

**PROJECT INFORMATION DOCUMENT (PID)
APPRAISAL STAGE**

Report No.: 33158

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	<input type="checkbox"/> A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> FI <input type="checkbox"/> 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\$540 (2003) and a population of 1.07 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.

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 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 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 (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.

While there are interstate 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 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 incidence of TB by about 5% every year. Yet, to reach the Millennium Development Goal 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 underperforming states and districts.

A recent Social Assessment has confirmed that there are still population groups such as tribals, rural poor and urban slum populations who face difficulties in accessing TB treatment. Their knowledge of 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 people in the world living with HIV. The probability that these people are infected with TB depends on their age and may vary from 20 – 60% in the age group from 20 – 40. It is estimated that 40% of those who have both infections (HIV-TB co-infection) will eventually develop

active TB disease. 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 'normal' 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 data available 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's pays for all TB drugs, contractual services, Information Education Communication (IEC), vehicles, microscopes and other 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 an estimate based on staff – time allocation in three states and a questionnaire filled by 15 states indicates that the GOI's contribution is 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. 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.

The proposed operation would support the Revised National Tuberculosis Control Program Phase II henceforth referred to as RNTCP II, which has been defined by the central Government

in their Project Implementation Plan (PIP) dated May 31, 2005. This document has been prepared by the Central TB Division of the Ministry of Health and Family Welfare, 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 financial inputs to weaker Empowered Action Group (EAG¹) states and a special provision has been 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 Information Education and Communication 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, provision of 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 Government of India has recently launched the National Rural Health Mission (NRHM), an initiative to improve the health status of the rural people by promoting convergence of Reproductive and Child Health, Family Welfare and a basic package of health services including RNTCP. Several components of the NRHM, such as merging the different state and district health societies into one, making the Chief Medical Officer overall responsible for program implementation at district level; supporting a local female volunteer, ASHA, 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.

¹ The EAG states include Bihar, Chattisgarh, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh and Uttaranchal

3. Rationale for Bank Involvement

IDA has been supporting the RNTCP since 1997 (National TB Control Project, Credit No. 2936 IN, US\$142 million; closing date 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 4.4 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. 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 other donors have agreed with the GOI on a shared results framework, on the estimated costs and overall financing plan for the centrally sponsored scheme. 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 source of program financing would be complying with a common set of financial management, procurement and program monitoring arrangements. Arrangements for joint GOI donor supervision missions are in the process of being developed.

It may also be noted that 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 IDA's strong commitment to the global goals.

4. Program Description

To achieve the PDO, two broad outputs are required: (i) DOTS services consolidated through enhancement of the quality of public DOTS provision; and (ii) expansion of TB services 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. 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 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. 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+².

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 boxes³ 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 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.

² DOTS+ is the acronym for treatment of multi-drug resistant TB

³ Patient wise boxes: cardboard boxes containing the full regimen of TB drugs for treatment of one patient – currently only used for adult DOTS.

Appropriate institutional capacity would be ensured at all levels to maintain program quality. It would include: (i) reorganizing and strengthening CTD through the provision of equipment and adequate physical facilities, and by having new units established and 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 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 state level 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 implement these activities as appropriate to the conditions of their state. 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-public 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 in the form of training for staff and non-public providers. It would also provide 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 two 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

Partnership arrangements

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. 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; 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 that it is complementary to the overall program financed from IDA and GOI funds.

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. Under RNTCP II, this arrangement would continue with the Joint Secretary from the administrative arm of the Ministry of Health and Family Welfare (MOHFW) overseeing the financial and administrative areas. The CTD has experienced technical staff that manages all aspects of the program, and also receives significant technical and administrative support from WHO consultants. During project implementation, additional staff may be hired with skills and specialties that complement existing staff. Three national institutions⁴ 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 have had the overall responsibility for overseeing TB program implementation. During RNTCP II, day to day implementation responsibility, however, will increasingly be with the State TB Officer (STO) who will be the responsible authority for all TB control activities in the state. He will be assisted by a team of professional and administrative staff, and by WHO consultants who provide technical support. State TB cells will undertake all program related activities such as preparing state plans and budgets based on the consolidation of districts plans, allocating funds received from CTD to districts based on their annual plans, 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. During the program period there will be increasing flexibility in the financial norms to allow states to reallocate budgets and funds between 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. 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.

⁴ Tuberculosis Research Center, Chennai, National Tuberculosis Institute, Bangalore, and Lala Ram Swarup Institute of TB and Allied Diseases, Delhi.

In any given district, DOTS implementation was initiated only after successful appraisal by the CTD. In the initial stage 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 in 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 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 RNTCP will integrate easily with 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 "ASHA's" as DOTS providers at the village level.

Monitoring and evaluation of outcomes/results

The RNTCP has in place a robust recording and reporting system. 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). A web based Tuberculosis Program Information System would be developed as part of the program.

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 the 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, DOTS and to allow follow up of 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.

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.

Each year there are two review meetings at the national level, quarterly state level program review meetings (usually chaired by the Secretary Health, who is the Chairman of the HFWS), 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. A country-wide internal evaluation of randomly selected districts, as well as a Joint International Evaluation, would be repeated every 2-3 years.

7. Sustainability

Political Sustainability. The RNTCP has demonstrated its value and enjoys strong backing from GOI; the program forms an integral 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 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 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.

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

The program design was informed by lessons learnt from RNTCP I, from other health, nutrition and population projects supported by IDA and by international best practice.

RNTCP I:

- 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.
- 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. Drug procurement will therefore remain the responsibility of the CTD during the proposed project.
- 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 central, state and district levels.
- Experience from the IDA assisted Reproductive and Child Health Project suggests that procurement of pharmaceuticals is vulnerable to fraud and corruption due to: weak implementation of WHO certification scheme for Good Manufacturing Practices; collusion amongst bidders; false performance certificates; weak complaint monitoring systems; sub-optimal capacity of procurement agents; and lack of public disclosure of information on procurement actions. During the first two years of the project, drugs will be procured through WHO while procurement systems are being strengthened.
- 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.

International best practice in TB control:

- The program has closely followed 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+.

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

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

