the Bank and GoI may agree.

8.23 Only drugs and medical supplies purchased from UN Agencies and GDF, or following ICB or LIB procedures with prior approval of the Bank will be financed from the IDA credit until the recommendations of the Bank DIR are incorporated into the GAAP and the concerns regarding revised Schedule M have been addressed in a way that is satisfactory to the Bank.

Procurement Plan and Manual

8.24 As stated earlier, procurement under shopping/direct contracting will be carried out at state/district level, while ICB and NCB will be carried out as stated in Para 8.21 above. In the event that IDA and GoI agree that a state has the requisite capacity to carry out ICB and NCB procurement, it will be allowed to undertake such procurement. The state level financing under the project is linked to their annual work plans which makes it difficult to precisely determine the quantity and the value of goods, works, and services to be procured by states and districts at this stage. MOHFW will be asked to provide aggregate values under shopping and DC under different categories of items, which will be reflected in the procurement plan with a note that these shall be procured by the states and value of each contract will be below the threshold for shopping/direct contracting.

8.25 CTD has finalized its Procurement Manual dated July 15 after consultation with IDA. A copy of this manual is available with the task team and CTD. CTD has also prepared annual plans for the full project period for contracts to be awarded under NCB and ICB, and procurement schedules for 2006-07 and 2007-08 for ICB/NCB which are attached to the PIP (dated 31/05/2005). These schedules specify the time required to carry out each activity from invitation of bid till delivery of goods and were approved by IDA on 31/05/2005. Year-wise procurement plans for the entire period have been prepared by CTD and incorporated in the PIP. The procurement plans are available in the RNTCP website and in IDA's database.

8.26 Method of procurement as well as thresholds for procurement review will be based on the total value of the bid, rather than the value of each individual contract/ schedule/ lot/ slice. Threshold values for prior review by IDA are:-

Works/Goods:	All contracts more than US $1.0 million equivalent;
Consultancy Services:	>US$200,000 equivalent for firms; and >US$50,000 equivalent for individuals

These thresholds are also indicated in the procurement plan. The procurement plan will be updated annually including prior review thresholds, if necessary, in agreement with the project team or as required to reflect the actual project implementation needs and institutional capacity.

Post Award Review

8.27 All contracts below prior review threshold procured either through the procurement agent or directly by the CTD/states will be subject to periodic post review which will cover (i) centre

and at least two states every year, and (ii) a minimum of 10% of contracts awarded under the program. These reviews are meant to ensure that the laid down agreed procurement procedures as per procurement manual are being followed.

8.28 The ex-post review by the Bank will be conducted either by Bank staff or by independent firms hired by the Bank in accordance with Paragraph 5 of Appendix 1 to the Bank's Procurement Guidelines.

8.29 In addition to the above reviews, all the procurement done by the central and state governments are subject to post audit by the Comptroller and Auditor General (CAG)/ State Audit Departments. Ex-post review would also be carried out by the CAG empanelled chartered accounts who will be carrying out the financial audit and their terms of reference would include procurement audit also for a minimum of 10% of contracts.

Mis-procurement

8.30 In case goods, works and services are not procured in accordance with the prescribed procedures outlined in (i) the Bank's Procurement Guidelines for all ICB and contracts estimated to cost more than US$ 100,000 for goods and works under NCB; (ii) the Bank's Consultancy Guidelines for consultancy services for firms and individual consultants costing more than US$ 50,000; and (iii) CTD's Procurement Manual for RNTCP II for other methods of procurement, IDA will declare mis-procurement and will cancel its portion of the credit allocated to the goods and works that have been mis-procured.

Frequency of Procurement Supervision

8.31 Monitoring the implementation of the GAAP would be an integral part of the project review and supervision plan. The GAAP has been agreed during the negotiations between the GoI, and the development partners including the Bank, and its implementation constitutes one of the legal covenants for the TB II project. In addition to regular monitoring and prior reviews, the designated procurement specialist will be participating in the 6 monthly joint review missions. Further, the periodic ex-post reviews, the ongoing procurement review by the international consultant supporting EPW and the report of the agent reviewing the quality and quantity of pharmaceuticals and medical goods will provide updates on implementation of agreed procurement processes.

Annex 9: Economic and Financial Analysis

INDIA: Second National Tuberculosis Control Program

9.1 The economic analysis of the program covers the following: (i) rationale for public sector involvement; (ii) cost effectiveness of the program interventions; (iii) financial sustainability of program interventions.

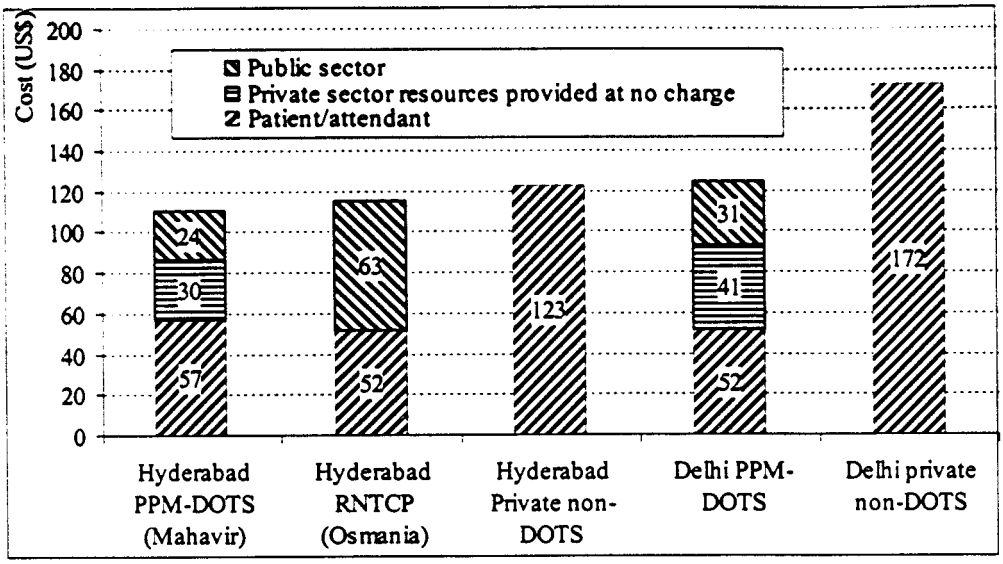
Rationale for Public Sector Involvement

9.2 The objective of a public health service is to increase the health and welfare of the public in a manner that no person would be excluded from accessing health services. However, as all countries, especially developing countries face budget constraints, investment of public resources for health services must be justified based on efficiency and public priorities. Regarding the TB Control Program in India, public sector investment is more efficient than most other public interventions in the health sector.

9.3 There are considerable externalities associated with TB detection and treatment because of its contagious nature. According to the RNTCP, one untreated smear positive TB patient can infect 10 persons in a year. TB prevention and treatment would therefore have large positive externalities since the non-infected population will indirectly benefit from TB patients being cured, as their chance of being infected will decline.

9.4 Due to the high financial burden associated with different treatment regimes, public involvement would provide TB patients with not only the most appropriate treatment but also reduce the financial burden on them, especially important for the poor. Patients are generally not sufficiently well-informed about the disease and availability of DOTS to make informed choices about health needs. The result is that a significant segment of the population is still seeking TB treatment from the more costly and often less effective private sector. A study undertaken by the World Bank in three RNTCP implementing states, namely Karnataka, Madhya Pradesh and West Bengal, concluded that the percent contribution of states (for infrastructure, staff time, etc.) to the total cost of RNTCP was about 66%. In the year 2004-05, the cost per patient incurred at central level, based on total program expenditure by the Central TB Division has been calculated as approximately Rs.1,000 per patient. Adding the state component of expenditure to it, the total cost per patient is approximately Rs. 2,940 per patient (US$65.0). In addition, TB households also incurred other opportunity costs in terms of days lost and school discontinuation of their children, etc. (Rajeswari et. al, 2000). Findings from studies based on two pilot programs in India indicate that TB patients pay significantly more for TB treatment by non-RNTCP providers than in the public sector or PPM scheme (Figure 1). Treatment in DOTS programs provided by the public sector facilitate a substantial reduction in costs compared with those associated with treatment by non-RNTCP providers, thus lessening the economic impact of TB on households.

Figure 1: Average cost per patient treated, and who bear costs, in selected PPM-DOTS projects, the RNTCP public sector DOTS program, and the private non-DOTS sector (*)



9.5 The DOTS is technically efficient and cost-effective as it relies on ambulatory short-course chemotherapy. Table 2 shows estimated average (total, incremental, and marginal) costs per case treated by different treatment regimes for TB patients in Malawi, Mozambique, and Tanzania. The ambulatory short-course chemotherapy is not only less expensive but also has higher compliance rates and leads to higher cure rates (from 85 % to 90%). A significant difference in preventing deaths due to TB in India between DOTS and non-RNTCP schemes is shown in Figure 2. It should be stressed that the regime with higher compliance rate and thus higher cure rate (as those used under the RNTCP) leads to a more rapid reduction in the infectivity of active TB. Under the RNTCP, TB chemotherapy is provided for free. However, further improvement in spatial and temporal ease of access to treatment could help to maximize both case detection and compliance.

Table 2: Estimated cost per case treated in Malawi, Mozambique, and Tanzania (1989 US dollars)

Treatment regime	Malawi	Mozambique	Tanzania
Short-course chemotherapy with hospitalization			
Average cost	160	217	174
Average incremental cost	99	155	127
Marginal cost	69	140	101
Standard chemotherapy with hospitalization			
Average cost	91	73	72
Average incremental cost	71	54	63
Marginal cost	42	40	37
Ambulatory short-course chemotherapy			
Average cost	66	55	50
Average incremental cost	45	36	41
Marginal cost	19	18	15
Re-treatment chemotherapy with hospitalization			
Average cost	209	323	252
Average incremental cost	141	232	182
Marginal cost	97	206	146

9.6 A full TB treatment requires extended drug therapy over 6-8 months; incomplete treatment contributes to MDR-TB. Treatment costs for MDR-TB are far higher than a normal TB case, at about US$2,000 a patient. Thus for every MDR-TB case averted, US$2000 is saved. A poorly performing program would create drug-resistant cases at a faster rate than these cases can be cured, even if unlimited resources are available. Approximately 5,000 TB cases in India develop MDR-TB per year, defined as resistant to at least isoniazid and rifampicin, the two most powerful TB drugs.

9.7 TB is a disease of the poor and public intervention in its detection and treatment could be an effective part of a poverty reduction program. The current DOTS has dramatically reduced more than a half of the financial burden of TB treatment for patients (Figure 1). If the poor are getting equal access to RNTCP services (through a well-designed, targeted RNTCP), the public intervention would clearly be an effective measure to protect them from financial hardship. Figure 1 also shows that although treatment is provided for free by the RNTCP, patient/attendant still incurs an average expenditure of US$50 per person for transportation, food, and loss of earnings. In the coming phase, the RNTCP services would be targeted to harder-to-reach TB patients, including the poor, tribals, migrant laborers, in order to optimize the benefits from the program and reduce the opportunity costs to the patients.

Cost effectiveness of the RNTCP interventions

9.8 Cost-effectiveness of the RNTCP interventions is analyzed in terms of lives saved and smear positive TB cases averted. These are direct benefits and do not take into account indirect benefits (further deaths prevented and additional smear-positive TB cases averted) associated with secondary infections. Other benefits not quantified here include cost savings from lower health care treatment costs, psychological benefits of a healthy population, poverty reduction, and improved productivity and efficiency among current and future workers, preventing children from dropping out of school, etc.

9.9 The concept of Disability-Adjusted Life Years (DALY)[15] is used in this analysis to measure the total number of healthy lives lost to all causes, whether from premature mortality or from some degree of disability. The cost per DALY is used to measure cost-effectiveness of the RNTCP as compared to non-RNTCP. The number of smear positive TB cases which could be averted by TB treatment depends on the capacity to detect TB patients and the efficacy of the treatment followed. In the absence of information on efficacy of treatment provided by the private sector, information on the government's National Tuberculosis Control Program (NTP) prior to the introduction of DOTS is used for non-RNTCP. Detection rate of 30% in non-RNTCP is used as compared to 70% in the RNTCP. As cure rates were not assessed in the NTP before DOTS, the rate of patients collecting medicines for the prescribed duration is used to compare with the cure rate of 85% in the RNTCP. Under RNTCP, it is assumed that the smear

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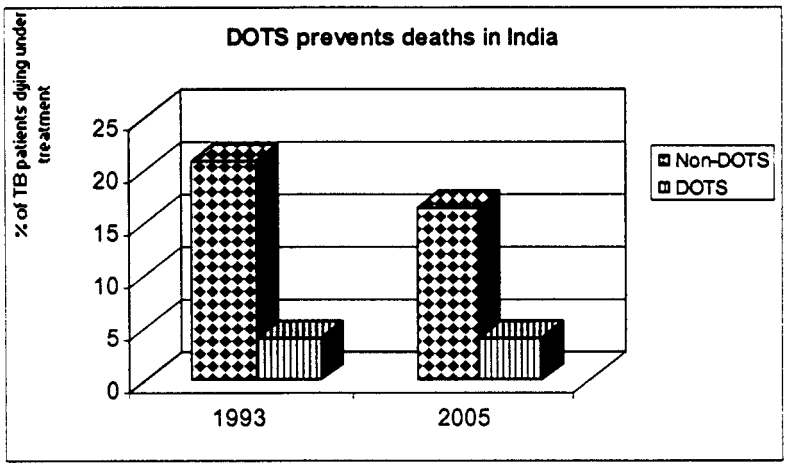
DALY is a measure for effectiveness. The DALY gain associated with averting a death is the number of years between the age at which the death would have occurred and the individual's expected age at death, given survival to the given age, with years gained in future years discounted back to the present at a discount rate of 3 percent per annum.

positive TB incidence rates would fall by about 5% per year, as was found in the first half of 2000.

9.10 A systematic evaluation of outcomes in the NTP indicated that 29% of the smear-positive patients died *(Datta et al. 1993)*. Data from the National Tuberculosis Institute, Bangalore and the Tuberculosis Research Center, Chennai suggest that approximately 10%-12% of smear-negative TB patients died. It is further assumed that death rates in non-RNTCP areas would decline 2% per year as has been recorded elsewhere (in China). In the RNTCP, death rates are 4%. Thus, taking a weighted average of smear-positive and smear-negative TB patients, the differential mortality in the period from 2005-2010 between non-RNTCP and RNTCP would be about 11-12%. That is, for every hundred patients treated under the RNTCP instead of non-RNTCP, at least eleven lives would be saved.

Figure 2: DOTS prevents deaths in India



9.11 Under these assumptions, the RNTCP could avert about 2 million additional smear positive TB cases and prevent an estimated 600,000 deaths as compared to the situation without the RNTCP. It is further assumed that the number of DALY reduced per smear positive TB cases averted is two months[16] of a healthy life and that the number of DALY reduced per death averted is 16 years[17]. Between 2006 and 2010, the effect would be a reduction of 11.8 million DALYs at a cost of US$34.01 per DALY reduced[18]. Most of the gain is achieved from deaths averted (99%). Results of risk-sensitivity analysis show that a 30% reduction in program benefits would result in 8.3 million DALY reduced at a cost of US$48.59 per DALY reduced. A 50% reduction in program benefits would result in 5.9 million DALYs reduced, at a cost of US$68.03 per DALY reduced. TB control is therefore one of the most cost-effective interventions in the health sector, as seen from the data in Table 3.

16 Assumed is equivalent to the intensive phase of TB treatment under DOTS

17 Calculated using current life expectancy at 43 years of 63 years for TB patients and assuming TB patients live at least two years after the onset of the disease, discounted at a rate of 3%. Based on these assumptions, averting an adult death would result in reducing 16.76 DALYs.

18 Total cost of the RNTCP over this five year period is projected as of US$ 336 million with the assumption that the average costs per treatment are US$60.

Table 3: Cost Effectiveness of Different Interventions

$25 per DALY
Breast-feeding promotion
TB and measles immunization
Malaria control with chemical pesticides
Blood screening for HIV
Condom use to prevent excess births and STDs
$25-75 per DALY
Use of ORS
Food supplements for children
Food supplements for pregnant women
Improved antenatal care by upgrading facilities and providing family planning
$75-250 per DALY
Cholera immunization
Medical treatment of tetanus
Onchocerciasis control with chemical pesticides
Malaria control with passive case finding and chemical pesticides with treatment
$250-$1000 per DALY
Improved dengue case management through education of health care providers
>$1000 per DALY
Dengue control with chemical pesticides, with or without improved case management
Dengue control by drainage and land management, with or without improved case management

(World Bank, 1997: Table 3.1).

Risk-sensitivity Analysis

9.12 The program could face the risk of a reduction in expected benefits due to less than expected number of cases averted and mortality reduced. This would result in a lower than expected effectiveness in the TB program. There are a number of other factors influencing the expected benefits, and thus cost-effectiveness of the program. As the program has expanded to more remote areas and harder-to-reach population, all output indicators in the new areas such as detection rate and cure rates may be lower while average cost per treatment may be higher. With the presence of HIV/AIDS, TB incidence may not decline at the same rate as assumed above. Finally the quality and capacity of program management may be stretched as the program is expanded to the entire country. These risks were highlighted in the 2003 Joint International Program Review.

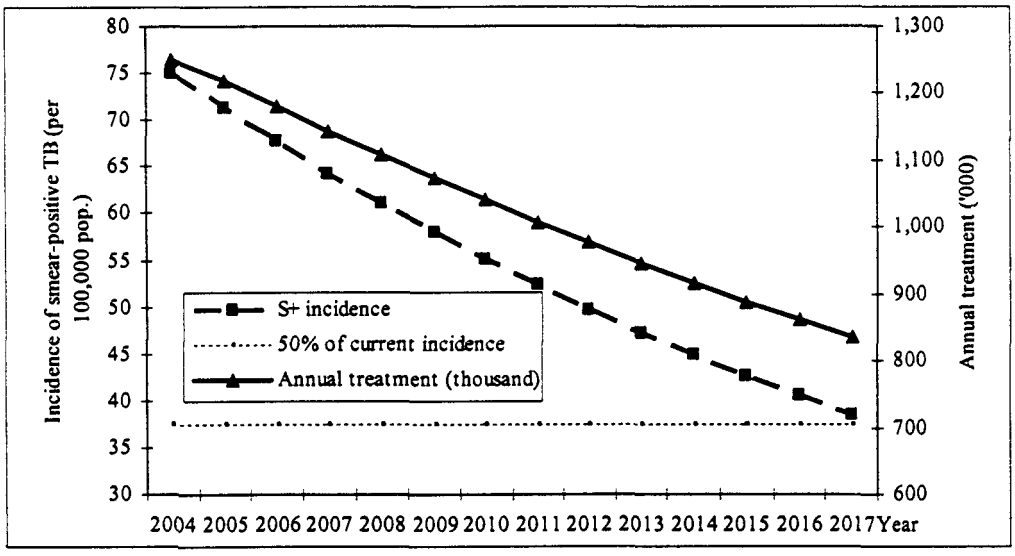
9.13 As it is not possible to quantify the potential reduction in benefits of the program in the above hypothetical conditions, simulations are presented to predict changes in effectiveness of

the program in the worst case scenario. A 30% reduction in program benefits due to a lower than expected number of cases averted and mortality reduction would result in 8.3 million DALYs reduced at a cost of US$48.59 per DALY reduced. A 50% reduction in program benefits would result in 5.9 million DALYs reduced at a cost of US$68.03 per DALY reduced. Even with this calculation of lower benefits of the program, the investment in the RNTCP is still highly cost-effective.

Financial Sustainability of Program Interventions

9.14 Between 2006 and 2010, the program would reach a population of 1.2 billion. The RNTCP has been successful in more than tripling treatment success rates from 25% in the earlier program to 86% in the RNTCP in 2004. Future costs of the program would depend very much on its long-term outcome, namely the impact on incidence, the cost of treatment, and the ability of the program to sustain the present level of detection and treatment. Studies have suggested that if the WHO target of TB control is met, a decrease in the incidence of smear positive pulmonary TB annually of 5% may be expected (Figure 3). With such a decrease it may be expected that within a 12-13 year period, the incidence of TB should be halved. With improvement in program management, detection rates may even be increased beyond the target of 70%. However, as the program is expanding to more remote and hard-to-reach areas, detection rate in these new areas may not be as high, thus the rate of 70% is used for the current analysis. Based on these assumptions, the RNTCP is expected to treat not less than one million TB patients annually between now and 2010.

Figure 3: Projection of incidence of smear-positive TB cases and total annual treatments



9.15 There are several estimates of treatment costs recently carried out in India. The per capita cost is US$0.05 for TB treatment for the whole population; the cost per TB case treated varies from US$46 to US$60 per case. The former approach is less relevant for long-term projection of total cost of TB treatment as it relies only on the size of the population and does not take into account changes in other important factors such as incidence, program capacity in

detecting and treating TB cases, and program effectiveness. As incidence is expected to decline at a faster rate than population growth, while the program is expected to be more efficient, the approach of using cost per case treated is used. Total financing need for the RNTCP up to 2010 is thus projected both in absolute value and as percentage of GDP.

9.16 Total financing need for the RNTCP in the coming five year period (2005-2010) is an estimated US$ 67 million per year, including infrastructure. It should be noted that this is based on the total cost of the program at the central level and it excludes state in-kind contributions. RNTCP expects to cover the whole country by the end of 2005 (which is feasible given current progress), and it is possible that the unit costs increase slightly as the program reaches more challenging segments of TB patients such as the poor, migrant, mobile laborers, TB-HIV patients, etc. The table below presents a cautious projection for RNTCP that takes into account improvements in current absorptive capacity by strengthening the program's financial management and implementation capacity at both central and state levels to ensure that available funding can be effectively used for program expansion, especially in under-served and more challenging areas.

Table 4: Projection of annual financing need for the RNTCP (US$ million)

Year	Estimated annual costs of RNTCP		As % of health expenditure	
	US$ 60 per treatment	US$ 46 per treatment	US$ 60 per treatment	US$ 46 per treatment
2005	73	56	1.3	1.0
2010	62	48	0.8	0.6
2017	50	38	0.4	0.3

9.17 Assuming that public spending of 0.9 % of GDP for health and that real GDP growth of 6% per year is maintained, the total cost of the RNTCP (excluding the costs funded by the states) could account for between 1.0-1.3 % of total government health expenditure between 2005 and 2010. Assuming there are efficiency gains and a reduction in incidence of TB by 2017, the total cost of the RNTCP could account for between 0.5% - 0.6 % of total government health expenditure. Given very strong commitment to combating TB by GoI, and recent achievement of the RNTCP, it is likely that the government would continue to sustain the benefits of the RNTCP.

9.18 Future continuous involvement of state government in providing TB services could argue for more sustainable finance of the RNTCP. Further study on contribution of central/state governments in financing RNTCP services is necessary and can help to confirm this. Currently, it is unofficially estimated that their contribution in terms of fixed costs of infrastructures, staff, etc. could well account for over 50% of total expenditure. As primary health care infrastructures already exist, and the majority of the national program's staff is in place, it is likely that the government can gradually take over financing of the variable costs of the RNTCP.

Annex 10: Safeguard Policy Issues

INDIA: Second National Tuberculosis Control Program

Environmental Issues

10.1 Under this program, the main environmental concerns are related primarily to clinical and infectious health care wastes (primarily needles, sputum cups and slides) given the infectious, communicable nature of tuberculosis. While the RNTCP is implemented through the state health system and forms a small component of a multi-pronged infrastructure, the management of waste generated from TB clinics is critical given its infectious nature. The focus therefore should be on handling of these waste materials and establishing strict quality control measures to mitigate risks.

10.2 The overall context for health care waste management is provided by the Government of India's Bio-Medical Rules (prepared in 1998 and amended in 2000). The Rules address administrative issues and technical matters and address bio-medical waste produced in health care facilities, which can be adequately managed, treated and disposed of to reduce adverse impacts on public health and the environment.

10.3 Under the RNTCP, there is a Manual for Laboratory Technicians which incorporates the basic steps of treatment and disposal of infectious waste. It recommends that all infectious laboratory waste be disinfected in 5% hypochlorite/phenol solution, after which they can be autoclaved, or as a last resort burnt in a pit. While provision of autoclaves in all facilities is not a feasible solution, it must be recognized that slow-burning of plastic waste is not an environmentally sound option as there is the high risk of toxic fumes, depending on the chemical components of the waste being burnt which can cause occupational and community risk.

10.4 A draft Infection Control and Infectious Waste Management Plan has been prepared for the RNTCP II. The Plan delineates guidelines for management of infectious wastes, including management of sharp items and would comprise clear protocols for segregation, treatment and disposal of such waste in accordance with size and location of facilities. An institutional framework for the management of the plan, along with a training plan, monitoring and reporting system, implementation schedule and time-frame for implementation have been detailed. The main modality of implementation of the plan would be by imposing compliance with the technical guidelines for disposal of bio-medial wastes as per revised RNTCP guidelines. Specifically the guidelines would encourage use of bio-degradable plastic like polypropylene, discourage incineration of plastic waste, discourage open dumping of slides and sharps, adoption of universal precautions and encourage waste reporting of centers to their prescribed authority. The plan will try to ensure 'behavioral changes' in the staff handling bio-medical wastes through training and repeated reminders for compliance with biomedical waste management guidelines during supervisory activities.

The plan includes the following key activities:

- Up-gradation of existing training modules
- Implementation of Universal Precautions
- Capacity building of laboratory technicians, medical officers, STLS, Class IV employees and other health care workers
- Review of procurement arrangements
- Supervision, monitoring and evaluation

10.5 Before finalization and implementation of the Plan, the CTD has undertaken consultation with state-level stakeholders, health care personnel, communities, NGOs, and other stakeholders such as Common Treatment Facilities and Pollution Control Boards to enhance ownership and involvement. Integration with existing waste management systems set up in each health facility will be undertaken.

Indigenous People

10.6 In IDA's policy on indigenous peoples outlined in its Operational Directive (OD) 4.20, the terms "Indigenous peoples," "Indigenous ethnic minorities," "tribal groups" and "scheduled tribes" describe social groups with a social and cultural identity distinct from the dominant society that makes them vulnerable to being disadvantaged. In accordance with this policy, the project has developed a Tribal Development Plan (TDP) to ensure that the tribal community would have better access to TB treatment and quality and efficient TB treatment services will be available in tribal areas. The TDP is based on primary data, review of available experience and consultations with tribal communities, women, NGOs and other development institutions, as well as other civil society representatives and health staff. Tribals constitute about 8.1% of India's population and largely inhabit geographically isolated, remote and inaccessible areas. The tribals are among the population groups with the poorest human development indicators and are among the poorest of the poor in India. The present poorly developed health infrastructure would require concerted efforts by RNTCP to improve the access and utilization of TB services by the tribals.

10.7 Among the major issues identified in providing TB services to the tribals are (i) inadequate health service provisioning in tribal areas, total absence of private sector and high dependence on Traditional Healers; (ii) inadequate accountability and monitoring of health service delivery to tribals in remote areas; (iii) poorly staffed facilities with unhelpful attitudes of staff; (iv) lack of effective IEC in tribal areas; (v) limited extension services and limitations of non-tribal staff to communicate with tribals; and (vi) poor transportation infrastructure and high cost of reaching health facilities.

10.8 In order to increase case detection and treatment success in districts and regions with high tribal population, the TDP has incorporated an action plan with salient features as presented in Table 1.

Table 1: Tribal Action Plan

Objective	Actions
Improve service coverage and provide quality RNTCP services	• Provide staff incentives in tribal areas • Support travel cost for patients to reach health facilities • Improve staffing and infrastructure at PHC level • Provide IPC training for all staff to ensure attitudinal change
Improve accessibility, acceptability, and utilization of services	• Utilize mobile units for increasing DOTS outreach • Establish a system of sputum collection and transportation by tribal youth and outreach workers • Train Tribal volunteers in case detection and case holding • Sensitize Traditional Healers and seek their support
Promote community participation and inter-sectoral coordination	• Involve NGOs, traditional healers, outreach workers, youth, cured patients and other community based organizations in IEC activities and DOTS provision • Involve PRIs, Tribal leaders, Self Help Groups and Community Based Organizations in supervision and monitoring of DOTS • Use locally and culturally relevant IEC material • Use non-traditional DOTS providers: chemists, local shop owners etc. • Use local village fairs, festivals and weekly markets for IEC
Operational research	• Carry out quantitative research to understand barriers in utilization of RNTCP services in tribal areas • Evaluate IEC effectiveness and redesign if necessary • Study effectiveness of the incentives provided under the program • Study case detection and treatment outcomes in tribal areas

Annex 11: Governance and Accountability Action Plan for

Centrally Sponsored Health and Family Welfare Programs INDIA: Second National Tuberculosis Control Program

Introduction:

The Ministry of Health and Family Welfare (MOHFW) is fully committed to ensuring better competition and transparency in procurement and supply of health sector goods and services required for delivery of quality services in all its programs. An Empowered Procurement Wing (EPW) has been established in MOHFW to support this process. To strengthen the capacities of the EPW in all aspects of procurement, the Department for International Development (DFID) is funding Technical Assistance.

Scope and Purpose:

The MOHFW has developed this Governance and Accountability Action Plan (GAAP), in consultation with the Bank, to address critical operational concerns in Bank and pooled partner funded procurement of health sector goods and services. The key issues and actions to address these concerns are included in the matrix below.

The GAAP applies to all centrally sponsored health and family welfare programs supported by the Bank, articulating the specific roles and responsibilities of different stakeholders (public, private and civil society institutions) in ensuring timely supply of quality commodities at a competitive price.

The GAAP will be strengthened, as necessary, based on risks identified and the recommendations of the RCH I investigations, the DIR, the procurement review by the EPW consultants, and the report on the quality and quantity of pharmaceuticals and medical goods.

The Bank financed "Food and Drugs Capacity Building project (Credit No. 37770)" would also support some of the broader issues related to strengthening of regulatory institutions especially effective implementation of GMP in the pharmaceutical sector as envisaged under the GAAP.

Issue	Agreed actions	Implementation Status	Person/agency responsible for implementation
I. Improving GMP certification process for pharmaceuticals	i. Making WHO GMP (TRS 863) certification mandatory for ICB	▪ Implemented	▪ Drugs Controller General of India
	ii. Pending new certification procedures (see next bullet) ensuring 100% post certification of all successful bidders recommended for award of the contract on the basis of existing WHO GMP certificates.	▪ Implementation will start from first Bank financed project after the date of this plan	▪ Joint Secretary and Project Director, Food and Drugs Capacity Building Project
	iii. (a) Issuing WHO GMP certificates in future only after a satisfactory joint inspection by the center, state and an independent expert; and (b) carrying out random post WHO GMP certification audits (covering about 10% awards in each year).	▪ A panel of six independent experts has been identified in August 2005 and this panel will be updated on a regular basis with the inclusion of experts adequately covering all regions of the country.	
	iv. Making list of companies with valid WHO GMP certificates available on public domain.	▪ The GOI has disclosed the list of over 600 manufacturers in February 2006 at the website of Central Drug Standards Organization.	
	v. Agreeing on actions for GMP certification process and implementation arrangements satisfactory to IDA for non-ICB procurement of pharmaceuticals and medical supplies under Bank financing.	▪ Completing the agreed actions and incorporating recommendations from the detailed implementation review in the GAAP will make non-ICB procurement eligible for Bank financing.	▪ Joint Secretary and Project Director, Food and Drugs Capacity Building Project

Issue	Agreed actions	Implementation Status	Person/agency responsible for implementation
II. Increasing competition and mitigating collusion	i. Finalizing future lot size, estimated prices and qualification criteria for procurement of pharmaceuticals and medical supplies based on manufacturers and market surveys about availability of products, costs of production and prices, and production capacity of manufactures.	(Ongoing) ▪ Based on "tool kit" developed by the Bank, the DFID has awarded the contract for market surveys and the results from first round are expected by	• EPW/CTD, MOHFW
	ii. Including a qualification requirement of minimum share of at least 20% revenue to be derived from non-Bank financed contracts in bid documents.	▪ Include qualification requirement immediately and implementation to start from the first Bank financed project after the date of this plan.	• EPW/CTD, MOHFW
	iii. Seeking "list of references" in the form of an affidavit in case of supplies made to public sector in past contracts. In the case of supplies made to private sector in the past, affidavit as well as supporting evidence will be sought. However, no bid would be rejected on the basis of non submission of documents on past performance above referred to.	▪ The MOHFW will verify the authenticity of referred documents on past performance only for the successful bidder ▪ Implementation to start from first Bank financed project after the date of this plan.	• EPW/CTD, MOHFW
	iv. Including "independent experts" in the bid evaluation process.	▪ Implemented	• EPW/CTD, MOHFW
	v. Sharing record of public opening of bids for all contracts with the Bank within 2 working days.	▪ Effective immediately, starting with first bids for FY 2005-06. ▪ Implementation to start from first Bank financed project after the date of this plan.	• EPW/CTD, MOHFW
	vi. Ensuring payment within 30 working days of receiving the bill with supporting documents from the suppliers or communicating deficiency in the Bill within 15 working days.	▪ Effective as of April 19, 2005. ▪ Implementation to start from first Bank financed project after the date of this plan.	• EPW/CTD, MOHFW
	vii. Establishing clear and concise bid evaluation criteria.	▪ Effective as of April 19, 2005. ▪ Implementation to start from first Bank financed project after the date of this plan.	• EPW/CTD, MOHFW
	viii. Evolving generic and broad technical specifications	▪ MOHFW is establishing a database of generic technical specifications for commonly procured equipment which will be disclosed at their website by	• EPW/CTD, MOHFW

Issue	Agreed actions	Implementation Status	Person/agency responsible for implementation
III. Strengthening procurement implementation and contract monitoring	i. Strengthening procurement supervision capacity at Empowered Procurement Wing (One JS, Two Directors and 10 Dy/Asst. Directors with support staff and infrastructure) including engagement of an external consultant firm selected through international selection process for capacity building and development of procurement monitoring and complaints data base.	▪ Underway ▪ The MOHFW has constituted an Empowered Procurement Wing (EPW, which oversees the TB-specific procurement carried out by CTD) with specific Terms of Reference. ▪ An International external consultant firm (Ms. Crown Agents) was selected to support EPW/CTD in the implementation of the GAAP. This consultancy is being supported by DFID TA. ▪ The first training in health sector goods procurement for the EPW/CTD staff, procurement consultants and state procurement officers was organized during January 16-25, 2006. A series of similar programs at regional and state levels are being planned.	▪ National Program Coordination Committee, National Rural Health Mission (NRHM) ▪ EPW, MOHFW
	ii. Establishing a "procurement monitoring and complaints" database* to monitor adherence to the standards listed in RCH Program Procurement Manual. This database would be online with restricted access.	▪ Manual database established in MOHFW and computerized database is expected by March, 2007	▪ EPW/CTD, MOHFW
	iii. Developing and deploying a software for the early identification of indicators of fraudulent or corrupt practices	▪ To be completed by July 1, 2008	▪ EPW/CTD, MOHFW
* The data base should specifically allow: (i) complete and adequate record keeping and retrieval of all documents supporting each bid including unit prices quoted and prices at which contracts are awarded; (ii) Quantities and dates of supply as per the contract and actual; (iii) Rejection of supplies, if any, with reasons; (iv) Date bill received, value, and date of payment and (v) complaints received, responses sent and actions taken by dates.			

Issue	Agreed actions	Implementation Status	Person/agency responsible for implementation
IV. Handling procurement complaints	i. Updating the "Procurement monitoring and complaints" data base on a monthly basis.	▪ Manual database established in MOHFW and computerized database to be operational by March, 2007	▪ National Program Coordination Committee, National Rural Health Mission (NRHM) ▪ EPW/CTD, MOHFW
	ii. Listing and discussing all complaints received and actions taken in the bid evaluation report.	▪ Implementation to start from first Bank financed project after the date of this plan	
	iii. Providing details of the administrative process for the disqualification of bidders who engage in misrepresentation in the bid process or in contract execution.	▪ Implemented	
	iv. Reporting the status of investigation of complaints and measures taken in monthly progress reports to the National Program Coordination Committee of the NRHM.	▪ Agreed. ▪ Implementation to start from first Bank financed project after the date of this plan.	
	v. Sharing complaints status with the Bank once every quarter	▪ Agreed ▪ Implementation to start from first Bank financed project after the date of this plan.	

Issue	Agreed actions	Implementation Status	Person/agency responsible for implementation
V. Disclosing Information and promoting oversight by the civil society	i. Making publicly available all annual procurement schedules promptly after finalization on the MOHFW website.	▪ Agreed. ▪ Implementation to start from first Bank financed project after the date of this plan.	▪ National program coordination committee, NRHM ▪ EPW/CTD, MOHFW
	ii. Posting all bidding documents and requests for proposals on the MOHFW website.	▪ Agreed ▪ Implementation to start from first Bank financed project after the date of this plan.	
	iii. Making available to any member of the public promptly upon request all shortlist of consultants and in case of pre-qualification, list of pre-qualified contractors and suppliers.	▪ Agreed ▪ Implementation to start from first Bank financed project after the date of this plan.	
	iv. Disclosing information on prequalification, all bids received reasons for rejections, and award of contracts at the MOHFW website and sharing the same with the Bank to disclose at their preferred Websites.	▪ Agreed ▪ Implementation to start from first Bank financed project after the date of this plan.	
	v. Posting annual progress and Mid Term Review reports of the program on the MOHFW website.	▪ Agreed ▪ Implementation to start from first Bank financed project after the date of this plan.	
	vi. Moving to e-procurement	▪ Will be developed under the Bank supported E-Bharat project	

Annex 12: Supervision Strategy

INDIA: Second National Tuberculosis Control Program

12.1 During this second phase of the RNTCP, the focus of the program is on expanding coverage to the weaker parts of the country, particularly areas where performance is below the national average. Further, IDA is providing broad support for the RNTCP rather than narrowly financing a set of activities or geographical areas. The RNTCP receives financial and technical assistance from a number of partners including: DFID, USAID, GFATM, GDF and WHO. Joint supervision missions would be a mechanism for facilitating increased coordination among partners and between government and partners to ensure that all efforts are channeled towards the same program objectives and to reduce the burden on the CTD of separate missions and reporting formats for different development partners.

12.2 The RNTCP has in place a robust recording and reporting system, which monitors the overall program regardless of financing source. See details in the PAD Section C3, Monitoring and Evaluation of outcomes/results. The system is based on quarterly and annual cohorts of TB patients registered for treatment. CTD further strengthened the surveillance system in the second quarter of 2005 with additional indicators and revised reporting formats. At the national level, a quarterly and annual performance report is generated with state and district performance indicators, and placed on the program website (www.tbcindia.org). The program also plans to develop a web based Tuberculosis Program Information System.

12.3 Each year, CTD holds two review meetings at the national level, quarterly state level program review meetings (usually chaired by the Secretary Health as the Chairman of the Health and Family Welfare Society), internal evaluations performed on two districts every quarter, and periodic supervisory visits and reporting carried out by STOs, DTOs, and TUs. The results of the reviews, visits and analysis of the reports are fed back to the relevant units to take corrective measures.

12.4 During the program preparation it was agreed that a system of *"joint program review"* would be institutionalized for the RNTCP II incorporating the following principles:

- *Participatory*: The joint review process would be led by the GoI with active participation of the states and all development partners
- *Strategic focus on weaker states:* Whereas some partners may select to supervise the states they directly support, there would be overall priority attention to improving program performance in EAG or other under-performing states and among the most vulnerable, hard-to reach populations
- *Results oriented*: The program will have strong results focus and achievement of agreed results would be monitored using the overall results framework, outlined in Annex 3.

12.5 The proposed supervision strategy would include the following:

(i) Continuous program support by IDA and development partners through ongoing interaction with government and field visits, in particular to weaker states. IDA is in the process of setting up a HNP Results Technical Support Activity (HNPRTSA) in the New Delhi office that could provide some additional resources to strengthen performance orientation of the weaker states. HNPRTSA can provide technical assistance to national and state counterparts in monitoring and evaluation, financial management, procurement, technical aspects and general program management.

(ii) Regular program review at the national level with a special focus on EAG states by CTD. Performance on agreed benchmarks would be assessed at semi-annual national level meetings and quarterly state-level review. These benchmarks would reflect performance on program management including financial, procurement, and service delivery improvements. Included in such reviews would be a review of fiduciary issues such as financial management and procurement. The CTD would undertake quarterly reviews of program implementation in EAG and other below average performing states with a specific focus on building institutional capacity and reaching hard-to reach populations. The objective is to identify implementation bottlenecks, and assist states to resolve them.

(iii) Joint donor review missions would initially be held at a mutually agreed frequency. IDA would undertake at least bi-annual supervision. During these missions, the program would be monitored based on the overall results framework and a review of technical, managerial and fiduciary aspects; data is available for the entire country in the quarterly report posted on the CTD website, and would be supported by financial management and procurement reports. While some donors would make field visits to the specific areas they support, others would monitor states/districts with below average performance and/or issues that require additional attention. A joint Aide Memoire would highlight progress of the overall program and include specific issues for the states under review as well as technical issues that may require additional technical assistance, supervision or review.

(iv) Workshops to exchange lessons learned and best practices between states and to promote coordination with other health programs

(v) Special studies and assessments. When required, special surveys and/or assessments (e.g. IEC, public-private mix) would be commissioned by GoI prior to, or during, each mission and/or for the Mid Term Review. A central level internal evaluation of randomly selected districts will be done quarterly. Joint International Evaluation would be conducted every 2-3 years.

12.6 During supervision, there would be specific focus on:

- States and districts which have below average performance in the form of case detection rate below 70% and/or cure rate below 85%
- Information Education and Communication capacity, products and processes
- Improving access for population groups such as tribals, rural poor and urban slum populations who face difficulties in accessing correct DOTS TB treatment
- Expansion of public – private partnership for including non-public providers in RNTCP and increasing provision of DOTS
- Increasing coordination between RNTCP and HIV/AIDS control programs to ensure that HIV positive persons suspected of TB have access to diagnosis and treatment
- Ensuring multi drug resistant patients receive quality treatment

12.7 There would initially be two supervision missions each fiscal year (see above 12.5 (iii)); during the course of the program the frequency could be adapted as per program needs. The mission composition would be determined according to the thrust of that mission as well as the program needs at that point of time. All development partners would be represented with one or more participants in the missions. The status of the agreed indicators would be assessed and a summary of progress and issues recorded in an Aide Memoire which would comprise a general part addressing overall program progress and annexes addressing specific issues and observations from the states visited.

12.8 A Memorandum of Understanding, describing this supervision mechanism, would be signed by all development partners, thereby confirming their participation in the same.

12.9 Overall, the IDA team will proactively coordinate with other relevant IDA-supported health programs in India. These include the HIV/AIDS Control Project, state-level Health Systems projects (currently in the states of Maharashtra, Orissa, Rajasthan, Tamil Nadu, Uttaranchal, Uttar Pradesh and planned for Karnataka and West Bengal), the Integrated Disease Surveillance Project and the Reproductive and Child Health Program.

12.10 In addition, the IDA team will coordinate closely with the National Rural Health Mission (NRHM), a recent initiative of the Government of India to promote convergence of severally sponsored schemes including the RNTCP.

Annex 13: Indicators and Performance of the RNTCP

INDIA: Second National Tuberculosis Control Program

Introduction

13.1 The two core issues of TB control are (i) to identify patients with symptomatic tuberculosis, especially those that represent the highest risk of transmitting TB disease (sputum smear positive pulmonary cases), and (ii) and to treat these patients in a way that they get cured.

13.2 Diagnosis is by means of sputum microscopy. Little less than half of all TB patients are sputum smear positive lung TB patients (S+ve). Approximately 40% are sputum smear negative lung TB patients and some 15% have extra pulmonary TB (e.g. lymph gland TB, bone TB). Whereas sputum microscopy is the diagnostic criterion for S+ve cases, diagnostic procedures (e.g. Chest X-Ray) and algorithms are followed to establish the other forms of TB.

Calculating Expected Incidence

13.3 There is an internationally accepted relationship between the number of people infected by TB bacilli and the number of new cases of S+ve pulmonary TB. By skin testing large groups of non-BGC vaccinated children following a standard design of survey (Tuberculin Surveys) *the annual risk of TB infection* (ARTI) may be calculated. Tuberculin Surveys in India in 2000-2003 arrived at an average Indian ARTI of 1.5%, varying somewhat between regions and between urban and rural areas. The accepted relationship between ARTI and the number of new S+ve lung TB cases is that an ARTI of 1% translates into an incidence of 50 S+ve new cases per 100 000 population (1 lakh) per year. The variation of ARTI between regions means that the basis for calculation of incidence also varies e.g. in Orissa the incidence of S+ TB is 85 per 100 000, in Maharashtra 80, in Punjab 75 etc. It is also estimated that incidence in urban areas is double that of rural areas

Evaluating Treatment Results

13.4 Sputum smear positive patients put on treatment will gradually be cured and the acid fast bacilli will disappear from their sputum. By the third month of treatment, the sputum should ideally be smear negative when examined by microscopy. This is an important parameter for the effectiveness of the DOTS.

13.5 A positive sputum after the fifth month of treatment signifies *treatment failure.* Ideally all patients should have their sputum examined by the end of treatment after six months. If the smear is negative the patient is per definition *cured.* If no sputum is done for various reasons, but the patient appears cured, the outcome is qualified as *treatment completed.* Alternative outcomes are *death*, that the patient has *defaulted,* or that the patient has been *transferred out* (and outcome thus was not registered by the Tuberculosis Unit). The combination of cure and completion rate is called *"treatment success rate".* The treatment outcomes are available for groups (cohorts) of new S+ve patients started a year previously.

Targets and Monitoring

13.6 The two most important and internationally accepted targets for diagnosis and treatment are case detection rate of 70% or above and a treatment success rate of 85% or above of new S+ve cases. To this can be added the sputum conversion rate at three months, which is expected to be 90% or above.

13.7 The RNTCP reports quarterly from all districts on a number of parameters in a standardized manner. Both detection and treatment outcome data are monitored and available in the quarterly and annual reports from the RNTCP. From 2005, the treatment outcome of S-ve patients, extra pulmonary and various groups of re-treatment cases is also available in the quarterly report.

Explanatory notes of Performance Data of the Quarterly Reports of the RNTCP

13.8 **Population:** Given in 100 000 s (= lakhs)

Number of suspected examined and number of suspects examined per 100 000 (Lakh)
13.9 All persons with chronic cough > 3 weeks should be suspected of having TB and hence have their sputum examined. However, only one in ten would be expected to have S+ ve TB. The number of suspected examined would ideally then be the expected incidence x 10, or 75 / 100 000 x10. Thus, on average 750 persons per 100 000 in India.

13.10 The findings reflect the effectiveness by which the general health system come into contact with and recognizes possible TB cases, and subsequently succeeds in having sputum examinations done.

Number of smear positive patients diagnosed.
13.11 Ideally this figure should equal the assumed incidence calculated on the basis of the population of the area in question.

Percentage of S+ cases among suspects
13.12 Generally the figure would be expected to be around 10%. Higher values could indicate that only very advanced cases reach the microscopy center or that there is still a considerable backlog of old S+ ve cases in society.

Percentage smear positive patients living in the district placed on DOTS
13.13 All patients with infectious TB (= S+ ve cases) must be treated to control transmission. This percentage should be 100%, as there would in principle be no geographical problem in the case holding or finding and retrieving of patients, who may have disappeared after diagnosis.

Total Patients initiated on treatment
13.14 These are absolute numbers of *all patients with all forms of TB* started on DOTS, and would be expected to be roughly double the number of all sputum smear positive cases.

Annualized total case detection rate

13.15 Based on the quarterly results the expected *number of all TB cases* per 100 000 (lakh) population in one year is calculated (projected) for this particular area.

New Smear positive patients initiated on treatment

13.16 Ideally this number should be identical to the total number of new S+ ve patients detected. However, some of these persons may live in another area and will not report for treatment in the district where s/he was detected and thus not be registered in that district. A number of people will take up treatment in the private sector and are thus normally lost to follow up in the RNTCP system. This explains part of the discrepancy of those diagnosed compared to those treated.

Annualized new sputum smear positive cases detection rate (%); this is one of the main target indicators

13.17 This is the incidence figure of new sputum smear positive cases per 100 000 calculated (= projected) for the whole year based on the actual number found in that particular quarter. The percentage (%) given in this column is the percentage that this projected incidence figure constitutes compared to the theoretical S+ ve incidence.

For example:
In the 4th Quarter of 2004 the annualized new sputum smear positive cases detection rate (%) in India as a whole was 48 S+ ve cases / 100 000. This is (64%) of the theoretical and expected incidence of 75 cases / 100 000. Thus the target of 70% case finding is not quite met for that quarter.

Percentage sputum positive of total new pulmonary cases

13.18 The expected % would be approximately 60%. Low figures could indicate that too many sputum smear negative cases were diagnosed due to poor clinical practices, or that too few TB patients have their sputum properly examined ("under-reading= low sensitivity). Too high a figure could be due to poor sputum microscopy ("Over-reading" = low specificity) or that the patients that reach the microscopy centers come in advanced stages of disease.

Three months conversion rate

13.19 ≥90% of S+ ve patients should become sputum smear negative within three months of treatment (= sputum conversion). Failure to do this might be due to drug resistant TB or poor patient adherence to treatment due to faulty supervision.

Cure rate of new sputum smear positive patients

13.20 ≥85% of those patients who manage to give in a sputum control sample at the end of DOTS after 6 months would normally have become sputum negative and thus per definition be cured. Low figures would either indicate poor treatment adherence /supervision or problems with MDR TB or a combination,

Success rate of new smear +ve patients; this is the main target indicator for treatment

13.21 The percentage of the combined cure and completion rate (successfully completed treatment without sputum examination at the end of treatment). The target is ≥85%. For interpretation of lower value see comments in the paragraph above.

Number of new smear negative cases initiated on treatment

13.22 Ideally this figure should be equal to all the sputum smear negative cases detected (a figure that is not reported in the quarterly report but may be derived from the total number of sputum+ cases and the percentage of pulmonary cases that are sputum smear positive). Deviations may be due to patients not coming back for DOTS because they have moved to another district, have been treated in the non public sector, or have been lost to treatment in other ways.

Number of new extra pulmonary cases initiated on treatment

13.23 The number of all extra pulmonary cases of TB (e.g. glandular, bone, meningeal, etc.) started on treatment. Again the total number diagnosed of this group of TB patients is not independently reported in the Quarterly Report but may be calculated from the next column.

Percentage of new extra pulmonary cases out of all cases

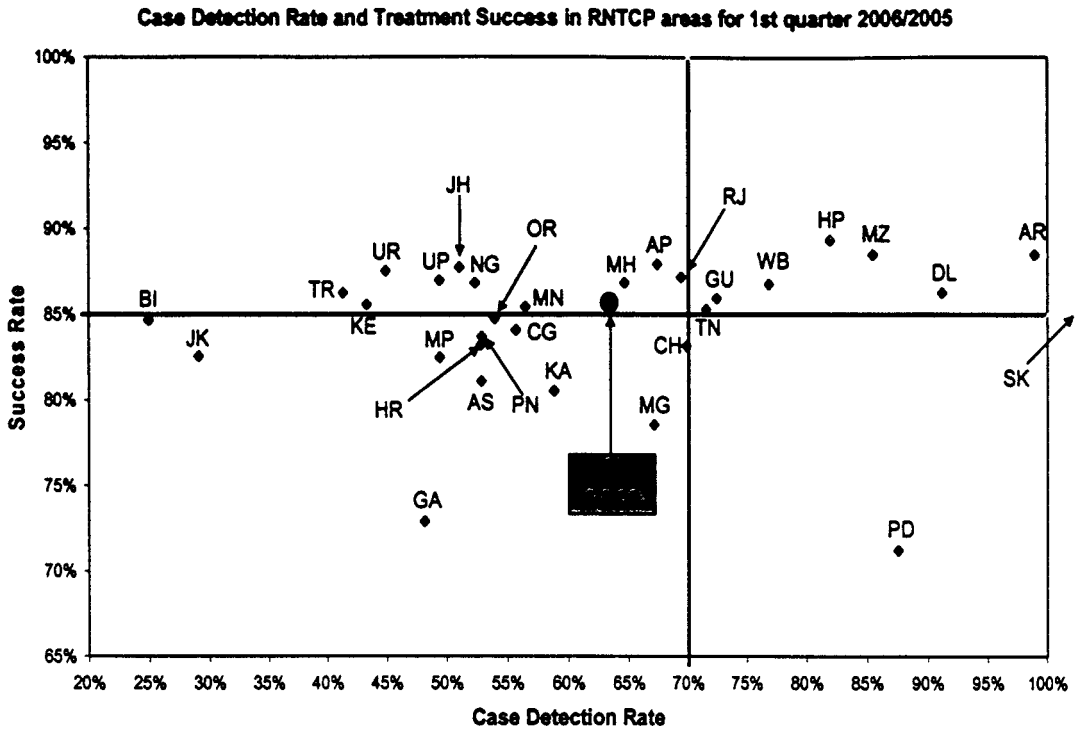
13.24 The expected figure would be 10-15%. A high proportion may be seen in places where there is a high prevalence of HIV infection among TB patients.

Number of smear positive re-treatment cases initiated on treatment

13.25 TB patients who have been previously treated and now are found to be sputum smear positive must be put on a re-treatment regimen (Category 2 treatment) for 8 months. Among previously treated and apparently cured TB patients, a certain number – around 10%) may later **relapse**. Depending on the size of the problem of MDR a number of patients treated with DOTS will become **failure** cases. Those who have been treated more than a month/have **defaulted** more than two months from treatment/are found sputum smear +ve, must also be put on re-treatment. The percentage of failure cases in India so far has been in the rage of 2-3 % (should of course ideally be 0%). Defaulters in 2003 were in the range of 5-7%.

Percentage of re-treatment cases out of all smear positive cases

13.26 The 10% relapse cases (those cured previously but now again with S+ ve TB) is probably an inevitable proportion, where the quality of DOTS and drug resistance plays a very minimal role. Additional re-treatment cases will depend on the quality of supervision and adherence and also reflects the problem of MDR in society.



AP- Andhra Pradesh; AR-Arunachal Pradesh; AS-Assam; BI-Bihar; CH-Chandigarh; CG-Chhatisgarh; DL-Delhi; GA-Goa; GU-Gujarat; HR-Haryana; HP-Himachal Pradesh; JK- Jammu & Kashmir; JH-Jharkhand; KA-Karnataka; KE-Kerala; MP-Madhya Pradesh; MH-Maharashtra; MN-Manipur; MG-Meghalaya; MZ-Mizoram, NG-Nagaland; OR-Orissa, PD-Pondicherry; PN-Punjab; RJ-Rajasthan; SK-Sikkim; TN-Tamil Nadu; TR-Tripura; UP-Uttar Pradesh; UR-Uttaranchal; WB-West Bengal

Note: There is a seasonal variation in the case detection with first and second quarter being lower and third and fourth being higher.

State	Population (in lakh) covered by RNTCP[1]	Suspects examined per lakh population	% of S+ve cases among suspects	Annualized total case detection rate	Annualized new smear positive case detection rate (%)		% new sputum positive out of total new pulmonary cases	% of new EP cases out of all new cases	No (%) of pediatric cases out of all New cases		3 month conversion rate of new smear positive patients[4]	Cure rate of new smear positive patients[5]	Success rate of new smear positive patients[5]
Andaman & Nicobar	4	255	8%	224	58	(77%)	43%	32%	29	15%	89%		
Andhra Pradesh	804	134	14%	131	51	(67%)	51%	11%	628	3%	90%	85%	88%
Arunachal Pradesh	12	221	14%	197	74	(99%)	58%	13%	12	3%	94%	86%	88%
Assam	290	84	16%	95	40	(53%)	57%	11%	207	4%	85%	77%	81%
Bihar	903	45	13%	64	19	(25%)	38%	5%	345	4%	81%	81%	85%
Chandigarh	10	385	10%	207	66	(70%)	62%	36%	59	14%	95%	83%	83%
Chhattisgarh	229	114	12%	118	45	(56%)	48%	12%	330	5%	88%	81%	84%
D & N Haveli	2	183	12%	153	77	(97%)	70%	20%	2	2%	80%		
Daman & Diu	1.8	451	6%	97	38	(48%)	53%	14%	0	0%	95%		
Delhi	161	271	15%	308	87	(91%)	58%	38%	1395	14%	90%	86%	86%
Goa	15	173	9%	116	39	(48%)	52%	24%	22	6%	87%	73%	73%
Gujarat	548	165	16%	145	58	(72%)	70%	18%	754	5%	91%	85%	86%
Haryana	230	171	14%	139	50	(53%)	61%	19%	283	5%	89%	82%	83%
Himachal Pradesh	64	258	13%	203	78	(82%)	69%	26%	43	2%	92%	88%	89%
Jammu & Kashmir	116	143	6%	83	28	(29%)	55%	31%	49	2%	87%	77%	83%
Jharkhand	292	82	15%	101	38	(51%)	47%	7%	269	4%	83%	77%	88%
Karnataka	561	159	11%	115	44	(59%)	61%	23%	786	6%	86%	80%	81%
Kerala	336	191	6%	76	32	(43%)	65%	26%	462	8%	86%	83%	86%
Lakshadweep	0.7	71	4%	55	12	(16%)	29%	22%	0	0%			
Madhya Pradesh	668	96	17%	105	40	(49%)	53%	12%	536	4%	87%	79%	82%
Maharashtra	1041	142	13%	135	52	(65%)	57%	18%	1762	6%	91%	86%	87%
Manipur	26	132	10%	177	42	(56%)	41%	24%	45	5%	90%	85%	85%
Meghalaya	25	112	16%	146	50	(67%)	62%	25%	55	8%	87%	77%	79%
Mizoram	10	209	10%	196	64	(85%)	60%	35%	19	5%	95%	88%	88%
Nagaland	21	108	10%	119	39	(52%)	58%	27%	43	9%	91%	86%	87%

Orissa	391	114	14%	107	46	(54%)	60%	18%	334	4%	86%	77%	85%
Pondicherry	10	387	9%	165	66	(88%)	61%	22%	0	0%	84%	68%	71%
Punjab	260	159	12%	126	50	(53%)	62%	22%	402	6%	87%	79%	84%
Rajasthan	624	139	18%	155	56	(69%)	54%	15%	934	5%	91%	86%	87%
Sikkim	6	298	12%	239	87	(116%)	72%	33%	34	13%	93%	85%	85%
Tamil Nadu	653	259	8%	142	54	(71%)	56%	23%	2323	11%	88%	83%	85%
Tripura	34	80	12%	58	31	(41%)	75%	15%	3	1%	88%	81%	86%
Uttar Pradesh	1839	122	14%	112	47	(49%)	56%	10%	2128	5%	90%	84%	87%
Uttaranchal	92	160	12%	117	43	(45%)	55%	16%	106	5%	94%	87%	88%
West Bengal	858	177	11%	128	58	(77%)	65%	16%	1182	5%	90%	86%	87%
Grand Total	**11136**	**140**	**13%**	**123**	**48**	**(63%)**	**57%**	**17%**	**15581**	**6%**	**89%**	**83%**	**86%**

Values for grey areas are not expected

Estimated New Smear Positive cases / lakh population based on ARTI data for North Zone (Chandigarh, Delhi, Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Uttar Pradesh, Uttaranchal) is 95; East Zone (Andaman & Nicobar, Arunachal Pradesh, Assam, Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, Tripura, West Bengal) is 75; South Zone (Andhra Pradesh, Karnataka, Kerala, Lakshdweep, Pondicherry, Tamil Nadu) is 75 and West Zone (Chhattisgarh, Dadra & Nagar Haveli, Daman & Diu, Goa, Gujarat, Madhya Pradesh, Maharashtra, Rajasthan) is 80; Orissa is 85

4 Smear conversion rate not expected for states that began implementing RNTCP during 4th quarter 2005

5 Cure rate and success rate are not expected for states that began implementing RNTCP after 4th quarter 2004

Annex 14: Incentives and Enablers for Improved DOTS Performance

INDIA: Second National Tuberculosis Control Program

14.1 Many TB programs throughout the world are seeking to improve patient adherence to DOTS and case detection through a variety of incentives and enablers provided for TB patients and DOTS providers. Since 2001, an international team with participation from USAID, STOP TB and IDA has attempted to look at the design, feasibility, effectiveness, and impact of incentives and enablers. The findings presented here are based on evidence gathered from: a literature review, an ongoing survey of global experiences, motivations mapping workshops conducted in three countries, technical assistance to the development of operations research (OR) studies of incentives and enablers, workshops on incentives and enablers held in global forums, and ongoing dialogue with country-level TB control programs and projects.

14.2 A range of variables affect the ability and motivation of stakeholders at all levels to engage in the DOTS approach. These variables include norms and knowledge, functional inputs, financial interests, social interests, and regulatory/management frameworks.

14.3 Incentives exist for all stakeholders, whether intended or unintended, and some may create motivations that may not fully support the objectives of TB control. Well-designed incentives and enablers schemes can overcome motivational barriers that may interfere with individual stakeholders' contributions to TB control goals. Disabling and de-motivating factors may disproportionately affect the poor and otherwise marginalized patients or providers. It is important that a well-functioning DOTS program is already in place, and that health systems strengthening interventions are not bypassed in favor of incentives and enablers. No set of incentives and enablers is likely to be appropriate, feasible, and/or effective across all countries or programs. Those schemes adopted should depend heavily on the underlying socioeconomic, health system, and DOTS expansion context.

14.4 Globally, a wide variety of incentives and enablers schemes are in use. Most have been implemented to increase treatment adherence; some were designed to target hard-to-reach populations. Increasingly, case detection is becoming the focus of incentives and enablers as treatment adherence levels reach the global target. A range of incentives and enablers schemes are being used, which may target patients or providers (e.g., public or private health workers at all levels, DOT providers, lab technicians), in some cases, programs combine patient and provider schemes. Importantly, many of the schemes in use are non-monetary, even for providers, both public and private. Both patient and provider schemes are most often based on performance.

14.5 Experience and evidence. Overall, evaluation of ongoing incentives and enablers schemes has been insufficient. Most of the evidence available is anecdotal or based on program data that measures performance improvements in incentives and enablers areas overall, without the capacity to separately measure incremental benefits of using incentives and enablers. However, it must be pointed out that incentives were perceived to contribute to improved performance by nearly all programs implementing such schemes, whether they were monetary or non-monetary, or for patient or providers. There is sufficient evidence to suggest potential roles for incentives and enablers in improving various aspects of TB program performance, and to

identify the relevance of incentives and enablers to particular DOTS expansion strategies. Key findings most relevant to the proposed activities of the RNTCP Phase II are presented below.

14.6 Documented experiences indicate that incentives and enablers which are directly linked to measurable performance improvements are more effective than unlinked measures. Improvements in core DOTS practice and health system functioning are themselves seen as critical enablers and motivators for both providers and patients. Data from 50 schemes in 25 countries show associations between patient I&E schemes and improved treatment adherence; between provider incentives and enablers schemes and increased case detection; and between DOTS-strengthening interventions and improvements in both outcomes.

14.7 Most incentives and enablers for providers are aimed at increasing capacity and willingness to seek out and serve patients beyond traditional DOTS clinics and are often linked to explicit performance measures. Providing incentives for the community health worker is the most common type of provider-targeted scheme. Rewards may be based upon referrals, diagnosis of sputum-positive patients, or cured patient/treatment completion, depending on the function of the community worker. PPM experiences demonstrate that non-monetary, non-material rewards can also serve as powerful incentives for private providers; networking, recognition, and certification can motivate PPs to provide or link with DOTS programs. Scheme design must ensure that the objective of the incentive or enabler is clear to patients, providers and program managers. The choice of beneficiaries also must be carefully thought out, as it can affect scheme success. Needs-based assessments prior to implementation were shown to be useful for identifying both target groups and the most appropriate type of incentive or enabler. There are significant management and administration requirements for all incentives and enablers schemes, especially for food support, and in particular for preventing and/or controlling for unintended perverse effects.

14.8 The RNTCP II offers several opportunities to apply lessons learned from global experiences of using incentives and enablers to improve TB program performance. The strongest global evidence to date suggests that the impact of incentives and enablers is greatest if:

- Incentives are linked directly to performance, for either patients or providers
- Schemes build on ongoing health systems and DOTS strengthening initiatives
- Scheme evaluations are designed to provide solid evidence for scaling up decisions
- Several stakeholders are linked through the scheme to take advantage of any potential synergies: e.g., patient; public and private DOTS providers; RNTCP managers.

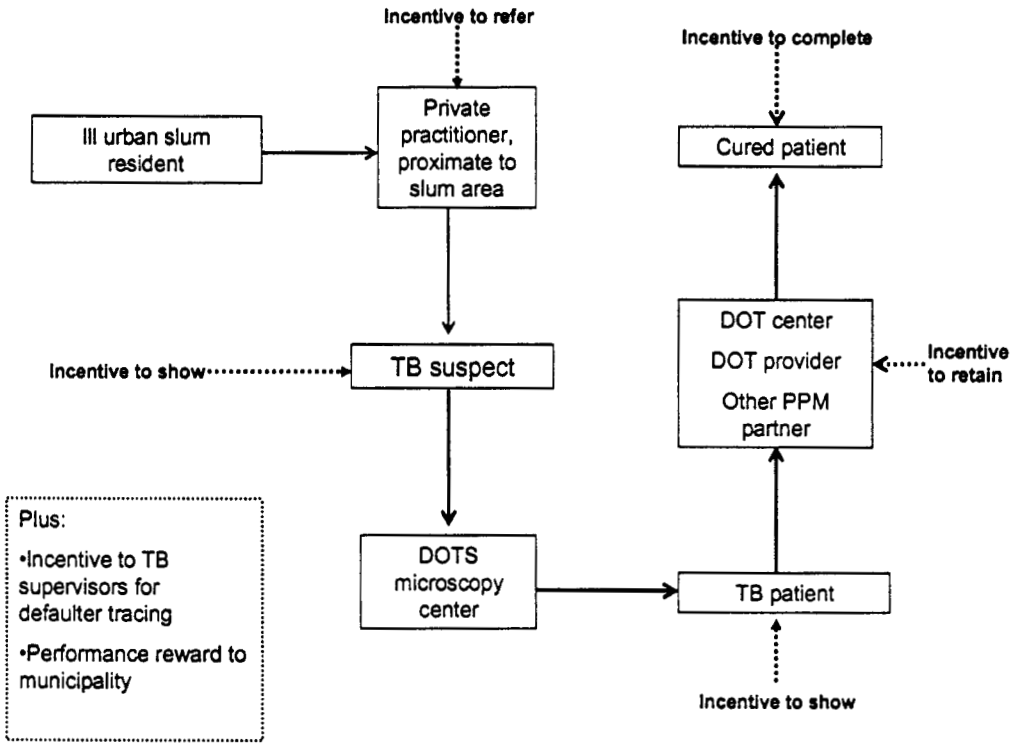
14.9 The proposals to include incentives and enablers in the RNTCP II incorporate these elements in order to maximize their potential impact. Among the variety of challenges that the RNTCP II proposes to address, five identified strategies present good opportunities to include some form of incentives and enablers:

- Increasing urban DOTS effectiveness
- Expanding PPM
- Targeting hard-to-reach populations
- Strengthening the performance of weak states/districts

- Greater involvement of medical colleges and operations research

14.10 Increasing urban DOTS effectiveness is an area where incentives and enablers can be used to potentially great effect, to improve program performance. A comprehensive urban DOTS strategy that includes incentives and enablers for patients and providers could also address three other key areas: expanding PPM in urban areas, targeting the hard-to-reach urban poor and homeless, and strengthening the performance of municipalities (Figure 1). The strategy to improve urban DOTS effectiveness could first be tried as an operations research study, managed by one of the medical colleges.

Figure 1. Potential Roles of Incentives and Enablers in Improving Urban DOTS Effectiveness



14.11 In addition, RNTCP II offers several other opportunities to implement incentives and enablers to strengthen overall DOTS performance (Table 1). Incentives and enablers could be effective for targeting tribal populations. In addition to providing incentives to NGOs or private providers to cover tribal areas (as part of PPM expansion), which is already being considered, provider incentives to districts based on case detection among the SC/ST (scheduled caste/schedule tribe) population and patient incentives, such as transport subsidies, to suspects and patients from tribal populations, could also be considered.

14.12 Budget allocation to states and districts could be partially tied to performance achievements as an incentive, for example, a fixed amount per cured patient could be distributed between district and state, which they could use as they see fit for DOTS activities. Other forms of reward, such as sponsorship to attend workshops or training; hiring of consultants to conduct workshops or evaluations; or support to produce papers for publication or presentation at conferences may also be effective. The incentives and enablers design could also support PPM by tying rewards to increased involvement of the non-public sector. Medical colleges should take the lead to undertake OR on the impact and cost-effectiveness of different incentives and enablers schemes, to inform decisions to scale up.

Table 1. Summary of Potential Incentives and Enablers for RNTCP Phase II

WHAT	HOW			
	Incentives to Patients	**Incentives to PPs or NGOs**	**Incentives to DOT Providers**	**Incentives to TB Control Managers**
Improving urban DOTS effectiveness	Transport subsidies/ food for diagnosis and/or for registration Cash reward upon treatment completion Patient deposit (returned upon treatment completion)	Payment as per current guide-lines Voucher-based subsidy for referral of suspects	Payment per patient completing treatment Incentives for (successful) defaulter tracing	Payment to municipal-ities for cured patient/ completed treatment Payment based on engagement of PPs
Reaching tribal populations	Transport subsidy for diagnosis and treatment	Contracts/ payment to cover tribal areas	Payment per completed treatment	Payment to districts based on performance improvements
Strengthening TB control performance				Payment or reward based on performance improvement

Annex 15: Program Preparation and Supervision

INDIA: Second National Tuberculosis Control Program

	Planned	Actual
PCN review		June 2004
Initial PID to PIC		June 2004
Initial ISDS to PIC		June 2004
Appraisal	August 2005	April 2005
Negotiations	August 2005	November 8, 2005 and July 12, 2006
Board/RVP approval	August 2006	
Planned date of effectiveness	October 1, 2006	
Planned date of mid-term review		
Planned closing date	March 30, 2012	

Key institutions responsible for preparation of the project: MOHFW, WHO, IDA.

IDA staff and consultants who worked on the project included:

Name	Title	Unit
Birte Holm Sorensen	Senior Public Health Specialist	SASHD
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Anthony D'Souza	Management Specialist,	Consultant
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Hadi Abushakra	Chief Counsel	LEGMS
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Maria Elena Anderson	Implementation Specialist	Consultant
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Tushar Kanti Ray	Social Development Specialist,	Danida
Varalakshmi Vemuru	Senior Social Development Specialist	SASES
Victoria Francis	Communications Specialist	Consultant

Bank funds expended to date on project preparation:

1.	Bank resources:	US$ 254,985.19
2.	Trust funds:	US$ 155,511.74
3.	Total:	US$ 410,496.93

Estimated Approval and Supervision costs:

1.	Remaining costs to approval:	US$ 50,000
2.	Estimated annual supervision cost:	US$100,000

Annex 16: Documents in the Program File

INDIA: Second National Tuberculosis Control Program

GoI DOCUMENTS

Revised National Tuberculosis Control Program (RNTCP) Phase II, National Implementation Plan 2005, MOHFW, India, draft, January 2005

Strategic Vision for Tuberculosis Control in India up to 2015, MOHFW, India, December, 2004

Strategic Vision for Tuberculosis Control up to 2015 for the States of Andaman and Nicobar, Andhra Pradesh, Assam, Bihar, Chandigarh, Chhattisgarh, Goa, Gujarat, Maharashtra, Mizoram, Tamil Nadu, Tripura, Uttaranchal, Uttar Pradesh, West Bengal., December, 2004

PROJECT BACKGROUND PAPERS

Options for Developing a Communication Strategy for the Revised National Tuberculosis Control Program (RNTCP) Phase II, India. Victoria Francis, Working Paper, January, 2005.

Management and Institutional Issues for the Revised National Tuberculosis Control Program (RNTCP) Phase II, India. Tushar Kanti Ray, Esben Sonderstrup, Draft Working Paper, January 2005

Incentives and Enablers for Improved DOTS Performance. Sangeeta Mukherjee, Background Paper , Management for Science Foundation, January 2005

EVALUATIONS AND STUDIES

Joint Tuberculosis Programme Review, World Health Organization Regional Office for South-East Asia: New Delhi. Report No. SEA-TB-265, 2003.

Availability of Anti-TB Drugs in Medical Shops: A Study in Six RNTCP Districts of Orissa. Asian Information Marketing and Social Research: Bhubaneswar. DANTB, 2002.

Effectiveness of Gender Sensitisation Strategies in RNTCP: A Comparative Study in Orissa. Indian Institute of Health Management Research: Jaipur. DANTB, 2002

Field Supervision in RNTCP: An Assessment of the Workload. Xavier Institute of Management: Bhubaneswar. DANTB, 2002.

Interaction Meetings under RNTCP: An Assessment. New Delhi: New Concept Information Systems. DANTB, 2002.

Low Utilisation of TB Services by Women: Study in Six Districts of Orissa. New Concept Information Systems: New Delhi. DANTB, 2002.

Impact of National Consultants on Successful Expansion of Effective Tuberculosis Control in India. Frieden, T.R. and Khatri, G.R. *International Journal of Tuberculosis and Lung Disease.* 7(9):837-841, 2003

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GoI, 2003, Central Tuberculosis Division, *"Accessibility and utilization of RNTCP services by ST/SC population".*

Singh et. Al., 2002, *TB controls, poverty and vulnerability in Delhi*, India. Tropical Medicine and International Health, Vol. 7 No. 8, pp. 693-700.

RNTCP Documents and Manuals are available on (Webpage: www.tbcindia.org)

Annex 17: Statement of Loans and Credits

INDIA: Second National Tuberculosis Control Program

			Original Amount in US$ Millions						Difference between expected and actual disbursements	
Project ID	FY	Purpose	IBRD	IDA	SF	GEF	Cancel.	Undisb.	Orig.	Frm. Rev'd
P079675	2006	Karn Municipal Reform	216.00	0.00	0.00	0.00	0.00	216.00	0.00	0.00
P079708	2006	TN Empwr & Pov Reduction	0.00	120.00	0.00	0.00	0.00	110.61	-6.98	0.00
P083780	2006	TN Urban III	300.00	0.00	0.00	0.00	0.00	283.29	7.37	0.00
P086414	2006	Power System Development Project III	400.00	0.00	0.00	0.00	0.00	400.00	0.00	0.00
P092735	2006	NAIP	0.00	200.00	0.00	0.00	0.00	200.02	0.00	0.00
P093720	2006	Mid-Himalayan (HP) Watersheds	0.00	60.00	0.00	0.00	0.00	56.13	-2.64	0.00
P077977	2005	Rural Roads Project	99.50	300.00	0.00	0.00	0.00	280.01	-26.99	0.00
P077856	2005	Lucknow-Muzaffarpur National Highway	620.00	0.00	0.00	0.00	0.00	524.23	-45.77	0.00
P075058	2005	TN HEALTH SYSTEMS	0.00	110.83	0.00	0.00	20.06	83.48	5.11	8.63
P094513	2005	India Tsunami ERC	0.00	465.00	0.00	0.00	0.00	393.97	137.87	0.00
P073651	2005	DISEASE SURVEILLANCE	0.00	68.00	0.00	0.00	0.00	63.03	13.07	0.00
P073370	2005	Madhya Pradesh Water Sector Restructurin	394.02	0.00	0.00	0.00	0.00	371.58	32.70	0.00
P084632	2005	Hydrology II	104.98	0.00	0.00	0.00	0.00	104.46	24.32	0.02
P084790	2005	MAHAR WSIP	325.00	0.00	0.00	0.00	0.00	293.18	-21.48	0.00
P084792	2005	Assam Agric Competitiveness	0.00	154.00	0.00	0.00	0.00	142.94	11.46	0.00
P086518	2005	IN SME Financing & Development	120.00	0.00	0.00	0.00	0.00	19.40	1.07	0.00
P073776	2004	ALLAHABAD BYPASS	240.00	0.00	0.00	0.00	0.00	176.04	94.44	0.00
P073369	2004	MAHAR RWSS	0.00	181.00	0.00	0.00	0.00	145.18	12.64	0.00
P078550	2004	Uttar Wtrshed	0.00	69.62	0.00	0.00	0.00	64.23	-2.33	0.00
P055459	2004	ELEMENTARY EDUCATION PROJECT (SSA)	0.00	500.00	0.00	0.00	0.00	98.45	-105.68	0.00
P079865	2004	GEF Biosafety Project	0.00	0.00	0.00	1.00	0.00	0.76	0.71	0.00
P082510	2004	Karnataka UWS Improvement Project	39.50	0.00	0.00	0.00	0.00	29.61	16.60	0.00
P050655	2004	RAJASTHAN HEALTH SYSTEMS DEVELOPMENT	0.00	89.00	0.00	0.00	0.00	78.46	32.72	0.00
P076467	2003	Chatt DRPP	0.00	112.56	0.00	0.00	20.06	88.45	34.27	0.00
P075056	2003	Food & Drugs Capacity Building Project	0.00	54.03	0.00	0.00	0.00	45.18	21.33	0.00
P073094	2003	AP Comm Forest Mgmt	0.00	108.00	0.00	0.00	0.00	57.15	-5.69	0.00
P072123	2003	Tech/Engg Quality Improvement Project	0.00	250.00	0.00	0.00	40.11	167.55	52.12	-27.10
P050649	2003	TN ROADS	348.00	0.00	0.00	0.00	0.00	271.73	60.77	0.00
P067606	2003	UP ROADS	488.00	0.00	0.00	0.00	0.00	355.53	154.36	0.00
P071272	2003	AP RURAL POV REDUCTION	0.00	150.03	0.00	0.00	0.00	54.33	12.27	0.00
P050668	2002	MUMBAI URBAN TRANSPORT PROJECT	463.00	79.00	0.00	0.00	0.00	377.90	150.21	0.00
P050653	2002	KARNATAKA RWSS II	0.00	151.60	0.00	0.00	15.04	85.81	54.49	0.00
P072539	2002	KERALA STATE TRANSPORT	255.00	0.00	0.00	0.00	0.00	138.78	29.12	0.00
P040610	2002	RAJ WSRP	0.00	140.00	0.00	0.00	15.04	86.19	46.93	0.00
P050647	2002	UP WSRP	0.00	149.20	0.00	0.00	40.11	103.34	102.13	0.00
P074018	2002	Gujarat Emergency Earthquake Reconstruct	0.00	442.80	0.00	0.00	80.23	149.28	153.74	10.22
P069889	2002	MIZORAM ROADS	0.00	60.00	0.00	0.00	0.00	34.60	10.37	0.00
P071033	2002	KARN Tank Mgmt	0.00	98.90	0.00	0.00	25.07	61.69	49.18	-5.16

P035173	2001	POWERGRID II	450.00	0.00	0.00	0.00	0.00	43.02	41.29	6.08
P050658	2001	TECHN EDUC III	0.00	64.90	0.00	0.00	0.00	14.43	7.49	-3.83
P010566	2001	GUJARAT HWYS	381.00	0.00	0.00	0.00	101.00	38.76	139.21	110.88
P055454	2001	KERALA RWSS	0.00	65.50	0.00	0.00	12.27	18.36	16.29	1.87
P071244	2001	Grand Trunk Road Improvement Project	589.00	0.00	0.00	0.00	0.00	236.51	231.85	0.00
P070421	2001	KARN HWYS	360.00	0.00	0.00	0.00	0.00	89.32	62.46	0.00
P067216	2001	KAR WSHD DEVELOPMENT	0.00	100.40	0.00	0.00	20.06	52.42	58.45	41.48
P038334	2001	RAJ POWER I	180.00	0.00	0.00	0.00	2.02	35.25	37.27	26.11
P059242	2001	MP DPIP	0.00	110.10	0.00	0.00	20.06	16.35	21.70	-11.09
P055455	2001	RAJ DPEP II	0.00	74.40	0.00	0.00	0.00	27.42	16.99	0.00
P059501	2000	IN-TA for Econ Reform Project	0.00	45.00	0.00	0.00	12.03	19.47	26.72	0.81
P050657	2000	UP Health Systems Development Project	0.00	110.00	0.00	0.00	30.09	38.32	57.77	-0.94
P049770	2000	REN EGY II	80.00	50.00	0.00	0.00	18.00	41.69	57.98	56.98
P045049	2000	AP DPIP	0.00	111.00	0.00	0.00	0.00	16.17	6.54	0.00
P010505	2000	RAJASTHAN DPIP	0.00	100.48	0.00	0.00	0.00	40.76	31.42	25.28
P009972	2000	NATIONAL HIGHWAYS III PROJECT	516.00	0.00	0.00	0.00	0.00	168.24	168.24	54.91
P050646	1999	UP Sodic Lands II	0.00	194.10	0.00	0.00	0.00	9.02	5.28	-6.89
		Total:	6,969.00	5,139.45	0.00	1.00	471.25	7,118.08	2,090.76	288.26

INDIA
STATEMENT OF IFC's
Held and Disbursed Portfolio
In Millions of US Dollars

		Committed				Disbursed			
		IFC				IFC			
FY Approval	Company	Loan	Equity	Quasi	Partic.	Loan	Equity	Quasi	Partic.
2005	ADPCL	40.77	7.00	0.00	0.00	0.00	0.00	0.00	0.00
2006	AHEL	0.00	5.08	0.00	0.00	0.00	5.08	0.00	0.00
2005	AP Paper Mills	35.00	5.00	0.00	0.00	15.00	5.00	0.00	0.00
2005	APIDC Biotech	0.00	4.00	0.00	0.00	0.00	1.24	0.00	0.00
2002	ATL	14.15	0.00	0.00	9.36	14.15	0.00	0.00	9.36
2003	ATL	1.00	0.00	0.00	0.00	0.68	0.00	0.00	0.00
2005	ATL	9.69	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2003	BHF	10.64	0.00	10.64	0.00	10.64	0.00	10.64	0.00
2004	BILT	0.00	0.00	15.00	0.00	0.00	0.00	15.00	0.00
2001	BTVL	0.72	5.00	0.00	0.00	0.72	5.00	0.00	0.00
2003	Balrampur	12.41	0.00	0.00	0.00	12.41	0.00	0.00	0.00
2001	Basix Ltd.	0.00	0.98	0.00	0.00	0.00	0.98	0.00	0.00
2005	Bharat Biotech	0.00	0.00	4.50	0.00	0.00	0.00	3.30	0.00
1984	Bihar Sponge	5.83	0.00	0.00	0.00	5.83	0.00	0.00	0.00
2001	CCIL	6.00	0.00	0.00	5.75	6.00	0.00	0.00	5.75
2003	CCIL	1.50	0.00	0.00	0.00	0.59	0.00	0.00	0.00
1990	CESC	6.87	0.00	0.00	0.00	6.87	0.00	0.00	0.00
1992	CESC	9.82	0.00	0.00	21.89	9.82	0.00	0.00	21.89
2004	CGL	15.00	0.00	0.00	0.00	8.00	0.00	0.00	0.00

2004	CMScomputers	0.00	10.00	2.50	0.00	0.00	0.00	0.00	0.00
2002	COSMO	3.75	0.00	0.00	0.00	3.75	0.00	0.00	0.00
2005	COSMO	0.00	3.73	0.00	0.00	0.00	3.73	0.00	0.00
2005	DCM Shriram	30.00	0.00	0.00	0.00	30.00	0.00	0.00	0.00
2003	DQEL	0.00	1.50	1.50	0.00	0.00	1.50	1.50	0.00
2005	Dabur	0.00	14.09	0.00	0.00	0.00	14.09	0.00	0.00
2003	Dewan	10.75	0.00	0.00	0.00	10.75	0.00	0.00	0.00
2006	Federal Bank	0.00	31.50	0.00	0.00	0.00	27.43	0.00	0.00
2001	GTF Fact	0.00	1.20	0.00	0.00	0.00	1.20	0.00	0.00
2006	GTF Fact	0.00	0.00	0.99	0.00	0.00	0.00	0.99	0.00
1994	GVK	0.00	5.00	0.00	0.00	0.00	5.00	0.00	0.00
2003	HDFC	100.00	0.00	0.00	100.00	100.00	0.00	0.00	100.00
1998	IAAF	0.00	0.47	0.00	0.00	0.00	0.30	0.00	0.00
2006	IAL	0.00	9.86	0.00	0.00	0.00	7.70	0.00	0.00
1998	IDFC	0.00	10.82	0.00	0.00	0.00	10.82	0.00	0.00
2005	IDFC	50.00	0.00	0.00	100.00	0.00	0.00	0.00	0.00
	IHDC	7.16	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2006	IHDC	8.15	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1995	IL&FS VC	0.00	0.03	0.00	0.00	0.00	0.03	0.00	0.00
2006	Indecomm	0.00	2.57	0.00	0.00	0.00	2.57	0.00	0.00
1996	India Direct Fnd	0.00	1.10	0.00	0.00	0.00	0.66	0.00	0.00
2001	Indian Seamless	6.00	0.00	0.00	0.00	6.00	0.00	0.00	0.00
1992	Indus VC Mgt Co	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.00
2006	JK Paper	15.00	11.50	0.00	0.00	0.00	11.26	0.00	0.00
2005	K Mahindra INDIA	22.00	0.00	0.00	0.00	22.00	0.00	0.00	0.00
2005	KPIT	11.00	2.50	0.00	0.00	4.00	0.00	0.00	0.00
2003	L&T	50.00	0.00	0.00	0.00	50.00	0.00	0.00	0.00
2002	MMFSL	8.69	0.00	7.76	0.00	8.69	0.00	7.76	0.00
2003	MSSL	0.00	2.29	0.00	0.00	0.00	2.20	0.00	0.00
2001	MahInfra	0.00	10.00	0.00	0.00	0.00	0.79	0.00	0.00
	Montalvo	0.00	3.00	0.00	0.00	0.00	1.08	0.00	0.00
1996	Moser Baer	0.00	0.82	0.00	0.00	0.00	0.82	0.00	0.00
1999	Moser Baer	0.00	8.74	0.00	0.00	0.00	8.74	0.00	0.00
2000	Moser Baer	12.41	10.54	0.00	0.00	12.41	10.54	0.00	0.00
2001	NIIT-SLP	8.37	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Nevis	0.00	4.00	0.00	0.00	0.00	4.00	0.00	0.00
2003	NewPath	0.00	9.31	0.00	0.00	0.00	8.31	0.00	0.00
2004	NewPath	0.00	2.79	0.00	0.00	0.00	2.49	0.00	0.00
2003	Niko Resources	24.44	0.00	0.00	0.00	24.44	0.00	0.00	0.00
2001	Orchid	0.00	0.73	0.00	0.00	0.00	0.73	0.00	0.00
1997	Owens Corning	6.83	0.00	0.00	0.00	6.83	0.00	0.00	0.00
2006	PSL Limited	15.00	5.19	0.00	0.00	0.00	4.98	0.00	0.00
2004	Powerlinks	75.34	0.00	0.00	0.00	66.24	0.00	0.00	0.00
1995	Prism Cement	5.54	0.00	0.00	1.50	5.54	0.00	0.00	1.50
2004	RAK India	20.00	0.00	0.00	0.00	20.00	0.00	0.00	0.00
1995	Rain Calcining	0.00	2.30	0.00	0.00	0.00	2.30	0.00	0.00
2004	Rain Calcining	10.00	0.00	0.00	0.00	10.00	0.00	0.00	0.00
2005	Ramky	3.86	10.61	0.00	0.00	0.00	0.00	0.00	0.00
2005	Ruchi Soya	10.00	10.00	0.00	0.00	0.00	7.50	0.00	0.00

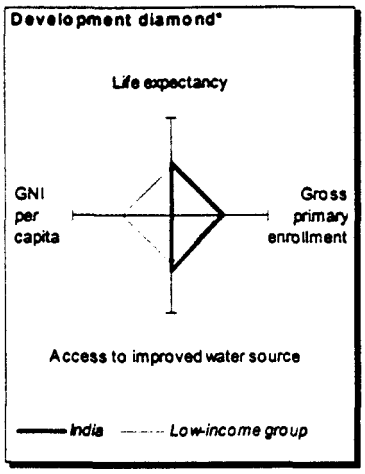
2001	SBI	50.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1997	SREI	3.21	0.00	0.00	0.00	3.21	0.00	0.00	0.00
2000	SREI	7.00	0.00	0.00	0.00	7.00	0.00	0.00	0.00
1995	Sara Fund	0.00	3.43	0.00	0.00	0.00	3.43	0.00	0.00
2004	SeaLion	4.54	0.00	0.00	0.00	4.54	0.00	0.00	0.00
2001	Spryance	0.00	1.90	0.00	0.00	0.00	1.90	0.00	0.00
2003	Spryance	0.00	0.95	0.00	0.00	0.00	0.95	0.00	0.00
2004	Sundaram Finance	44.32	0.00	0.00	0.00	44.32	0.00	0.00	0.00
2000	Sundaram Home	0.00	2.18	0.00	0.00	0.00	2.18	0.00	0.00
2002	Sundaram Home	7.39	0.00	0.00	0.00	7.39	0.00	0.00	0.00
1998	TCW/ICICI	0.00	0.80	0.00	0.00	0.00	0.80	0.00	0.00
2005	TISCO	100.00	0.00	0.00	300.00	0.00	0.00	0.00	0.00
2004	UPL	16.48	0.00	0.00	0.00	16.48	0.00	0.00	0.00
1996	United Riceland	6.25	0.00	0.00	0.00	6.25	0.00	0.00	0.00
2005	United Riceland	8.50	0.00	0.00	0.00	3.00	0.00	0.00	0.00
2002	Usha Martin	0.00	0.72	0.00	0.00	0.00	0.72	0.00	0.00
2001	Vysya Bank	0.00	3.66	0.00	0.00	0.00	3.66	0.00	0.00
2005	Vysya Bank	0.00	3.51	0.00	0.00	0.00	3.51	0.00	0.00
1997	WIV	0.00	0.37	0.00	0.00	0.00	0.37	0.00	0.00
1997	Walden-Mgt India	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.00
	Total portfolio:	931.38	230.79	42.89	538.50	563.55	175.61	39.19	138.50

		Approvals Pending Commitment			
FY Approval	Company	Loan	Equity	Quasi	Partic.
2004	CGL	0.01	0.00	0.00	0.00
2000	APCL	0.01	0.00	0.00	0.00
2004	CIFCO	0.00	0.00	0.02	0.00
2006	IDFC B Inc	0.00	0.00	0.00	0.10
2001	Vysya Bank	0.00	0.00	0.00	0.00
2006	Federal Bank	0.01	0.00	0.00	0.00
2001	GI Wind Farms	0.01	0.00	0.00	0.00
2004	Ocean Sparkle	0.00	0.00	0.00	0.00
2005	Allain Duhangan	0.00	0.00	0.00	0.00
2006	Lok Microfinance	0.00	0.00	0.00	0.00
	Total pending commitment:	0.04	0.00	0.02	0.10

Annex 18: Country at a Glance

INDIA: Second National Tuberculosis Control Program

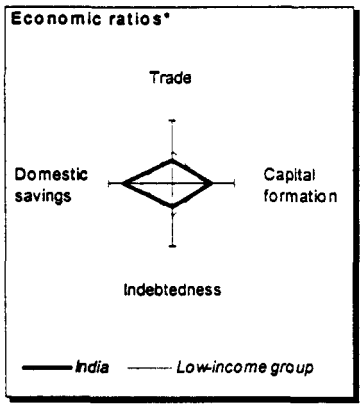
POVERTY and SOCIAL	India	South Asia	Low-income
2004			
Population, mid-year *(millions)*	1,079.7	1,447	2,343
GNI per capita *(Atlas method, US$)*	630	590	510
GNI *(Atlas method, US$ billions)*	680.3	859	1,188
Average annual growth, 1998-04			
Population *(%)*	1.8	1.7	1.9
Labor force *(%)*	1.9	2.1	2.2
Most recent estimate (latest year available, 1998-04)			
Poverty *(% of population below national poverty line)*	29	..	..
Urban population *(% of total population)*	29	29	31
Life expectancy at birth *(years)*	63	63	58
Infant mortality *(per 1,000 live births)*	62	66	79
Child malnutrition *(% of children under 5)*	47	49	43
Access to an improved water source *(% of population)*	86	84	75
Literacy *(% of population age 15+)*	61	61	61
Gross primary enrollment *(% of school-age population)*	107	103	100
Male	111	108	105
Female	104	97	94



KEY ECONOMIC RATIOS and LONG-TERM TRENDS

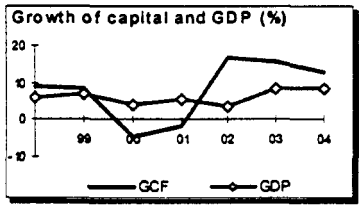
	1984	1994	2003	2004
GDP *(US$ billions)*	206.5	322.6	600.7	694.7
Gross capital formation/GDP	21.6	23.4	27.2	30.1
Exports of goods and services/GDP	6.5	10.0	14.8	19.0
Gross domestic savings/GDP	18.8	24.8	28.9	29.1
Gross national savings/GDP	19.4	26.0	32.0	31.4
Current account balance/GDP	-1.4	-1.2	1.7	-1.0
Interest payments/GDP	0.5	1.3	1.4	1.8
Total debt/GDP	16.5	31.8	19.2	17.5
Total debt service/exports	18.3	26.6	12.6	7.3
Present value of debt/GDP	..	..	16.7	..
Present value of debt/exports	..	..	87.4	..

	1984-94	1994-04	2003	2004	2004-08
(average annual growth)					
GDP	5.4	5.8	8.3	8.5	6.9
GDP per capita	3.3	4.1	6.7	7.0	5.5
Exports of goods and services	9.0	13.3	5.8	39.3	..

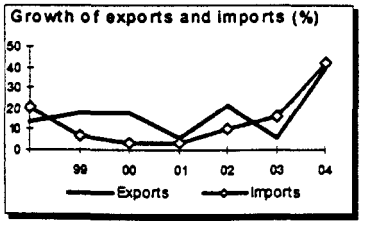


STRUCTURE of the ECONOMY

	1984	1994	2003	2004
(% of GDP)				
Agriculture	35.2	30.4	21.0	19.6
Industry	26.2	27.1	26.4	27.3
Manufacturing	16.4	16.9	15.4	16.0
Services	38.7	42.5	52.5	53.2
Household final consumption expenditure	69.0	66.2	62.9	60.7
General gov't final consumption expenditure	10.8	10.7	11.2	11.3
Imports of goods and services	7.9	10.3	15.1	21.0



	1984-94	1994-04	2003	2004
(average annual growth)				
Agriculture	3.4	2.1	10.0	0.7
Industry	6.3	5.7	7.6	8.6
Manufacturing	6.2	5.5	7.1	8.1
Services	6.7	8.1	8.2	9.9
Household final consumption expenditure	5.7	5.3	8.9	7.2
General gov't final consumption expenditure	4.8	6.0	2.4	9.2
Gross capital formation	5.0	6.1	15.8	12.8
Imports of goods and services	8.4	11.0	16.8	41.9

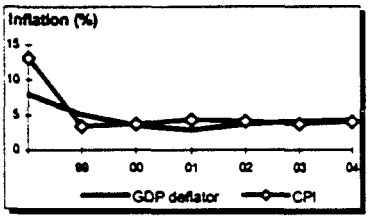


Note: 2004 data are preliminary estimates. 2004 represents Indian Fiscal Year 2004-05, which runs from April 1 to March 31.

*The diamonds show four key indicators in the country (in bold) compared with its income-group average. If data are missing, the diamond will be incomplete.

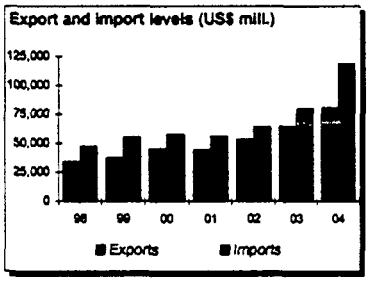
PRICES and GOVERNMENT FINANCE

	1984	1994	2003	2004
Domestic prices				
(% change)				
Consumer prices	4.3	7.6	3.7	4.0
Implicit GDP deflator	7.4	9.7	4.1	4.2
Government finance				
(% of GDP, includes current grants)				
Current revenue	..	18.0	17.9	19.6
Current budget balance	..	-3.7	-6.4	-4.2
Overall surplus/deficit	..	-7.6	-9.0	-7.9



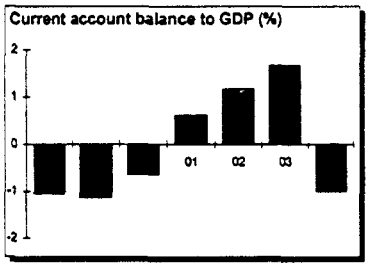
TRADE

	1984	1994	2003	2004
(US$ millions)				
Total exports (fob)	10,061	26,855	64,723	80,831
Tea	321	1,126	1,329	1,268
Iron	453	988	2,369	4,193
Manufactures	5,614	20,404	48,492	58,168
Total imports (cif)	15,715	35,904	80,177	118,961
Food	1,384	1,144	3,073	3,014
Fuel and energy	4,596	5,928	20,570	29,844
Capital goods	2,546	7,638	18,279	22,567
Export price index *(2000=100)*	103	115	106	107
Import price index *(2000=100)*	122	106	100	101
Terms of trade *(2000=100)*	84	109	107	107



BALANCE of PAYMENTS

	1984	1994	2003	2004
(US$ millions)				
Exports of goods and services	13,508	32,990	89,672	132,157
Imports of goods and services	18,065	41,437	98,535	155,657
Resource balance	-4,557	-8,447	-8,863	-23,500
Net income	-838	-3,431	-3,972	-3,979
Net current transfers	2,496	8,093	22,833	20,459
Current account balance	-2,899	-3,785	9,998	-7,020
Financing items (net)	2,516	9,526	25,560	35,143
Changes in net reserves	383	-5,741	-35,558	-28,123
Memo:				
Reserves including gold *(US$ millions)*	5,952	25,186	111,648	140,076
Conversion rate *(DEC, local/US$)*	11.9	31.4	46.0	44.9



EXTERNAL DEBT and RESOURCE FLOWS

	1984	1994	2003	2004
(US$ millions)				
Total debt outstanding and disbursed	34,036	102,483	115,277	121,456
IBRD	1,688	11,244	4,126	4,865
IDA	8,545	17,758	22,351	23,662
Total debt service	2,973	10,951	14,469	11,337
IBRD	257	1,641	2,079	288
IDA	109	325	771	755
Composition of net resource flows				
Official grants	483	416	563	589
Official creditors	1,363	970	2,231	..
Private creditors	1,895	1,438	8,565	..
Foreign direct investment (net inflows)	0	983	3,420	3,037
Portfolio equity (net inflows)	0	3,824	11,356	8,907
World Bank program				
Commitments	2,651	2,064	1,600	2,705
Disbursements	1,114	1,783	1,717	1,835
Principal repayments	129	1,062	2,468	784
Net flows	985	721	-751	1,051
Interest payments	237	904	381	259
Net transfers	748	-183	-1,133	792