PROJECT INFORMATION DOCUMENT (PID)
APPRAISAL STAGE

Report No.: AB1484

Project Name	Second National Tuberculosis Control Project
Region	SOUTH ASIA
Sector	Health (100%)
Project ID	P078539
Borrower(s)	GOVERNMENT OF INDIA
Implementing Agency	
	Department of Economic Affairs, Ministry of Finance India Tel: +91 11 23094140
	Ministry of Health and Family Welfare India Tel: +91 11 23018126
Environment Category	[ ] A [X] B [ ] C [ ] FI [ ] TBD (to be determined)
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1. Country and Sector Background

India is a low-income country with a gross national income per capita of US$480 (2002) and a population of 1.07 billion people. The economy has grown 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 halved and fertility has declined during the last fifty years.

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.

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 and is not well targeted to the poor. 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, 70% of outpatient care for those below the poverty line is provided by the private sector, much of which is of high cost and low quality provided by un-registered practitioners.

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 on an average infecting ten people.

TB afflicts nearly all age groups although most cases are among adults aged 15 to 59, 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 1992 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 currently makes DOTS available in 550 of the 600 districts and by the end of 2005 is expected to be available in every district of the country.

The RNTCP has received financial and technical assistance from a number of sources including Canadian International Development Assistance (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 through its previous National Tuberculosis Control Project

2. Objectives

India has already reached the global targets of 70% case detection rate and 85% cure rate on a nationwide basis in areas where DOTS is being implemented. However there are large differences in program performance across the country, with many 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 these 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 100% of the districts; and (ii) for the zones where DOTS has been under implementation for five or more years, the incidence of smear-positive TB starts to decline. 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 85%; and (ii) the incidence of smear-positive TB in zones where DOTS has been implemented for five years or more.

3. Rationale for Bank Involvement

IDA has been supporting the RNTCP since 1997 (National TB Control Project, Credit No. 2936 IN, US$142 million). 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. At the end of 2004 DOTS had been introduced in 482 districts and the average case detection and cure rates had reached the global targets set for effective national TB programs (for TB performance indicators see Annex 11). Since 1997 more than 4.3 million TB patients have been successfully treated. The program is now entering 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 entering a challenging phase of expanding coverage to the most difficult areas of the country. IDA has considerable experience with and involvement in the general health sector at national as well as state level. Insights into the inherent weaknesses of government health service delivery would be used to introduce appropriate measures for ensuring that quality services are maintained across the country.

One of the health-related Millennium Development Goals (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 IDAs strong commitment to the global goals.

4. Program Description

To achieve the PDO three broad outputs are required: (i) DOTS provision introduced in every district; (ii) DOTS services consolidated through enhancement of the quality of public DOTS provision and: (iii) expansion of TB services to generally under-served populations. At the start of this program, DOTS has 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. 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 quality public service provision, special emphasis would now be given to the quality of laboratory services, supervision and monitoring, continuous operations research, advocacy and health communication and strengthening of institutional capacity to implement the program.

Service Quality would be consolidated through (i) establishment of a network of intermediate reference laboratories (IRL) at 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 blinded 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. Central TB Division (CTD) regularly visits the states; State TB officers supervise the districts and the District TB officer travels for 15 days in a month to supervise laboratory and other field staff as well as the DOTS providers. 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) when required. This is one of the first DOTS programs worldwide to use a comprehensive, computerized management information system for data collection and transmission. In addition to the regular DOTS reporting system, the RNTCP would continue to use a reporting system specifically focused on process indicators covering all five elements of the DOTS strategy. To monitor the impact of the RNTCP on the incidence of tuberculosis, ARTI surveys would be repeated every 3-5 years.

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+.

Information, Education and Information (IEC) would be strengthened to (i) create awareness of TB symptoms and demand for free DOTS services in patient-wise boxes among the public and the health providers; (ii) advocate for political, 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 centre 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, given the current national coverage. It would include: (i) reorganizing and strengthening CTD through the provision of equipment and adequate physical facilities, and having program managers in charge of supervision and monitoring; human resource management and development; financial management, procurement, advocacy and health communication, and epidemiology/surveillance to better address already identified 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 revise their curricula to include DOTS as the prescribed treatment for TB, to provide training on DOTS and DOTS monitoring to the faculty, to support existing TB task forces in defining their role and plan 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 expansion of DOTS to all districts in the country the program would now prepare 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 countrywide 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 prepare a strategy to help identify hard to reach population groups and enable them to access quality TB care. Special incentives will be provided to health staff 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 non-RNTCP health care provider (the term non-public health care 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 as many of the presently unregistered and undetected cases under the RNTCP as possible and promote the involvement of non-public health care providers in the RNTCP and in DOTS provision. In continuation of the current efforts that appear to be yielding results, RNTCP II would provide additional support such as training for staff and non-RNTCP providers and additional technical assistance in the states to: (i) draw from the experiences of current Non Governmental Organizations (NGO) and Private Practitioner (PP) schemes and revise them, if necessary; (ii) prepare a framework for phased expansion of Public Private Mix (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 level 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 will 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 2 drug regimen. Due to the high cost of second line drugs, DOTS+, 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.

5. Financing

Source:		($m.)
BORROWER/RECIPIENT		41
INTERNATIONAL DEVELOPMENT ASSOCIATION		165
	Total	206

6. Implementation

The borrower has in the past received assistance from a number of bilateral 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. Some support is short term and limited in scope i.e. Global Fund for AIDS, TB and Malaria (GFATM) in each round supports a number of states or districts within states based on a GOI application; WHO provides consultant support on an annual basis depending on funds availability; United States Agency for International Development (USAID) supports all the RNTCP activities in one state and DFID may provide drugs through the Global Drug Facility to ensure a buffer stock of TB drugs. The GOI is coordinating this support to ensure it is complementary to the overall program financed from IDA and GOI funds. IDA also plays a central role as the Local Fund Agent for a tuberculosis-related grant from the GFATM.

Institutional Arrangements. The Program has been successfully managed for several years by the Central TB Division (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 MOHFW overseeing the financial and administrative areas. Although it is presently severely understaffed, the CTD does have experienced technical staff that manages all aspects of the Program, and also receives significant technical and administrative support from WHO consultants. CTD is in the process of appointing a procurement agency to support it in the procurement of drugs. Three national

institutions[1] support CTD by carrying out basic and operational research, performing quality control functions, developing training materials, providing training to State TB Officers and trainers from the State Demonstration and Training Centers (SDTC).

At the State level, the Director of Medical Services and the Director of National Programs are responsible for overseeing TB program implementation. Day to day implementation responsibility, however, lies primarily with the State TB Officer (STO) who is the responsible authority for all TB control activities in the state. He is assisted by a team of professional and administrative staff, and by WHO consultants who provide technical support. State TB cells undertake all program related activities such as allocating funds received from CTD to districts based on their plans. These include training various levels of staff, managing logistical and supply requirements, ensuring that districts comply with program guidelines and directives, preparing technical and financial reports, and timely reporting. States have the responsibility to provide adequate space and human resources for the State Training and Demonstration Centers (STDCs) that have three units: (i) an intermediate reference lab; (ii) a supervision and monitoring unit; and (iii) a training unit. Those states that have not yet established STDCs would obtain these services from public/private institutions that have shown to provide quality services. 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) is 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 District Medical Officer. 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.

CTD has proved to have satisfactory management capacity to meet IDA's financial management requirements; while procurement of drugs will be undertaken by the CTD, most other procurement is small and will be undertaken at state and district level.

Notwithstanding the above, the rapid Program expansion has now outstripped capacity of the central, state and WHO structures. RNTCP II therefore aims to strengthen CTD's management capacity, and states' and districts' management and program implementation capacity with additional staff and a more appropriate skills mix to meet the projected increase in services and address weaknesses in the non-clinical components of the Program.

Flow of Funds. The Central TB Division undertakes planning and budgeting for TB control in India. Based on the approved plan, the GOI makes allocations for TB Control for every five-year plan. The amounts for each year are planned and allocated in the annual Central Budget and Central TB Division can spend only within each annual capped allocation.

To ensure continuous funding from the Central TB Division down to each state and district, a system of funding through societies has been adopted. Each state government receives funds for

[1] Tuberculosis Research Center, Chennai, National Tuberculosis Institute, Bangalore, and Lala Ram Swarup Institute of TB and Allied Diseases, Delhi.

TB control from the GOI via their state's State TB Control Society (STCS). The STCS further allocates and disburses funds to the District TB Control Society (DTCS) account. State and district societies have now been regularized in most states into Health and Family Welfare Societies with a separate RNTCP account. The STCS and DTCS are administered by senior state/district government officers. All financial management systems of the RNTCP are governed by GOI guidelines.

7. Sustainability

Political Sustainability. The RNTCP has demonstrated its value and enjoys strong backing from GOI; the program forms an integrated part of India's 10th five-year plan and India is an active member of 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 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 Central Government contribution (that amounted to between 35% and 65% of the program costs during 2003) is a supplement to that of the States, who provide physical facilities, assigns personnel and covers the costs of office and other supplies. All activities are undertaken through the use of government rules and procedures, and the state and district societies have now been regularized in most states into Health and Family Welfare Societies with a separate RNTCP account. 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 this, institutional sustainability is considered relatively 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 closely monitor states with below average performance.

8. Lessons Learned from Past Operations in the Country/Sector

The program design was informed by analytical work, and implementation experiences from health, nutrition and population project supported by IDA, by international best practices as well as lessons learnt from RNTCP I.

- 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 the program ownership and capacity at the central, state and district levels.
- 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 will also be continued.

- The preparation and field testing of policies and guidelines and a system of appraisal of each district before 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+ and other initiatives to expand services to all TB patients.
- Central level drug procurement has ensured a continuous supply of drugs. An attempt to decentralize the procurement of loose drugs was made during RNTCP I; no states were able to procure the drugs, and in the interest of decentralized procurement, the economy of scale was lost.
- Delivery of RNTCP services through a mix of public-private providers has resulted in an increased case detection. With 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 throughout the country, the PPM can now be more aggressively expanded
- 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, and strengthen the demand for quality services.

9. Safeguard Policies (including public consultation)

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]

10. List of Factual Technical Documents

The Second National Tuberculosis Control Program Implementation Plan, MOHFW, May 31, 2005.

11. Contact point

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

Contact: Birte Holm Sorensen
Title: Sr Public Health Spec.
Tel: 202-458-5191
Fax: 202-522-2955
Email: bsorensen@worldbank.org
Location: Washington D.C

12. For more information contact:

The InfoShop
The World Bank
1818 H Street, NW
Washington, D.C. 20433
Telephone: (202) 458-5454
Fax: (202) 522-1500
Web: http://www.worldbank.org/infoshop