STAFF APRAISAL REPORT

INDIA

PROPOSED TUBERCULOSIS CONTROL PROJECT

January 6, 1997

South Asia Country Department II (Bhutan, India and Nepal) Population and Huaman Resources Operations Division
CURRENCY EQUIVALENTS
(As of July 1996)

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METRIC EQUIVALENTS

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GOVERNMENT FISCAL YEAR

April 1 - March 31

ABBREVIATIONS AND ACRONYMS

ADGHS  Assistant Director General of Health Services
AFB    Acid Fast Bacilli
AIDS   Acquired Immunodeficiency Syndrome
ARI    Annual Risk of Infection
BCG    Bacilli of Calmette and Guerin
BRS    Basic Radiological System
CDC    Centers for Disease Control and Prevention
CHC    Community Health Center
CHEB   Central Health Education Bureau
DALYs  Disability Adjusted Life Years
DANIDA Danish Development Agency
DDG    Deputy Director General
DGHS   Director General of Health Services
DHO    District Health (Medical) Officer
DOT    Directly-Observed Therapy
DTC    District Tuberculosis Center
DTO    District Tuberculosis Officer
E      Ethambutol
GOI    Government of India
H or INH Isoniazid
ABBREVIATIONS AND ACRONYMS (Continued)

HIV Human Immunodeficiency Virus
IDA International Development Agency
IMA Indian Medical Association
LCC Long Course Chemotherapy
LSHTM London School of Hygiene and Tropical Medicine
MIS Management Information System
MO Medical Officer
MOHFW Ministry of Health and Family Welfare
MPHW Multi-Purpose Health Worker
NGO Non-Governmental Organization
NTI National Tuberculosis Institute
NTP National Tuberculosis Control Program
ODA Overseas Development Administration
PHC Primary Health Center
PHI Peripheral Health Institutions
PPD Purified Protein Derivative
PPF Project Preparation Facility
R Rifampicin
RNTP Revised National Tuberculosis Control Program
S Streptomycin
SCC Short Course Chemotherapy
SIDA Swedish International Development Agency
STO State Tuberculosis Officer
STDTC State Tuberculosis Demonstration and Training Center
STLS Senior Tuberculosis Laboratory Supervisor
STS Senior Tuberculosis Supervisor
T Thiacetazone
TAI Tuberculosis Association of India
TB Tuberculosis
TRC Tuberculosis Research Center
TU Tuberculosis Unit
VHAI Voluntary Health Association of India
WHO World Health Organization
Z Pyrazinamide

Vice President: Joseph Wood
Director: Robert Drysdale
Division Chief: Richard Skolnik
Staff: Maria Donoso Clark
DEFINITIONS

Acid Fast Bacilli: Mycobacterium (M.) tuberculosis, unlike other bacteria, cannot readily be stained by the Gram stain method. A harsh staining procedure is required. Carbol-fuchsin, a red dye, is taken up and retained after washing in an acid-alcohol solution. Thus, the bacteria of this genus are referred to as Acid Fast Bacilli.

Annual Risk of Infection: The annual risk of infection tells us the probability that any individual will be infected or re-infected in one year with M. tuberculosis, causative agent of human tuberculosis derived from human sources. The annual risk of infection has become the standard indicator of the tuberculosis burden in a community.

BCG: An attenuated strain of M. bovis (or bovine type M. tuberculosis). Drs. Albert Calmette and Camille Guerin started making subcultures every three weeks of the virulent organism in 1906 in Lille, France. Twelve years later in 1918 the attenuated strain was isolated. It was first used as a vaccine in 1921.

Case Detection: There are two types of case detection, active and passive. Active Case Detection refers to community activities in which the tuberculosis health services are actively search for new TB cases through screening examinations (radiographic or Passive Case Detection refers to community activities in which the public health and medical services, including the regularly constituted tuberculosis control staff, detect new TB cases among the population who present themselves with symptomatic complaints.
<p>| <strong>DALYs:</strong> | Disability Adjusted Life Years. DALYs represent the sum of years lost both from premature death and from disability associated with disease and injury. |
| <strong>Directly Observed Treatment (DOT):</strong> | An anti-tuberculosis drug treatment which is taken in the presence of, and is directly observed by a health care worker or other trained person, and is duly recorded in the patient's treatment card. |
| <strong>DOTS Strategy:</strong> | The WHO strategy or DOTS--directly-observed treatment, short-course--is designed to make a significant impact in slowing down the TB cycle of infection. The major technical features of the strategy are: (a) targeting the infectious TB subgroup of smear-positive individuals through passive case finding; (b) using sputum examination for diagnosis and treatment evaluation; (c) prescribing a six- to eight-month, multi-drug, SCC treatment regimen; (d) applying directly observed Treatment (DOT) in case management; and (e) emphasizing treatment completion and cure of TB patients and cohort analysis of results through simple registers at the sub-district level. |
| <strong>Epidemiology:</strong> | The study of the distribution and determinants of diseases and injuries in human populations. It is concerned with the frequencies and types of illnesses and injuries in groups of people and with the factors that influence their distribution. |
| <strong>Incidence:</strong> | Number of new cases of a disease or condition over a period of time as a proportion of the population at risk at midpoint. Incidence means &quot;new&quot; and is a direct indicator of risk. |
| <strong>Long-Course Chemotherapy (LCC):</strong> | Drug treatment for tuberculosis, recommended by the World Health Organization (WHO) Expert Committee on Tuberculosis in 1974. It's a chemotherapy regimen that is administered for twelve to eighteen months and uses fewer and cheaper drugs, such as, isoniazid, streptomycin and thiacetazone. |</p>
<table>
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<tr>
<th>Prevalence:</th>
<th>Number of cases of a disease or condition at a given point in time as a proportion of the total population. Prevalence means &quot;all&quot; and is used by health planners to assess workload and service delivery needs.</th>
</tr>
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<tr>
<td>Revised National Tuberculosis Control Program (RNTP):</td>
<td>The new approach for the National Tuberculosis Control Program adopted by the Ministry of Health and Family Welfare in 1992. Its primary features include: (a) strengthening and reorganizing the Central TB Control unit; (b) adopting new and more rigorous methods for diagnosis, treatment and monitoring of patients, with emphasis on their cure; (c) decentralizing service delivery to the periphery; (d) strengthening training and research capacity; (e) targeting infectious, smear-positive cases; (f) providing SCC with DOT treatment; and (g) introducing a rigorous system of patient recording and monitoring through patient registration books and treatment cards.</td>
</tr>
<tr>
<td>Short-Course Chemotherapy (SCC):</td>
<td>Tuberculosis treatment that lasts from six to eight months, using multiple and more potent drugs, such as, isoniazid, rifampicin, ethambutol and pyrazinamide. Short-Course Chemotherapy converts most patients to smear negative faster than the long course chemotherapy and more effectively due to higher cure rates and higher compliance. It leads to a more rapid reduction in the risk of infection and incidence of clinical tuberculosis.</td>
</tr>
<tr>
<td>Smear-Negative Patient:</td>
<td>A tuberculosis patient with radiographic abnormalities consistent with active pulmonary tuberculosis, at least three negative sputum specimen, (for the Acid Fast Bacilli) and decision by a physician to treat with a full curative course of anti-tuberculosis chemotherapy.</td>
</tr>
<tr>
<td>Smear-Positive Patient:</td>
<td>A tuberculosis patient with two sputum specimen positive for the AFB, or with one sputum specimen positive for the AFB and radiographic abnormalities consistent with active pulmonary tuberculosis.</td>
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INDIA
PROPOSED TUBERCULOSIS CONTROL PROJECT

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This report is based on an appraisal mission that visited India on June, 1996, on the work carried out through pilot projects during the past two years, and on proposals and reports submitted by the Ministry of Health and Family Welfare (MOHFW). The mission comprised Ms. Maria Donoso Clark (Senior Anthropologists and Mission Leader), Kevin Casey (Sr. Implementation Specialist), Larry Geiter (International Union Against TB and Lung Diseases, IUATLD), Fabio Luelmo (Medical Officer, WHO-Geneva), Laurie Krieger (Social Issues Consultant), and Raj Kumar (Public Health Specialist, New Delhi Office). Significant contribution to project preparation was provided by several members of the WHO Global Tuberculosis Program, particularly Richard Bumgarner, Paul Nun, F. Luelmo, and Drs. Karl Styblo (WHO Consultant), Tom Frieden. (Medical Officer, WHO-Delhi), John Porter (School of Hygiene and Tropical Disease), Tony Ringdal (WHO Consultant) and Victor Ibabao (SA2PH Consultant). Salim Habayeb (Senior Public Health Specialist), Keith Hinchliffe (Senior Economist), Paramita Sudharto (Public Health Specialist), and Linda Pfeiffer and Michelle Loosli (INMED) also contributed to project preparation. Ms. Paula Walden assisted in the preparation of this document. The Peer Reviewers included Don Enarson (IUATLD), Dixie Snider (CDC), Dean Jamison (HDD), Christopher Murray (Harvard University), Sergio Spinaci (WHO) and Jagadish Upadhyay (EA2HR). The report is endorsed by Kazuko Uchimura, Project Advisor, Richard Skolnik, Division Chief (SA2PH), and Robert Drysdale, Director, South Asia Country Department II (India, Nepal, Bhutan).
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INDIA

PROPOSED TUBERCULOSIS CONTROL PROJECT

CREDIT AND PROJECT SUMMARY

Borrower: India, acting by its President

Beneficiaries: A total of 102 districts under the Revised Strategy for Tuberculosis control (RNTP) and 357 districts under a strengthened National Tuberculosis Control program throughout India.

Amount: SDR 98.4 million (US$142.4 million equivalent)

Terms: Standard, with 35 years maturity.

On-Lending Terms: Government of India to all the States and Union Territories in accordance with standard arrangements for development assistance to the States of India.

Description: The project would constitute a time-slice financing of the National TB Control Program over five years with the purpose of setting up the institutional and managerial infrastructure to establish the Revised Strategy for Tuberculosis Control (RNTP) on a larger scale, and to facilitate its gradual expansion to the entire country within an 8-12 year time frame. The major features of the RNTP strategy which differentiates it from the current National Program include: (a) a focus on patient diagnosis based on sputum analysis rather than X-ray; (b) emphasis on cure of infectious or smear-positive patients through passive case finding to reduce the risk of infection; (c) administration of short-course treatment under directly-observed therapy (DOTS) to prevent development of drug resistance and ensure patient adherence to treatment; (d) a rigorous system of patient registration, monitoring and follow up to ensure high cure rates; and (e) decentralized service delivery to the periphery to facilitate access for the poor.

The project would involve: (a) gradual implementation of the Revised Strategy for TB control (RNTP) in 102 districts, (b) strengthening of the National TB Program (NTP) in 203 short-course chemotherapy districts (SCC) as a transitional step to adopt the RNTP, and (c) strengthening of conventional treatment in the remaining non-SCC districts.
The project has been designed on the basis of the lessons learned from two sets of pilot projects implemented during the past two years to test the feasibility of a revised strategy for Tuberculosis control in India. The foundations built through the pilots and the inputs associated with their implementation provide a sound basis for the proposed project and have resulted in increased interest in TB control in India.

The project components include: (a) improving the quality of care and access to TB Control services through new strategies, policies, technical and operational guidelines; improved drug procurement storage and distribution, and rigorous supervision and monitoring; (b) developing institutional and operational research capacity and enhancing technical and managerial skills by strengthening the National and State Tuberculosis Demonstration and Training Centers, strengthening the Central, State and District TB units, establishing an appropriate management information system, identifying and carrying out priority operational research and upgrading the skills of relevant health personnel and program managers; and (c) developing information, communication and outreach activities and promoting community involvement by implementing a new communication strategy that focuses primarily on improved interpersonal skills between providers and patients, outreach to the private sector and active involvement of NGOs for community participation.

The project’s goal is to reduce preventable mortality and morbidity due to Tuberculosis (TB) by preventing the increase of infectious TB, the annual risk of infection and the development of drug resistance. Specifically, the project would: (a) diagnose and treat a minimum of 1.9 million TB cases including more than 800,000 smear-positive and severe TB cases; and (b) achieve cure rates of at least 85% of newly-diagnosed smear-positive cases in the RNTP districts, the rates achieved in the pilot sites; c) provide treatment with daily short-course chemotherapy to 850,000 smear positive patients in the SCC districts and prepare those districts to adopt the revised strategy; (d) treat about 230,000 smear-positive patients with conventional drugs in non-SCC districts; (e) improve diagnosis to reach at least 50% smear-positive cases as a percentage of total diagnosed cases in RNTP and SCC districts; and (f) improve the system of patient registration and follow up to allow monitoring of treatment completion and cure in the SCC districts.
The proposed project would finance drug purchases, medical and laboratory equipment and supplies, civil works, vehicles, office equipment, communication and educational materials, management information systems and equipment and supplies, professional services, training materials, contractual and consulting services, workshops, fellowships, operations research activities, operational expenses, honoraria and salaries of incremental staff, on a declining basis.

Benefits:

It is expected that by introducing a new paradigm for TB control, the proposed project would begin to reverse the trend of several years of sub-optimal results which has led to a continued high incidence of TB as well as drug-resistant cases. It is estimated that the project would treat about three million TB cases in five years of which about 1.9 million cases would be treated under the revised strategy, including 800,000 new smear-positive or infectious cases. The risk of infection comes primarily from this latter group. If the project objective of 85% cure rate is achieved, a minimum of 1.5 million TB patients would be cured and many more millions of non-infected individuals would potentially be freed from the risk of TB infection and the development of TB disease\(^1\). It is estimated that after the second year of the project, India would be saving about 140,000 deaths from TB per year. This is especially important considering that the TB burden adversely impacts the most economically and socially productive members of Indian society, the 15-44 year old age group.

Moreover, the changes introduced by the project are likely to improve awareness about TB among the people and improve detection and treatment among private physicians who play an important role in TB care.

TB disproportionately impacts those of low socioeconomic status by virtue of their poor living conditions and poor nutritional status. The proposed project would benefit primarily the poor, particularly the rural poor, the urban slum dwellers, and tribal populations by providing them access to appropriate and effective TB care.

Risks and Safeguards:

Most of the common risks associated with PHR projects such as issues of procurement, late disbursement, inadequate

maintenance of equipment, and the software aspects have been considerably minimized by the implementation experience and the commitment gained through the pilot projects. Nonetheless, the project presents other risks, most typically associated with TB control and the introduction of a new technical paradigm. They include:

(a) the risk of significant variation between the estimated number of cases and the actual cases due to the fact that firm information on TB incidence in India is not available;
(b) the inherent risks of a shift in technological and behavioral practices, particularly the difficulties of persuading providers and patients to accept the practice of directly observed treatment and the rigorous features of the DOTS strategy;
(c) the risk of poorly administered short-course chemotherapy drugs and of poor quality anti-TB drugs which would increase the probabilities of developing drug resistance;
(d) the risk that the Central and State TB Cells would be unable to provide the leadership and services required to ensure proper implementation of the program given the scope, the managerial complexity of the revised strategy, and the need to maintain an active constituency for TB control in the government and the community;
(e) the risk of an uneven supply of drugs in light of the spotty record of drug deliveries in India combined with the availability of large quantities of drugs which could be misused;
(f) the risk that the project would not succeed in influencing the private providers in changing their TB practices; and
(g) the continuous challenge of dealing with mobile migrant populations, particularly in urban slum settings.

The estimates of TB incidence in India are based on the best information available at present; however, to ensure greater accuracy on the quantitative objectives, the mid-term review would be used to make a readjustment of the project objectives, as needed, based on the actual experience of the project. This would reduce the risk associated with possible inaccuracies on case estimates; nonetheless, future incidence is likely to be affected by the potential impact of HIV/AIDS.

The Phase I and II pilots implemented as part of project preparation have helped to identify the risks associated with the new approach and to find ways to mitigate them. They have also provided the Central Unit in the Ministry of Health (MOH) with hands-on experience on running the new program, understanding the demands and constraints involved and having the opportunity to make corrections as the project developed. Although the Project’s scope is large, the possibility of expanding the revised strategy to a wider geographical area has generated enthusiasm and
greater commitment among government officials, the medical associations, and other groups. Similarly, the efforts to involve the private sector and the NGOs are beginning to pay off.

The introduction of an appropriate Management Information System (MIS) would help keep adequate control of registration and patient records, including mobile populations. A decentralized approach to treatment with the involvement of the community would facilitate the implementation of DOT. Interruption in the drug supply would be minimized through buffer stocks and monitored through annual independent audits of the drug inventory, distribution and utilization. Quality control of anti-TB drugs would be monitored through independent scientific institutions in addition to the standard government procedures. The packaging of drugs in multi-drug blister packs and per-patient treatment boxes, as well as the introduction of multi-drug combination pills at a later stage would help reduce misuse of medicines; and, the formal involvement of non-government sector representatives in the coordinating bodies of the program and other linkages with the sector would help promote the RNTP approach among private practitioners.
Estimated Project Cost: /a

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<td>61.6</td>
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<td>Capacity Building</td>
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<td>- Institutional &amp; Operations Research Capacity Building</td>
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<td>- Enhancing Technical &amp; Managerial skills</td>
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<td>Develop IEC &amp; Community Involvement</td>
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<td>TOTAL BASE COST</td>
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<td>Contingencies</td>
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<td>TOTAL PROJECT COST</td>
<td>88.3</td>
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<td>176.4</td>
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/a Including Taxes and Duties equivalent to US$11.1 million.
/b Figures may not appear to add due to rounding

Financing Plan:

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Estimated Disbursements:

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<td>Cumulative</td>
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<td>72.8</td>
<td>101.5</td>
<td>129.0</td>
<td>142.4</td>
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Economic Rate of Return: Not Applicable

Poverty Category: Program of Targeted Intervention. One of the main objectives of the proposed project is to expand service delivery to poor and underserved areas and to improve access for women, tribal populations, and the urban and rural poor. The proposed project contains specific strategies for delivering services to these groups.
INDIA
PROPOSED TUBERCULOSIS CONTROL PROJECT

I. INTRODUCTION

A. The Health Sector in India

1.1 India’s health sector agenda of the past decade is based on the 1983 National Health Policy which gives high priority to fertility control, infectious and endemic diseases of public health significance and preventable causes of maternal and child mortality and morbidity. Despite the focus on appropriate priorities, India’s efforts to implement its policies have been weakened due to various managerial and technical reasons. Related to this, India’s burden of disease accounts for over a fifth (21%) of the global burden of disease. Communicable diseases take the greatest toll, accounting for over half (51%) of the Disability Adjusted Life Years (DALYs) lost. In addition, with a growing population of more than 18 million per year and concurrent improvement of life expectancy, India finds itself in the middle of a demographic and epidemiological transition, facing a double burden of communicable and non-communicable diseases which take a special toll on the poor. In recent years, GOI has sought the support of the World Bank's International Development Agency (IDA) to provide financial and technical assistance in eliminating Leprosy, controlling HIV/AIDS, reducing the backlog of Cataract Blindness, strengthening state health systems and promoting state health reforms, and reducing mortality and morbidity from tuberculosis and malaria.

1.2 In this context, the proposed Tuberculosis Control Project would help advance India’s health agenda and meet the long-term goal of helping reduce the incidence of infectious and drug-resistant tuberculosis. The proposed project would be fully consistent with the Government's stated objectives of improving the delivery of health and family welfare services to the poor through the established health system. It would also support GOI's policies and objectives for major disease control, which include: use of appropriate technology; enforcement of appropriate standards of care; improved quality of service delivery through increased emphasis on training, retraining, and non-salary inputs; active participation of the private sector and NGOs; strengthening the capacity of the states and districts in program planning and implementation; and involving the beneficiaries and the communities in their own health care.

B. The Epidemiology of Tuberculosis

1.3 Approximately 2.9 million people die from tuberculosis each year worldwide; about one fifth of them in India alone. The annual incidence of new cases of all forms of tuberculosis is over eight million in the developing world. Resurgence of TB in the
developed world has put the disease back on the front page of the health agenda in cities like New York, Baltimore and Chicago.

1.4 Tuberculosis is unique among the main disease killers of the developing world in that it afflicts nearly all age groups. But the greatest burden of tuberculosis morbidity, disability and mortality is concentrated in adults aged 15 to 59, the most economically active and productive segment of society. It is estimated that 26% of all deaths in this age group is due to tuberculosis. Studies have also shown that tuberculosis affects disproportionately the lower socio-economic groups.

1.5 Tuberculosis is transmitted through inhalation of infectious mycobacteria-laden particles emitted in coughs, sneezes or similar airborne mechanisms. Unlike other diseases, such as measles, in which infection is usually followed by disease, only about 5% to 10% of those infected with the tuberculosis bacilli develops clinical disease. In 80% of such cases, clinical tuberculosis develops within two to five years of infection. 50% of infected adults who develop the disease are smear-positive; they are the source of infection in the community. In the absence of adequate treatment, an untreated smear-positive person might infect, on average, 10 to 14 persons per year.

1.6 Tuberculosis can be controlled with existing technology because the infectious agent is almost exclusively in the tuberculosis person who can be quickly rendered non-infectious. A five percent decrease in the annual risk of infection (ARI) would ensure that the tuberculosis problem in a given community or country would be reduced by one half about every fourteen years. However, inappropriate treatment of TB may lead to continued TB infection and the development of drug-resistant TB.

1.7 Tuberculosis is cured through multi-drug therapy regimens which include combinations of the following drugs: isoniazid, rifampicin, pyrazinamide, ethambutol and, in some cases, streptomycin, as a supplement. Different combinations are prescribed for smear-positive, smear-negative and re-treatment cases. Treatment lasts between 6-8 months under short course chemotherapy (SCC), and 12-18 months under conventional or long course chemotherapy (LCC). Annex 2 provides detailed information on the chemotherapy regimens prescribed for the project under SCC as recommended by WHO.

1.8 Reducing tuberculosis becomes more pressing with the appearance of the HIV/AIDS epidemic. The major effect of HIV infection has been to increase the rate of progression to clinical disease in those already infected with tuberculosis because of the weakness of the immune system which allows the bacteria to develop unchecked. The epidemiological impact of HIV on tuberculosis results in: (a) the reactivation of latent tuberculosis with a high fatality rate; (b) new infection and high rate of progression to active tuberculosis with high death rates, and (c) tuberculosis transmission from these dually infected individuals to the general population, especially in places where the tuberculosis control program is inadequate. An increase in HIV/AIDS cases is likely to result in an increase in TB incidence.
1.9 To arrest this increase in TB, a new strategy for TB control was developed by the International Union Against Tuberculosis and Lung Diseases (IUATLD) and adopted by WHO as the recommended strategy for TB control in the world. The strategy has two goals: to cure the patient and to prevent transmission. The WHO strategy or DOTS--directly observed treatment, short-course--is designed to respond swiftly to these increased risks and make a significant impact in slowing down the TB cycle of infection. The major technical features of the strategy are: (a) targeting the infectious TB sub-group of smear-positive individuals through passive case finding; (b) using sputum examination for diagnosis and treatment evaluation; (c) prescribing a six or eight month recommended multi-drug, SCC treatment regimen; (d) applying directly observed treatment (DOT) in case management; and (e) emphasizing treatment completion and cure of TB patients and cohort analysis of results through simple registers at the sub-district level. In addition, the strategy calls for political commitment, adequate financial resources and regular drug supply. The proposed project would introduce the WHO strategy adapted to the Indian context in selected districts and city corporations, and would promote a major shift in the national strategy for TB control in India.

II. TUBERCULOSIS IN INDIA

A. The Current Situation

2.1 The burden of tuberculosis in India is staggering by any measure. Over 1.2 million TB cases are reported every year through the National Program and the annual mortality rate is estimated at around 500,000. While prevalence rates have remained stagnant at around 1.5% of the population, the number of new cases has been growing steadily. It is estimated that about 1.0 million new smear-positive TB cases develop every year. Without appropriate intervention, it is estimated that cumulative mortality during this decade, leading up to the year 2000, could be as high as 5.0 million tuberculosis deaths. It is estimated that up to 50% of the Indian population is infected with tuberculosis. About 75% of the diagnosed cases occur between the ages of 15 and 45 years old. While two thirds of these cases are estimated to occur in males, TB, takes a disproportionately larger toll among young females, with more than 50% of female cases occurring before 34 years of age.

2.2 HIV/AIDS and Tuberculosis. While the spread of HIV in India may be a recent phenomenon, it is estimated that there could be 250,000 HIV-related TB cases annually by the year 2000. Although they represent only a fraction of the cumulative cases of TB between the years 1990 and 2000, they are a cause of concern since they will be added on to the expected growth of TB incidence in the country. Increasing prevalence of the HIV virus and AIDS, and the evidence of drug-resistant tuberculosis mean that, without a reoriented and enhanced public TB control program, TB will pose an increasingly serious public health hazard with a high economic burden for India for several decades to come.
B. **The National Tuberculosis Control Program**

2.3 **Background.** The National Tuberculosis Control Program (NTP) was initiated in 1962 as a decentralized program in which District TB Control Centers (DTCs) were established to implement the NTP at the District level. In 1976, the NTP was included in the Prime Minister's 20 Point Development Program.

2.4 At the central level, the NTP is managed by the technical arm of the Ministry of Health and Family Welfare (MOHFW), which is the Directorate General for Health Services (DGHS). The Deputy Director General for TB is the technical program director, and the Joint Secretary from the administrative arm of MOHFW looks after the financial and administrative control of the NTP. The Program is supported by selected national and state institutions, prominent among them being the National Tuberculosis Institute (NTI), Bangalore, the Tuberculosis Research Center (TRC) in Madras and the Lala Ram Swarup Institute of TB and Allied Diseases (LRS) in Delhi.

2.5 At the State level, the NTP has a similar dual structure with the Director of Medical Services and the Director of National Programs being responsible for overseeing implementation. Implementation responsibility, however, lies primarily with the State TB Officer. At the state level, in all major states, the NTP is supported by 16 State TB Demonstration and Training Centers (STDTCs) for training and research to help supplement the work of the Central Training Institutions. However, until now these centers have operated primarily as TB Centers for curative care in addition to providing epidemiological data and monitoring the Program at the state level. Their role as training institutions has been minimal.

2.6 At the District level, the District Tuberculosis Officer (DTO), under the direction of the District Medical Officer and the District Public Health Officer, is responsible for implementing the program through the general health care system.

2.7 The major objectives of the NTP are to: (a) diagnose as large a number of cases as possible and provide efficient treatment, giving priority to smear-positive patients; and (b) implement these activities as an integral part of the general health services.

2.8 **Main Issues.** Despite the program's objectives and the importance of the tuberculosis problem, the NTP has been unable to make a significant impact in the epidemiology of TB in India. Overall, the results of the Program have been disappointing. One of the most significant problems has been the focus on case detection which has distracted attention from the prime aim of TB control which is patient cure. Other key factors constraining the effectiveness of NTP have been: (i) low political commitment and serious lack of funds at the central and state levels; (ii) institutional and managerial weakness due to insufficient trained staff, vacant posts and weak linkages with the other TB services and the health system in the periphery; (iii) technical weakness characterized by lack of rigor in the use of short-course chemotherapy (SCC) and reliance on X-ray instead of sputum analysis for diagnosis; (iv) a proliferation of drug regimens;
(v) a private sector which treats over 50% of new TB with an extraordinary variety of ineffective and potentially harmful drug regimens; (vi) a lack of systematic training, quality control and regular supply of drugs; (vii) lack of strategies to ensure the poor have access to TB care and complete treatment; (viii) reluctance of service providers to give adequate information to patients because of stigma and lack of good communication skills; (ix) a poor recording and monitoring system; (x) lack of quality control of laboratory results, and (xi) low cure rates.

2.9 At the same time, because of lack of resources, the NTP has continued to rely on Long-Course Chemotherapy (LCC) treatment of either 12 or 18 months which discourages patients from completing treatment. Although short-course chemotherapy (SCC) has been introduced in almost two-thirds of the country's districts (292 out of 496 districts), drugs are often unavailable or treatment is administered without direct observation and appropriate patient follow-up. The shortage of drugs, the lack of adequate information available to doctors and patients, and the fact that pharmaceutical companies advertise only the drugs they produce and not all the drugs needed for cure, has led to a proliferation of treatment regimens. This, in turn, has led to low treatment completion and cure rates and has raised considerably the risk of increased drug-resistant TB. One of India's major problem with TB is the number of re-treatment cases resulting from previous incomplete treatments.

2.10 Annex 3 provides a detailed description of the organization and functioning of the NTP (including the RNTP) at the different levels with the modifications introduced by the proposed project to correct the shortcomings described above.

2.11 Recent Efforts to Improve the NTP. Recognizing the shortcomings of the National TB Program and the expected increase in the TB incidence, GOI, with support from WHO and the Swedish International Development Agency (SIDA), undertook a detailed program evaluation of the NTP in 1992. The joint review called for a significant overhaul of the NTP and the adoption of a new approach to TB control as advocated by WHO and proven successful in other countries. It recommended: (a) strengthening and reorganizing the Central TB Control unit; (b) adopting new and more rigorous methods for diagnosis, treatment and monitoring of patients, with emphasis on their cure; (c) decentralizing service delivery to the periphery; (d) strengthening training and research capacity; (e) targeting infectious, smear-positive cases; (f) providing SCC with DOT treatment; and (g) introducing a rigorous system of patient recording and monitoring through patient registration books and treatment cards. This new approach, or the Revised National Tuberculosis Control Program (RNTP), was adopted by the Ministry of Health and Family Welfare in 1992. Annex 4 provides further details on the findings of the joint GOI-WHO-SIDA review of the NTP.

2.13 Pilot Activities. The logistical inputs, technical skills and quality of supervision demanded by the RNTP required a carefully orchestrated management system which had
to be tested under real-life conditions in the Indian context. Similarly, the need to involve key stakeholders called for a participatory approach in project design through pilot and other participatory activities. The first set of five pilots (Phase I) was initiated in 1993 with financing from SIDA and technical assistance from WHO. It tested and demonstrated the technical feasibility of the RNTP in India. Sputum conversions and patient cure using SCC with directly observed treatment (DOT) were achieved with high success rates, compared to those obtained from the previous NTP.

2.14 However, while the Phase I pilots showed successful outcome in terms of patient cure, it also pointed to numerous institutional and managerial weaknesses which had to be addressed before a large scale intervention could be considered. Failures in timely delivery of inputs, supervision and follow-up during Phase I raised questions about the feasibility of program implementation in several states. This prompted the Government of India to request financing for a second phase of pilots. A Project Preparation Facility (PPF) advance was approved by the Bank on November 30, 1994 to initiate new pilot sites in several more states and city corporations under a Phase II. Phase II was designed to test the technical and managerial feasibility of implementing the revised strategy on a larger scale, including the institutional capacity of the central, state and district authorities to carry out the RNTP with the necessary rigor to ensure efficient and effective program implementation.

2.15 The Government of India and the World Bank agreed that the findings of the two sets of pilots (Phases I and II) would serve as the basis for considering World Bank financing of the proposed Tuberculosis Control Project in a larger number of districts. The findings of the IDA Pre-appraisal mission (January 22- February 9, 1996), which reviewed the implementation of the pilots in Phases I and II, confirmed that the revised strategy, with all its features, could be implemented successfully in India.

2.16 The proposed project would constitute Phase III of this process and it would address the issues currently constraining the NTP by: (i) introducing a new and rigorous strategy for TB control; (ii) strengthening the managerial, technical and training capacity of the NTP, (iii) introducing a comprehensive approach to information, education and communication (IEC) that involves private physicians, NGOs, and the communities, and focuses on patient-provider communication; (vi) strengthening the technical knowledge and skill of service providers inside and outside the government; and (v) promoting the integration of TB services throughout the health system.

C. External Assistance to the NTP

2.17 In the past three years, especially with the pilots in Phase I, the NTP has benefited from the financial assistance of SIDA and the technical assistance of WHO. In addition, the British Overseas Development Administration (ODA) was a co-finanier on the Phase II pilots, with an investment of US$1.4 million to cover immediate staffing needs in the Central TB Division and equipment and facility expenses which were not covered by the PPF advance. In view of the progress made in the pilots of Phase I and II, the Danish
International Development Assistance (DANIDA) is financing the implementation of the new RNTP in 14 tribal districts in the State of Orissa with an investment of approximately US$14 million, and ODA is considering financing a similar intervention in the State of Andhra Pradesh for approximately US$25 million. IDA has worked closely with the other donors to ensure coherence and complementarity of investments and approaches.

D. Lessons from Experience

2.18 The WHO tuberculosis control strategy to be adopted by the proposed project is based on the lessons learned from rigorous evaluations of TB control projects throughout the world by notable TB experts. These lessons have been incorporated in the five key elements of the WHO policy for TB control: (a) the need for government commitment to an effective TB program; (b) a focus on case detection through predominantly passive case finding; (c) administration of standardized short-course chemotherapy to at least all smear-positive cases, under directly observed treatment; (d) establishment and maintenance of a system of regular drug supply, and (e) establishment and maintenance of an effective monitoring system for program management and evaluation. The WHO strategy has been proven effective in several countries including Tanzania, China, Bangladesh, and Peru. Experience from Bank lending for TB Control has been limited to projects that do not focus on TB control alone, e.g., Lesotho’s Health and Population project, China’s Infectious and Endemic Disease Control Project, Bangladesh’s Fourth Population and Health project and Zimbabwe’s Sexually Transmitted Infections Prevention and Health Care project. The China and Bangladesh projects offer the best example for India as they follow the WHO strategy and, in the case of China, it faces a problem of similar magnitude as in India. The main lessons learned from these projects pointed to the need for case detection through passive case finding, avoiding government charges for TB services, and issues of sustainability for directly observed treatment. These lessons have been taken into account in the design of this project. The proposed project would be the first Bank lending operation to focus solely on tuberculosis control responding to the particular situation of India and its burden of disease.

2.19 The findings from Phase I and II pilots in India provided the most relevant lessons for the design of the proposed project. They yielded critical information to help define the roles of the management units at each level, the amendments needed in the technical and operational guidelines, the technical specifications of certain medical inputs, and the procurement and distribution systems. They also pointed to the need for: (a) a strong Central Management Unit that would provide clear and decisive leadership and management direction; (b) a broader project scope in order to elicit the political will needed for successful TB control; (c) an effective and rigorous training program that would facilitate the transfer of knowledge needed to implement the new technical approach; (d) creative institutional arrangements to help promote the adoption of the revised strategy not only within the existing TB structure but most importantly throughout the health system; and (e) a strong involvement of the private and NGO sector given the important role private physicians play in TB treatment in India. Further details
on the lessons learned are given in Annex 5. An expanded description of the pilots and
their findings is given in Annex 11.

E. **Country Assistance Strategy and Rationale for IDA Involvement**

2.20 The World Bank Group’s Country Assistance Strategy (CAS) for India (June 20,
1995, Report No. 14509-IN and update of August 15, 1996) is designed to support the
efforts of the Government of India in promoting economic growth through strong private
sector involvement and developing India’s human capital resources. The Bank’s
assistance strategy for the health sector in India is consistent with the CAS and is
implemented through a two-pronged approach. The first is to reduce the burden of
diseases from major public health problems by supporting priority programs, and the
second is to strengthen state health systems and promote state health sector reform to
provide more efficient and effective health care, particularly for the poor. The proposed
project is an integral part of both IDA’s Country Assistance Strategy and its health
strategy for India.

2.21 IDA investment in the proposed project is justified on several grounds. First, the
project would direct resources to one of the most cost-effective health interventions, i.e.,
short course chemotherapy for smear-positive TB patients\(^2\). Second, it would advance
IDA’s health strategy to support India’s efforts in fighting major public health problems
and strengthening its health systems by integrating TB care with the general health
services. Third, it would support IDA’s objective to reduce inequalities in health care by
improving access for disadvantaged populations, particularly women, slum dwellers and
scheduled tribes. Fourth, IDA has a comparative advantage in serving as a catalyst in
bringing the changes needed for tuberculosis control in India because of IDA’s ability to
harness cooperation of important institutions in the health sector, both in India and
worldwide. Finally, IDA’s intervention would provide a unique opportunity to shift the
current focus of TB control from a purely medical to a public health approach,
emphasizing the cure of infectious cases to reduce TB transmission. The anticipated
reduction in the risk of infection of TB would benefit the whole community, producing
significant positive externalities.

III. THE PROJECT

A. **Background**

3.1 As noted earlier, the proposed project has been prepared through the implementation of pilot projects in India designed to test a new strategy for Tuberculosis control with a focus on patient cure rather than case detection. Through September 1996, the pilot projects have treated a total of 15,821 patients in a population base coverage of roughly 12 million with cure rates as high as 92% and 80%, on average, for all the sites.

3.2 The implementation of the pilot projects involved field testing the revised strategy in 15 different urban and rural sites in India. This required intensive work on the part of the central, state and district TB officials and renowned TB specialists from major international and Indian TB organizations to supervise and monitor the pilot projects and complete the preparation of the proposed project. Project preparation also involved interactions with pharmaceutical manufacturers of anti-TB drugs worldwide to discuss and find solutions to issues related to availability, packaging and testing of anti-TB drugs within the context of a large public health intervention and exchanges with numerous representatives of the private and NGO sector in India to encourage their participation in the design, preparation and implementation of the project and to learn from their own experiences. Paras. 4.31 through 4.41 and Annex 22 give a fuller account of the status of preparation of the project.

3.3 The experience of the pilot projects described above served as the basis for the project design and has led to an increased demand for TB control services throughout the country. To a large extent, the project activities related to the revised strategy are already under implementation; the challenge for the project would be to expand those activities, with the same degree of success, to new project areas.

B. **Project Strategy**

3.4 The project would be the main vehicle to facilitate the transition of the National Tuberculosis Control Program (NTP) to the revised strategy for TB control (RNTP). The project’s strategy to achieve this goal is two-fold: (a) to consolidate the implementation of the revised strategy initiated through the pilot projects by expanding it to cover 30% of the population of the country; and (b) to pave the way for a full expansion of the strategy to the rest of the country through selected investments. In view of the rigor required by the implementation of the revised strategy, this expansion would be achieved in a phased manner and through a system of district eligibility for entry into the RNTP.

C. **Project Scope**

3.5 The Project would constitute a time-slice financing of the national TB Control Program over five years with the purpose of setting up the institutional and managerial infrastructure to establish the Revised Strategy for Tuberculosis Control (RNTP) in a
larger scale, and to facilitate its gradual expansion to the entire country within an 8-12 year time frame.

3.6 The project would strengthen the National TB Program for the entire country through the following interventions: (a) full implementation of the Revised Strategy for TB control (RNTP) in 102 districts; (b) strengthening of the National TB Program (NTP) in 203 districts now nominally under short-course chemotherapy (SCC), in preparation for initiating RNTP activities in the future; and (c) strengthening provision of services under conventional TB treatment in 154 non-SCC districts. This would involve modification of Program policies and procedures through new operational and technical guidelines, strengthening of the National and State Tuberculosis Demonstration Centers, strengthening of the central, state and district TB units, establishment of the required management systems for implementation of the RNTP, improved and expanded selection, training and retraining of staff, improved drug procurement, planning, storage and distribution, rigorous monitoring and supervision, and effective communication and information systems. Table 3.1 on page 11 provides a summary of these interventions, their coverage and the inputs required.

D. Project Goal and Objectives

3.7 The main feature of the proposed project is the introduction of a revised strategy for Tuberculosis control to cover one third of the Indian population. It involves a major paradigm shift designed to focus on the cure of infectious cases. The goal of the proposed project is to reduce mortality, morbidity and disability due to TB by curing TB cases, thereby reducing the incidence of infectious TB, the annual risk of infection and the development of drug resistance.

3.8 Within this overall goal, the specific objectives of the project would be to: (a) effectively diagnose and treat about 1.9 million TB cases, including an estimated total of more than 800,000 smear-positive and severe TB cases under the revised strategy (RNTP) for TB Control; (b) achieve 85% cure rate in the RNTP districts for newly diagnosed smear-positive cases; (c) provide treatment with daily short-course chemotherapy to 850,000 smear positive patients in the SCC districts, achieving a 60% cure rate while preparing those districts to adopt the revised strategy; (d) treat about 230,000 smear-positive patients with conventional drugs in non-SCC districts; (e) improve diagnosis to reach at least 50% smear-positive cases as a percentage of total diagnosed cases in RNTP and SCC districts; and (f) improve the system of patient registration and follow up to allow monitoring of treatment completion and cure in the SCC districts. The above quantitative objectives are based on the best estimates of TB prevalence and incidence in India and may require revision during the mid-term review based on actual experience.
Table 3.1 - Project Areas at a Glance

<table>
<thead>
<tr>
<th>RNTP Project Districts</th>
<th>SCC Districts (Not yet planned for implementing all RNTP measures)</th>
<th>Non-SCC Districts</th>
</tr>
</thead>
<tbody>
<tr>
<td>89 Already SCC Districts</td>
<td>166 in initial 15 RNTP states</td>
<td>96 in 8 of the &quot;RNTP Project&quot; states</td>
</tr>
<tr>
<td>13 Non-SCC Districts</td>
<td>-37 in 14 &quot;already SCC&quot; states</td>
<td>55 in 11 of the &quot;already SCC&quot; states</td>
</tr>
<tr>
<td>102 Total Districts</td>
<td>203 Total Districts</td>
<td>3 districts in 3 states that are neither RNTP or &quot;already SCC&quot;</td>
</tr>
<tr>
<td>271 million population</td>
<td>447 million population</td>
<td>154 Districts (some of which may have already been split)</td>
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<tr>
<td>(30%)</td>
<td>(49%)</td>
<td></td>
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<tr>
<td>15 Total States</td>
<td>29 Total States</td>
<td>14 &quot;already SCC&quot; states</td>
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<td></td>
<td>11 Total States</td>
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<td>3 New States</td>
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<td></td>
<td>22 Total States</td>
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<td>Project Interventions</td>
<td>Project Interventions</td>
<td>Project Interventions</td>
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<td>- Strengthening State TB Cell</td>
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<td>- Strengthening State TB Cell</td>
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<td>- Strengthening Tr &amp; Demo Centre</td>
<td>- Strengthening Tr &amp; Demo Centre</td>
<td>- Strengthening Tr &amp; Demo Centre</td>
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<tr>
<td>- Training at all levels</td>
<td>- Training to District Level</td>
<td>- Training to District Level</td>
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<tr>
<td>- Strengthening Labs</td>
<td>- Strengthening Labs</td>
<td>- Strengthening Labs</td>
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<tr>
<td>- Patient Records per RNTP</td>
<td>- Patient Records (like RNTP system)</td>
<td>- Patient Records (like RNTP system)</td>
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<tr>
<td>- IEC for Service Providers</td>
<td>- NGO/Private Sector Strategy</td>
<td>- NGO/Private Sector Strategy</td>
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<td>- Operations Research</td>
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<td>- Monitoring &amp; Evaluation system</td>
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<td>- NGO/Private Sector Strategy</td>
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<tr>
<td>Bank Funding for Drugs...</td>
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<tr>
<td>- Cat I, II &amp; Ill Drugs under DOT</td>
<td>- Modified Regimen for</td>
<td>- Conventional drugs for smear +ve</td>
</tr>
<tr>
<td>- Cat I, II for smear +ve until DOT is fully phased into district</td>
<td>Cat I, II Drugs for smear +ve</td>
<td></td>
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<tr>
<td>- Conventional Drugs for smear +ve until DOT is phased into district</td>
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<tr>
<td>Roughly US$ 98.6 Million Total Project Cost</td>
<td>Roughly US$ 67.1 Million Total Project Cost</td>
<td>Roughly US$ 10.7 Million Total Project Cost</td>
</tr>
</tbody>
</table>

E. Policies and Strategies

3.9 The project would bring a significant change in the main policies of the National Tuberculosis Control Program. The following policies and strategies have been adopted by the Ministry of Health and Family Welfare as part of the implementation of the Pilot projects and would be extended to all areas covered by the proposed project under the revised strategy (RNTP). In addition, certain policies would be adopted by the National...
Program for application nationwide. These new policies and procedures would address the Program's issues and constraints identified in para. 2.8 above. They include:

(a) A new **technological paradigm** for case identification, diagnosis, treatment and follow up which involves (i) focus on infectious, smear-positive patients; (ii) passive case finding; (iii) diagnosis and treatment evaluation based on sputum analysis rather than X-ray; (iv) case management under directly observed treatment (DOT); (v) appropriate patient follow-up to ensure patient adherence to the drug regimen and the treatment evaluation protocols; (vi) consolidation of diagnostic capacity at selected sites and decentralization of treatment to the periphery to facilitate access; and (vii) provision of drugs, generally in blister packs or combination pills for all patients who have started treatment.

(b) A **modified organizational structure** at the central, state, district and sub-district level that would be more consistent with the technical, operational and managerial requirements of the revised strategy and would facilitate the integration into TB services to the general health system.

(c) New **training policies** consistent with the requirements of the revised strategy and designed to strengthen the role of the training and technical institutes in training and quality control. Training would combine hands-on clinical and laboratory training with first-hand observation of the new operational practices as applied in the pilot areas.

(d) New methods of **assessment and quality control** based on outcome indicators such as sputum conversions from positive to negative and on cure rates of 85% under RNTP and 60% in SCC districts, rather than case finding targets. These assessments would rely on a rigorous new patient registration and notification system which is based on quarterly cohort analyses, and collects essential data such as previous history of TB, treatment completion and cure, transfers, defaulters, deaths and treatment failures.

(e) A **new approach to drug procurement, inventory and distribution** to ensure uninterrupted supply and availability of high quality drugs.

(f) **New information, education and communication strategies** that focus primarily on provider-patient interpersonal communication and are designed to help patients overcome the barriers to treatment adherence.

(g) **Targeted strategies** to facilitate access and improve quality of services for disadvantaged groups, particularly tribal populations, women and mobile groups.

(h) New mechanisms for **NGO/government collaboration**.

(i) New mechanisms to promote the **involvement of the private sector** in the RNTP through better case notification, more accurate patient diagnosis,
treatment and evaluation, or appropriate referral to government diagnostic and treatment facilities.

3.10 These policies are consistent with the recommendations of the 1995 Central Council of Health which underscored the seriousness of the Tuberculosis problem in India as described in Annex 6.

3.11 During negotiations, the Government of India provided assurances that it will implement the project and shall cause the Project States to implement the project according to the policies and norms agreed to during preparation and described in this document, and they will not make any changes to the Program policies or guidelines, which, in the reasonable opinion of IDA, would adversely affect the project.

F. Project Description

3.12 To meet the stated objectives, the project would finance activities and inputs under three main components: (i) improving the quality, access and outcomes of TB treatment; (ii) developing institutional and operational research capacity and enhancing technical, managerial and interpersonal skills; and (iii) developing information, communication and outreach activities and promoting community involvement. Overall, the project would initiate a shift in the epidemiological profile of tuberculosis in India by focusing on the cure of infectious patients.

IMPROVING THE QUALITY, ACCESS AND OUTCOMES OF TUBERCULOSIS TREATMENT (US$130.0 million, 85% of the base costs)

3.13 Under the project, service delivery would be provided under three different modalities based on the TB control strategy operating in each category of districts as described in Table 3.1 on page 11. The three modalities are: (a) the revised strategy of directly-observed, short-course chemotherapy (DOTS) for TB control or RNTP, to be fully implemented in 102 districts; (b) the regular short-course chemotherapy (SCC) approach currently in effect, at least nominally, under the National Program in 203 districts; and (c) the conventional, long-course chemotherapy approach (non-SCC) currently under effect in 154 districts. The project would finance interventions in each of these three categories of districts with the purpose of raising the quality of treatment under all three approaches. This would allow for a gradual transition to the revised strategy while optimizing the resources available for TB throughout the country.

3.14 Directly Observed, Short-Course Chemotherapy (DOTS) or Revised National Tuberculosis Program (102 districts). The center-piece of this component is the full package of services provided under the revised strategy for TB control in 102 districts and metropolitan cities, covering a population of 271 million in 15 states. This involves (a) accurate patient diagnosis through accurate history taking followed by high quality sputum microscopy, to determine the appropriate category of TB patient and treatment regimen; (b) appropriate communication between service provider and patient to ensure
understanding of the treatment involved; (c) appropriate dispensation of medicines under
direct observation to guarantee treatment adherence and patient satisfaction; (d) strict
follow up and evaluation to ensure sputum conversion to non-infectious status; and (e)
rigorous registration, supervision and monitoring system for cohort analysis to evaluate
treatment outcomes and risks. The technical, operational and laboratory guidelines
completed as part of project preparation provide detailed explanations about patient
classification, types of drug regimens to be administered, case diagnosis, registration,
management, and patient follow up. Excerpts from these guidelines are included in

3.15 Clinical diagnosis would be performed at any health facility selected by the
patient; however, laboratory diagnosis would take place at selected microscopy centers
(MCs) which would be upgraded under this project component. Concentration of
diagnostic work in selected facilities would raise the proficiency of laboratory workers
and increase the level of accuracy in diagnosis. The selected diagnostic or microscopy
centers would become referral centers for diagnostic and follow up purposes only. Once
the patient has been identified and diagnosed as having TB, treatment would be delivered
at the health facility closest to the patient’s home and a designated health worker or
community volunteers would be identified to provide directly observed treatment (DOT).
The short-course chemotherapy (SCC) regimen used requires that the medicines be
administered under direct observation and strict patient follow up and evaluation. Quality
control of laboratory diagnosis, patient registration and final outcomes would be
monitored by a sub-district team (Tuberculosis Unit) according to a regular supervision
program and reporting responsibilities. The different regimens to be used for each
category of patient under the revised strategy are described in Annex 1 and Annex 2.

3.16 Expansion of the revised strategy (RNTP) would be done in a phased manner. It
is expected that 39 districts would initiate activities in the first year, 39 in the second and
24 in the third. In all cases, however, participation by a district under the RNTP would
be based on the districts meeting the eligibility criteria described in Annex 7.

3.17 For these 102 RNTP districts under this component, the project would finance
investments in civil works, laboratory and other equipment, vehicles, drugs, salaries of
additional staff, honoraria to DOT workers (excepting salaried government health
workers), incremental operating costs, laboratory supplies, vehicle and equipment
maintenance.

3.18 Standard Short-Course Chemotherapy (203 SCC districts). Under this
component, the project would finance inputs and activities to strengthen existing TB
services and introduce certain features of the revised strategy in 203 districts currently
operating nominally under short-course chemotherapy regimens. Despite their
denomination as “short-course chemotherapy” districts, many of them lack sufficient
inputs to provide appropriate services under SCC. Through this project, such districts
would receive a regular supply of short-course chemotherapy drugs for smear-positive
patients under the standard regimen for short-course chemotherapy used by the National
Program (see Annex 2). The project would also provide inputs to improve laboratory diagnosis, patient classification and registration, and evaluation of treatment results through cohort analysis. The SCC drugs for smear-positive patients would be provided by the center to the states with the understanding that the state would provide a regular supply of conventional drugs to treat smear-negative patients according to the regimen described in Annex 2. The 203 districts would adopt the diagnostic and registration system of the RNTP in preparation for full transition to the revised strategy.

3.19 During negotiations, the Government of India provided assurances that: (a) the SCC treatment regimen provided for the SCC districts would not include rifampicin in the continuation phase; (b) the RNTP patient registration and reporting system would be utilized in those districts and (c) the supply of SCC drugs by the Project to a district will be liable to be discontinued if the district fails to maintain an annual average of 60% cure rate after the first two quarters of implementation.

3.20 For these 203 SCC districts, the project would finance investments in civil works, laboratory and other equipment, drugs for smear-positive patients only, vehicles and salaries of additional staff at the district level only, incremental operating costs, laboratory supplies, vehicle and equipment maintenance.

3.21 Long-Course Chemotherapy Districts (154 non-SCC districts). Under this component, the project would finance inputs to improve the quality of TB treatment under conventional or long-course chemotherapy (LCC) for smear-positive patients by ensuring a regular supply of LCC drugs. The Center would provide LCC drugs for smear positive patients while the states would provide the same drugs for all other patients. For the 154 non-SCC districts, the project would finance conventional or LCC drugs for smear positive patients.

3.22 During negotiations, the Government of India provided assurances that it will provide drugs on a regular basis to all smear-positive cases in the non-RNTP districts, and it will ensure that conventional drugs have been provided for smear-negative patients based on expected case load.

3.23 NGO and Private Sector Involvement in Service Delivery. The project would give particular emphasis to NGOs and private practitioners involvement in the RNTP districts. Several modalities for their involvement have been discussed and would be implemented through the project; these would include, for example: (a) providing free medicines to NGOs who adopt the RNTP strategy; (b) arranging to provide training and orientation to private practitioners in exchange for managing TB patients under agreement of case notification to the government; (c) involving NGOs and private practitioners in operations research activities which involve service delivery; (d) providing free directly observed treatment to patients diagnosed by private practitioners who are following the RNTP criteria; (e) providing educational materials and other IEC inputs to NGOs or private practitioners for community involvement; (f) providing diagnostic facilities at identified centers, treatment evaluation, drug supply referral sites
for referrals from private practitioners and NGOs; and (g) possibly contracting with an organization to provide comprehensive RNTP services at a district or sub-district level.

3.24 During negotiations the Government of India provided assurances that, where RNTP is being carried out, the Project States will develop and implement (a) a strategy for involvement of NGOs and Associations such as the Indian Medical Association; (b) a strategy for qualified medical practitioners which could include medical education, information and communication on various aspects of TB and referral mechanisms for RNTP; and (c) a strategy to promote referral of symptomatic patients to RNTP by other health practitioners. It was also agreed that specific annual plans for such strategies would be furnished to the Association no later than March 31 every two years.

DEVELOPING INSTITUTIONAL, OPERATIONAL AND RESEARCH CAPACITY AND ENHANCING TECHNICAL, MANAGERIAL AND INTERPERSONAL SKILLS (US$16.2 million, 11% of base costs)

3.25 The success of the project would depend largely on increased institutional capacity at the central, state and district level and upgrading the technical, managerial and interpersonal skills of the different categories of staff involved in the project. To achieve this, the project would finance activities related to organizational development and training.

3.26 Institutional Capacity. Managerial effectiveness is a central requirement for the success of the program, particularly under the RNTP. The project would provide inputs for strengthening the Management Cells at the central, state, city, district and sub-district level and adopting effective supervision, monitoring and communication systems. It would also support inputs for strengthening the Central Training and State Institutes and State Demonstration and Training Centers.

3.27 The Organizational Design of the RNTP. The organizational structure of the RNTP requires: (a) a strong Central Management Cell that can provide technical and operational guidance, appropriate supervision, adequate inputs and close program monitoring to the States; (b) a State Management Unit that would ensure integration of the strategy into the general health system, would coordinate all state TB activities and monitor the program throughout the state; (c) a District Management Unit responsible for providing technical guidance, supervision, and logistical support to the periphery; and (d) a number of Sub-district Tuberculosis Units (TU) to act as links between the district and the periphery and carry out strict supervision and quality control of the program including patient registration, diagnosis, case management and reporting. These supervisory units (TUs) constitute the only new feature of the organizational structure. The success of the RNTP depends heavily on the effective functioning of these units. A network of "microscopy centers" established per 100,000 population in different health facilities would report to the TUs and serve as diagnostic and evaluation centers. Treatment would be offered in the periphery at PHCs and subcenters by health staff and community health workers. The project would support strengthening of the management units at different
levels as described below.

3.28 Management Unit at the Central Level. The Central Tuberculosis Division in the Ministry of Health has been strengthened during the past two years based on the requirements of the pilot projects. During this time, they have played a major role in the preparation of the project and the staff are fully familiar with the requirements for project implementation. However, with the new project scope, the Central Division would need to be strengthened further. The Division would manage the project at the central level. Its overall responsibility would be to provide leadership, supervision and direction to the program and be accountable for consolidating the transition to the RNTP. A National Program Director at the level of Deputy Director General (DDG) dedicated solely to the management of the TB Program has been appointed.

3.29 The Division's main responsibilities would be to prepare, disseminate and enforce technical and operational policies and guidelines; ensure compliance with the program policies, provide technical assistance to the states and districts; ensure quality control and monitor program implementation. The supervisory and monitoring role of the Central Management Unit is described in Annex 20.

3.30 The planning, administrative policy decisions, accounting, budgeting, financial management, other administrative decisions, recruitment and coordination would be undertaken by the administrative division of the Ministry of Health under the supervision of the Joint Secretary responsible for the Tuberculosis Program. This administrative division will be strengthened by adding one new official at the level of Undersecretary and two assistants. The training, IEC and staff recognition activities of the project would be a joint responsibility with the technical unit. A Coordination Committee or National Tuberculosis Control Board would be established at the National level to review the planning, implementation and evaluation of the program, make financial recommendations and coordinate activities with NGOs, the private sector and international donors. In addition, the Central Division would identify areas and mechanisms of coordination with the National AIDS Program to ensure adequate inter-program support.

3.31 Management at the State Level. The State TB Cells have been strengthened as part of the pilot projects in the States where the RNTP would be implemented. However, further strengthening would be needed with the expansion of the project scope. The State Tuberculosis Control Cell would be responsible for overseeing the implementation of the project in the participating districts. Specifically, they would be responsible for (i) ensuring adequate supply of inputs to the service facilities, including drugs and laboratory supplies; (ii) ensuring district compliance with eligibility criteria for participating in the proposed project; (iii) overseeing the functioning of the District TB Centers; (iv) coordinating TB activities with other health institutions; (v) identifying and correcting bottlenecks in implementation; (vi) overseeing implementation of staff training plans; and (vii) ensuring quality control and appropriate recording for monitoring of project outcomes.
3.32 The State Cell would be responsible for the supervision and monitoring of the program throughout the state, including metropolitan cities, and for ensuring the integration of the revised strategy throughout the health system. To respond to these demands, the existing State TB cells would be strengthened with additional staff and equipment. The position of TB State Program officer would be upgraded to give the program the prominence required. The State TB Officer would be assisted by a Medical Officer, an IEC officer, a Personal Assistant and an Accountant. A State Coordinating Committee would be established to ensure appropriate integration of the RNTP with health institutions outside the National TB Program and with NGOs and the private sector.

3.33 **District Level Management.** The District Tuberculosis Center (DTC) is the key organizational unit responsible for implementation of the Revised Tuberculosis Control Program (RNTP). The role of the DTC would change from being only a service provider to one involving Program management, training, drug distribution, supervision, and monitoring at the district level. The success of the Program would depend largely on the effectiveness of the District TB Center, and the District TB Officer would play an essential role in ensuring that the operational and technical policies of the program are appropriately implemented in the district. The DTCs would be strengthened with medical and laboratory equipment and supplies, civil works, office supplies, vehicles and office equipment. The District TB Center would be supported by Sub-district TB Units (TUs) comprising of a Senior TB Supervisor (STS) and a Senior TB Laboratory Supervisor (STLS). These sub-district supervisory units serve as the link between the district level and the periphery and provide the rigor to the program’s management system as they ensure appropriate case management and patient registration and reporting. The supervisory team would supervise the work of different categories of staff at the periphery in their jurisdiction. TUs would be established at existing CHCs or Taluk or sub-district hospitals for every 300,000 - 500,000 population. The composition and role of the Tuberculosis Unit is described in Annex 3.

3.34 During negotiations, the Government of India provided assurances that the Central Unit and the RNTP units in the Project States will be adequately staffed and maintained for the duration of the Project and at least 50% of the additional staff at the Central and the RNTP State Cells will be in position by July 1, 1997, and 90% of the staff shall be in place by December 31, 1997. It was also agreed that a full time State TB Officer would be in position by July 31, 1997 in all RNTP states, and District TB Officers will ordinarily remain in their posts for a minimum of two years.

3.35 **District Tuberculosis Societies.** To provide administrative support to the District TB Center or corporation subdivision, a District TB Society or equivalent society would be formed prior to the implementation of the RNTP. The purpose of the society would be to facilitate the transfer of funds from the center to the periphery, plan and coordinate TB activities with the NGO and the private sector, engage temporary workers, purchase small quantities of medical and office items, and carry out other administrative responsibilities.
An important innovation of the TB Society is that they would be authorized to raise their own funds for TB control. In some states, the existing District Leprosy Society would be expanded to include TB while in others a new Society would be established for TB. The role and constitution of the Society is described in para. 4.27 below and in Annex 8.

3.36 During negotiations, the Government of India provided assurances that: (a) all District TB Societies, or equivalent society, will have been established by March 31, 1997 in the first 39 RNTP districts, by January 31, 1998 in the next 39 RNTP districts, and by January 31, 1999 in the remaining 24 RNTP districts; and (b) no RNTP activities can be initiated prior to the establishment of a District TB Society.

3.37 City Level Management. Cities operate under a separate and independent organizational structure outside of the structure of the Tuberculosis Control program. The TB Management Unit at the city level would be the responsibility of the designated Health Officer of the municipal corporation, under the overall guidance of the Corporation Commissioner. The District TB Officer of the District where the corporation is embedded would also be a member of that management team. As in the case of the districts, the larger cities would be divided into zones. TB Units with supervisory teams would be established to supervise the microscopy or diagnostic centers designated for every million population. These units would be staffed with one Senior Laboratory Supervisor (STLS) available for every 500,000 population and one Senior Tuberculosis Supervisor (STS) available for every three to four microscopy centers.

3.38 Central Training Institutes. The National TB Institute (NTI) in Bangalore, the Tuberculosis Research Center (TRC) in Madras, the Lala Ram Swarup Institute of TB and Allied Diseases (LRS) in Delhi, and the All India Institute of Hygiene and Public Health (AIH&PH) in Calcutta would play a pivotal role in the implementation of the RNTP by providing the training and quality control required by the revised strategy. In addition to these institutes, other institutions such as the National Institute of Communicable Diseases (NICD), selected medical colleges, and institutions of prominence in the states would also be designated as Central Institutes following an evaluation based on the criteria stated in Annex 9 and in consultation with the Association. All these institutes would have responsibility over designated districts or subdistricts as assigned by the Central TB Division. They would be responsible for training trainers, monitoring and evaluating the quality of training, and producing appropriate training materials. In addition, the institutes' responsibilities may include ensuring quality of laboratory work, performing culture and sensitivity tests for epidemiological purposes, and involving under and post-graduate medical students and the faculty of medical colleges and affiliated hospitals. The selected institutes would be provided with laboratory equipment, vehicles, all training materials for the expected category of trainees.

3.39 During negotiations, the Government of India provided assurances that (a) the designated Central Institutions would adopt and promote RNTP in all activities relevant to the Project and will carry out their training, monitoring and quality control functions,
including the development and maintenance of demonstration sites for field practice, in accordance with agreed procedures; (b) an annual report on the Central Institutions’ performance and recommendations for action will be furnished to IDA by December 31 of each year during the first three years of the Project; and (c) continued involvement of these institutions in the activities of the Project will be determined by mutual agreement between IDA and MOHFW based on their performance.

3.40 State Demonstration and Training Centers. One of the most important project interventions for capacity building is the strengthening of 16 State Demonstration and Training Centers which would play a major role in training of several categories of staff at the district level, conduct surveillance of drug resistant cases, and operations research, on a selective basis. Given the uneven performance level of these institutes, strengthening would be linked to their level of effectiveness in implementing their expected functions. Initially they would receive equipment, vehicle and training aids. Inputs for civil works, additional laboratory equipment, other equipment, salaries, vehicles and related expenses would be linked to performance after the first year of the project. Centers would be evaluated according to the criteria detailed in Annex 9.

3.41 Strengthening Monitoring and Evaluation. The project provides for several mechanisms to ensure appropriate project monitoring, ensuring quality control and rewarding good performance. The strategy to be used for this purpose includes: (a) a system of regular supervisory visits at all levels which include bi-annual appraisal missions by the Central TB Division to assess readiness of districts to move into the RNTP, based on agreed eligibility criteria; (b) a management and information system that would allow for data analysis at different levels and as input for management decisions; (c) a set of clear performance indicators to measure project performance; and (d) a recognition system to acknowledge successful performance by units, teams or individuals at different levels. Details of the monitoring process are discussed in paras. 4.42-4.43 below. For this portion of the institutional building component, the project would finance local and international travel expenses, workshops, hardware and software, equipment maintenance, consulting services, and incremental salary costs. During negotiations, the Government of India provided assurances that: (a) only such districts which have met the eligibility criteria for each level of participation will participate in the RNTP; (b) the first two appraisals of the districts’ eligible to enter the RNTP will be submitted to IDA for review prior to MOHFW approval; and (c) the borrower would provide IDA a sample of 20% of district project appraisals approved by the borrower for review by IDA on an ex-post basis.

3.42 Management Information Systems. An important institutional strengthening aspect of the project would be the establishment of an effective (MIS) system that would facilitate project monitoring. The rigorous registration and recording system characteristic of the revised strategy and the cohort analysis approach provide sound basis for project management if the information can flow effectively from the districts to the project management units. Until now, the information collected in the pilots is paper-based. This approach would continue during the first year of the project as the amount
and source of the data would still be limited; however, by the second year, a system would be in place to allow for electronic flow of data from the periphery to the Center through the intermediate units.

3.43 The Management Information System (MIS) for the program would be linked to NICNET, the national health information management system used by the MOH to collect data nationwide. The system would be the main vehicle for the communication of information from the district level to the state, and then to the central level, and back down again. The primary advantage of NICNET in the proposed MIS is that it is already functioning and that the network reaches all district, state, and key central government institutions. The use of NICNET would also be consistent with existing government policy to support a standardized health information management system.

3.44 However, to meet the need for more user friendly interfaces than what NICNET can offer, a new system would be developed so that while NICNET would be the communication medium, the system interface would be more user friendly for program managers at the central, state, and district levels, and would allow for the compilation, analysis, and graphic presentation of information for a user specified time frame, for any combination of reporting units responsible to the unit performing the analysis. This would allow for a District to produce reports for any Tuberculosis Unit or units in the district; a state to produce reports for any district or combination of districts; and the Central Unit to produce reports for any combination of states or districts. Appropriate hardware and software configurations to support the system would be purchased. During negotiations, the Government of India provided assurances that the MOHFW will establish an appropriate information system no later than November 30, 1997; and by December 31, 1998, an information system to allow electronic reporting, based on technical specifications to be agreed with IDA.

3.45 Developing Operations Research Capacity. With the introduction of a new technical and operational paradigm, operations research is critical in guiding the implementation of the revised strategy and assessing the effectiveness of the operational design for program delivery. Operations research activities are being carried out primarily by the four Central Institutes mentioned above; however, because of a lack of trained operational researchers, emphasis has been on clinical and laboratory research with little understanding of operational factors affecting results. It is expected that the project would reverse this trend and help India pave the way for achieving its long term goals of: (a) establishing a cadre of researchers able to carry out high quality operational research in the field of TB and able to teach those skills to others; (b) determining the best operational methods for TB control in different Indian settings; and (c) forging useful links between the community of Indian researchers working on TB and other experts throughout the world. Within the scope of the project, the objective would be to (a) identify the main operational research priorities for TB in the next ten years and develop appropriate research protocols and terms of reference for future research; (b) establish a system for designing, developing, implementing, analyzing and monitoring research projects; (c) design and initiate a researchers training program; (d) establish a
mechanism to ensure that the findings of operations research activities are incorporated into the national program; (e) carry out a minimum of four operational research studies during the five years of the project; (f) coordinate operational research activities with those supported by other donors such as ODA, WHO and DANIDA; and (g) bring into operations research new important dimensions of TB control such as economic and socio-behavioral aspects and the role of the private sector. Possible areas of research have been identified in Annex 10.

3.46 Operational research activities would be organized and managed by the Central Program Division of the Director General of Health Services in the Ministry of Health and approved by the Health Secretary, Government of India. A Technical Steering Committee chaired by the Director General of Health Services with the Deputy Director General Health Services (TB) as member secretary and comprised of members of the main research institutions, medical colleges, other National Health Institutes, NGOs, and concerned donor representatives would be responsible for reviewing the terms of reference, protocol pro formas, and making recommendations to the Secretary of Health for administrative approval of activities to be undertaken. The approved activities shall then be submitted to IDA and WHO or other donors for review to determine funding. The committee will have representatives of disciplines such as economics, and other social sciences to ensure a broad understanding of issues related to TB control. Further details on the operational research component of the project are given in Annex 10.

3.47 Enhancing Technical, Managerial and Interpersonal Skills. The shift to the revised strategy for TB control and the strengthening of the Program nationwide, would require significant efforts in training. The project would focus primarily on training of staff for the RNTP. The training strategy emphasizes the following: (a) a decentralized approach to training through an initial program of “train the trainers” to build a cadre of key trainers in the RNTP for all categories of staff; (b) a participatory training approach focusing on hands-on, experimental training to ensure not only improvement in knowledge, but also improvement in skills; (c) a program for development of management and organizational skills for project managers through participation in national and international management courses; and (c) a program for developing interpersonal skills for health personnel as an integral part of the technical training for service providers.

3.48 The Central Institutes would train State TB officers and trainers from the State Demonstration and Training Centers (SDTC). The 16 State and District Demonstration Centers and other selected government and NGO institutions judged to be qualified to impart training would train all District Trainers and district-level officers, and the supervisory staff at the district levels (Senior TB Supervisor and Senior TB Laboratory supervisor). Translation of training materials into the local languages would be the responsibility of the State TB Cell in consultation with the State Demonstration and Training Centers. A total of 8,840 State officials would be trained at the Central Institutes and the SDTCs. Trainers would be selected from a range of health officials as described in Annex 9.
3.49 Training of all district staff would take place in the District TB Centers, selected District or Taluk hospitals, Medical Colleges, and Family Welfare Training Centers. In addition, the District Tuberculosis Center, with guidance from the central and state cells, would assess training needs, monitor and report all training activities in the district. Annex 9 provides a description of the categories and number of staff to be trained, duration and areas of training.

3.50 A newly designed curricula for all categories of staff for the RNTP is being developed with the involvement of the Central training institutes. Some modules have been completed and are being tested and revised based on the experience of the pilot projects. During negotiations, the Government of India provided assurances that the new RNTP curricula, including the new curricula for participatory training in interpersonal skills, will be used in training for all categories of staff no later than September 30, 1997.

3.51 **Management Training.** This would involve selective, short-term training for Project managers at all levels based on the required skills needed for their functions at management and technical institutes in India or outside India, or through field visits to successful programs. Selection for management training would be based on performance and commitment to continue in the assignment for at least the following two years after training.

3.52 **Interpersonal Skills Training.** This training would be linked to the Information, Education and Communication (IEC) strategy described below and it would focus on participatory training for service providers who interact directly with patients. Interpersonal communication training would be an integral part of the technical training design.

3.53 In summary, for the capacity building and skills enhancement component, the proposed project would finance investments in civil works, laboratory and other equipment, vehicles, salaries of additional staff, training and workshops, incremental operating costs, vehicle and equipment maintenance.

**DEVELOPING INFORMATION, EDUCATION AND COMMUNICATION, AND PROMOTING OUTREACH ACTIVITIES AND COMMUNITY INVOLVEMENT (US$5.9 Million or 4% of base cost).**

3.54 **Information, Education and Communication (IEC).** The main purpose of this component is to raise the quality of care given to TB patients, promote a better understanding of tuberculosis and its cure, and reduce the stigma associated with TB where this exists. The purpose is to address not only the technical and clinical aspects of TB treatment, but the social and communication dimensions to achieve greater patient satisfaction. This strategy should enhance case holding and increase the number of cases that present themselves for treatment through passive case finding. A sequenced
approach to IEC would include activities with specific goals in addition to the overall
goal of improving the quality of care; these would involve: (a) training in IEC to
strengthen state and central IEC cells; (b) production of educational and counseling
materials for health providers in the public and private sectors; (c) integration, through a
newsletter, of program information, recognition schemes, and basic medical information
on RNTP and NTP norms; (d) development of counseling materials for patients; and (e)
development of materials (including limited use of mass media) for opinion leaders and
the public to sensitize them to the problems faced by TB sufferers and to create a more
favorable social environment for those with TB.

3.55 Interpersonal communication and counseling (IPC/C) for patients would be
improved through training TB health care providers at all levels of the health delivery
system, from state TB officers to multipurpose workers, as indicated in para. 3.47 above.
Materials to support training (e.g., video) would be developed. IPC/C training would
constitute an integral part of clinical TB training methodology. The training would use a
modified tier approach: state level trainers would be trained at the Center and would be
responsible for implementing training in their states. All personnel who would train
others would receive training on how to conduct training, and those responsible for
supervising others as part of the RNTP would receive training in supervisory skills. A
supervisory checklist and monitoring procedures would be developed and integrated into
training. Details about the IEC Strategy are given in Annex 18.

3.56 Promoting Outreach Activities and Community Involvement. This aspect of this
component is geared primarily to promoting better TB care among service providers in
the NGO and private sector and involving the community in TB control. This would be
done by providing informational seminars, workshops and conferences through the Indian
Medical Association (IMA) and other professional organizations, to disseminate the
principles of the revised strategy, the government approach to TB control, and to
encourage case notification and referral, when appropriate. High quality printed materials
would be provided to private and NGO physicians. In addition, NGOs working in TB,
through national and state participation of umbrella NGOs and participation of grassroots
NGOs at the local level, would be included in policy planning and implementation.
Cured patients who have adhered faithfully to the treatment would be invited to receive
training as needed and be incorporated into the interpersonal communication program in
the capacity of educator and counselor for TB patients and symptomatic community
members. Similarly, several outreach activities would be implemented to involve
community leaders such as the Panchayats, women's groups, NGOs and grass-roots
organizations to support initiatives to help TB patients deal with the disease and support
the directly observed treatment approach. IEC efforts would be coordinated and advised
nationally by an IEC Advisory Committee and the IEC specialist hired for this purpose at
the Central level.

3.57 For this component, the project would finance publicity services including
education materials, informational pamphlets, consulting services, as well as workshops,
and support to NGOs.
IV. PROJECT COSTS, FINANCING AND IMPLEMENTATION

A. Costs

4.1 Summary of Costs. The total cost of the project is estimated at Rs. 7,492.8 million or US$176.4 million equivalent including taxes and duties estimated at US$11.1 million equivalent. The direct and indirect foreign exchange cost is estimated at US$88.1 million. The project would finance civil works, equipment, vehicles, drugs, publicity services, support to NGOs, training and workshops. The project would also finance operational expenses, laboratory supplies, maintenance of vehicles and equipment purchased with project funds, honoraria to non-salaried workers involved primarily with directly observed treatment (DOT), and salaries of incremental staff, all on a declining basis. Details of cost estimates, the financing plan, procurement arrangements and disbursement plans are shown in Annex 12.

4.2 The breakdown of project costs by components and categories of expenditure are summarized in Tables 4.1 and 4.2 below:

Table 4.1 - Details of Expenditures
(Cost By Component)

<table>
<thead>
<tr>
<th>Component</th>
<th>(Ruppe Million)</th>
<th>(US$ Million)</th>
<th>% Exchange</th>
<th>% Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve Quality, Access &amp; Outcomes of TB Treatment</td>
<td>2,137.5</td>
<td>2,374.8</td>
<td>4,512.3</td>
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<td>Capacity Building</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institutional and Operations Research Capacity Building</td>
<td>237.8</td>
<td>23.2</td>
<td>261.0</td>
<td>6.9</td>
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<tr>
<td>Enhancing Technical &amp; Managerial Skills</td>
<td>259.5</td>
<td>42.9</td>
<td>302.4</td>
<td>7.5</td>
</tr>
<tr>
<td>Develop IEC and Community Involvement</td>
<td>204.4</td>
<td></td>
<td>204.4</td>
<td>5.9</td>
</tr>
<tr>
<td>Total BASELINE COSTS</td>
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<td>2,440.8</td>
<td>5,280.1</td>
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<td>Physical Contingencies</td>
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<td>440.0</td>
<td>684.6</td>
<td>7.0</td>
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<td>Price Contingencies</td>
<td>694.9</td>
<td>833.1</td>
<td>1,528.0</td>
<td>-6</td>
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<tr>
<td>Total PROJECT COSTS</td>
<td>3,778.8</td>
<td>3,714.0</td>
<td>7,492.8</td>
<td>88.3</td>
</tr>
</tbody>
</table>

4.3 Basis of Cost Estimates. In all categories of cost, estimates are based largely on the actual experience for similar work now underway as pilot project work. Estimated cost for drug regimens, laboratory supplies, equipment and printing are all based on actual purchase prices. All estimates for goods purchases include import duties and taxes. Estimated costs for the salaries of additional staff are based on the basic pay scales, including standard allowances for social and other benefits applicable in each of the project states.
Table 4.2 - Details of Expenditures  
(Cost by Expenditure Accounts)

<table>
<thead>
<tr>
<th></th>
<th>(Rupee Million)</th>
<th>(US$ Million)</th>
<th>%</th>
<th>% Total</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Local</td>
<td>Foreign</td>
<td>Total</td>
<td>Local</td>
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<td><strong>Investment Costs</strong></td>
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<td>Civil Works</td>
<td>144.5</td>
<td>7.6</td>
<td>152.1</td>
<td>4.2</td>
</tr>
<tr>
<td>Laboratory Equipment</td>
<td>116.5</td>
<td>271.9</td>
<td>388.4</td>
<td>3.4</td>
</tr>
<tr>
<td>Other Goods or Equipment</td>
<td>134.9</td>
<td>23.8</td>
<td>158.7</td>
<td>3.9</td>
</tr>
<tr>
<td>Vehicles</td>
<td>83.8</td>
<td>14.8</td>
<td>98.6</td>
<td>2.4</td>
</tr>
<tr>
<td>Drugs</td>
<td>222.9</td>
<td>2,005.8</td>
<td>2,228.7</td>
<td>6.4</td>
</tr>
<tr>
<td>Publicity Services</td>
<td>136.6</td>
<td>-</td>
<td>136.6</td>
<td>3.9</td>
</tr>
<tr>
<td>Training and Workshops</td>
<td>204.9</td>
<td>4.2</td>
<td>209.0</td>
<td>5.9</td>
</tr>
<tr>
<td>Support to NGO's</td>
<td>67.8</td>
<td>-</td>
<td>67.8</td>
<td>2.0</td>
</tr>
<tr>
<td>Project Preparation Facility</td>
<td>8.3</td>
<td>33.3</td>
<td>41.6</td>
<td>2.0</td>
</tr>
<tr>
<td><strong>Total Investment Costs</strong></td>
<td>1,120.2</td>
<td>2,361.4</td>
<td>3,481.6</td>
<td>32.3</td>
</tr>
</tbody>
</table>

| **Recurrent Costs** |       |         |       |       |         |       |                  |           |
| Salaries of Additional Staff | 581.5 | -       | 581.5 | 16.8 | -      | 16.8 | -                 | 11%        |
| Incremental Operating Costs   | 270.9 | 14.3    | 285.2 | 7.8   | .4     | 8.2   | 5%                | 5%         |
| Lab Supplies                  | 708.3 | 53.3    | 761.6 | 20.4 | 1.5    | 21.9 | 7%                | 14%        |
| Honorarium to DOT Workers     | 64.7  | -       | 64.7  | 1.9   | -      | 1.9   | -                 | 1%         |
| Vehicle Maintenance           | 71.0  | 7.9     | 78.9  | 2.0   | .2     | 2.3   | 10%               | 1%         |
| Equipment Maintenance         | 22.7  | 4.0     | 26.7  | .7    | .1     | 8.8   | 15%               | 1%         |
| **Total Recurrent Costs**     | 1,719.0 | 79.5    | 1,798.5 | 49.5 | 2.3    | 51.8 | 4%                | 34%        |

| **Total BASELINE COSTS**      | 2,839.2 | 2,440.8 | 5,280.1 | 81.8 | 70.3 | 152.2 | 46%              | 100%       |
| Physical Contingencies        | 244.6  | 440.0   | 684.6  | 7.0   | 12.7  | 19.7  | 64%              | 13%        |
| Price Contingencies           | 694.9  | 833.1   | 1,528.0 | -.6  | 5.1   | 4.5   | 113%             | 3%         |
| **Total PROJECT COSTS**       | 3,778.8 | 3,714.0 | 7,492.8 | 88.3 | 88.1 | 176.4 | 50%              | 116%       |

4.4 **Customs duties and taxes.** All imported goods are subject to customs duties and taxes. The estimated cost of the project includes import duties and taxes valued at about US$11.1 million equivalent.

4.5 **Foreign exchange component.** The estimated foreign exchange component of US$86.7 million is calculated on the basis of estimated foreign exchange proportions as follows: (a) civil works 5%; (b) laboratory equipment 70%; (c) other equipment 15%; (d) locally manufactured vehicles 15%; (e) drugs 90%; (g) foreign fellowships or external training 2%; (h) incremental operating costs 5%; (i) laboratory supplies 7%; (j) vehicle maintenance 10%; and (k) equipment maintenance 15%.

4.6 **Contingency allowances.** Estimated project costs included physical contingencies (US$19.7 million) estimated at 10% for civil works, equipment of all types, vehicles, laboratory supplies and training, and 5% for all salaries, publicity services,
support to NGOs, honoraria to volunteer DOT workers and maintenance items. Due to the uncertainty of patient demand and drug pricing, especially as the project moves toward the introduction of multi-drug combination pills, the estimate includes a 20% physical contingency amount for the drug component. The estimated costs of the project also include price contingencies (US$4.5 million) to account for expected price escalation at the following rates:

<table>
<thead>
<tr>
<th>Year</th>
<th>Foreign Costs</th>
<th>Local Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>CY1997</td>
<td>2.3%</td>
<td>8.0%</td>
</tr>
<tr>
<td>CY1998</td>
<td>2.5%</td>
<td>7.5%</td>
</tr>
<tr>
<td>CY1999</td>
<td>2.5%</td>
<td>7.0%</td>
</tr>
<tr>
<td>CY2000</td>
<td>2.5%</td>
<td>6.0%</td>
</tr>
<tr>
<td>CY2001</td>
<td>2.5%</td>
<td>6.0%</td>
</tr>
<tr>
<td>CY2002</td>
<td>2.4%</td>
<td>6.0%</td>
</tr>
</tbody>
</table>

**B. Financing Plan**

4.7 The project would be centrally sponsored. The proposed IDA Credit of US$142.4 million equivalent would cover 86.1 percent of the incremental net cost of the TB Program, above the level of financing for the National Tuberculosis Control Program in Indian fiscal year 1994-95 as shown on page 28 as Table 4.3. The IDA portion of the financing arrangements amounts to about 86.1 percent of the total project costs net of taxes. The Government of India would finance the remaining costs of US$22.9 million plus all taxes and duties (US$11.1 million).

4.8 The credit would be made available to GOI on standard terms and conditions and made available to the states on a grant basis under standard arrangements for development assistance to the states.

**C. Economic Analysis**

4.9 **Economic Benefits** The Burden of Disease study for India, undertaken for the 1993 World Development Report, indicated that tuberculosis is responsible for 3.7 percent of the country’s total burden of disease. Seen in another perspective this is eleven times more than malaria, six times more than the tropical cluster of diseases and two and a half times more than AIDS. The incidence of TB tends to peak among those in mid-adulthood. This age group has the highest level of labor productivity and is the group in which society has already invested the largest amounts of human capital. In addition, studies in Bangladesh indicate that children of parents with illnesses such as TB are two and a half times more likely to suffer severe malnutrition. The economic and social costs of TB are likely to be high.

4.10 Results from the more recent and detailed Burden of Disease study for the state of Andhra Pradesh provide more details of the destructive nature of the disease. Among the causes of death in rural areas 1988-93, TB was exceeded only by bronchitis and heart
Table 4.3 - IDA Share of Incremental Costs

<table>
<thead>
<tr>
<th>IDA Assisted TB Control Project</th>
<th>IDA Assisted Revised TB Program</th>
<th>Existing MOH Centre Spending Levels for TB Program</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Rs. Million)</td>
<td>Annual Plan Costs</td>
</tr>
<tr>
<td>Investment Cost</td>
<td>Rs. 3,481.6</td>
<td>Current Funding Projected Over 5 Years</td>
</tr>
<tr>
<td>Recurrent Cost</td>
<td>Rs. 1,798.5</td>
<td>(Rs. Million)</td>
</tr>
<tr>
<td>Physical Contingencies</td>
<td>Rs. 684.6</td>
<td>US$ 54.1</td>
</tr>
<tr>
<td>Price Contingencies</td>
<td>Rs. 1,528.0</td>
<td></td>
</tr>
<tr>
<td>Other Conventional TB Drugs</td>
<td></td>
<td>Less existing GOI Centre Funding Levels</td>
</tr>
<tr>
<td>and other goods/services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>provided by the Centre</td>
<td></td>
<td></td>
</tr>
<tr>
<td>outside the Project</td>
<td></td>
<td></td>
</tr>
<tr>
<td>funding provisions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated 5-yr costs</td>
<td>Rs. 2,300.4</td>
<td></td>
</tr>
<tr>
<td>Total TB Program Costs</td>
<td>Rs. 9,793.1</td>
<td></td>
</tr>
<tr>
<td>Incremental Costs of Entire</td>
<td>Rs. 7,493.1</td>
<td></td>
</tr>
<tr>
<td>Revised TB Program</td>
<td>US$ 176.4</td>
<td></td>
</tr>
<tr>
<td>Incremental Portion of Entire</td>
<td>US$ 176.4</td>
<td></td>
</tr>
<tr>
<td>TB Program</td>
<td>Incremental Program Net of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Taxes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>US$ 165.3</td>
<td></td>
</tr>
<tr>
<td>Proposed IDA Credit</td>
<td>US$ 142.4</td>
<td></td>
</tr>
<tr>
<td>IDA Credit as Percentage of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incremental TB Program</td>
<td>$142.4 = 8.6 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$165.3</td>
<td></td>
</tr>
</tbody>
</table>

attacks for males, and by these illnesses plus fever, cancer and child-bearing deaths among females. For 1993, TB was responsible for ten percent of all DALYs for males and just over five percent for females. Among the 15-45 year age group, TB was the leading cause of death among both the urban and rural population. Twenty percent of all DALYs for males between 15 and 60 are caused by TB. For females the figure is ten percent. TB is the major cause of death among the economically active population.

4.11 The population of India is roughly 920 million. Those regarded at risk (above five years of age) number 798 million. Applying the results of discussions of expert groups utilized for the burden of disease study in Andhra Pradesh across the whole country suggests that 20 million TB symptomatics (2.5%) exist annually. Of these, 16.4% or 3.27 million would develop the disease each year. Tuberculosis is not fatal for
all those who contract the disease. The spontaneous cure rate is roughly 30%. Those requiring treatment would be 2.3 million. Sixty percent of these patients, or 1.4 million, are expected to seek treatment in the public sector. Currently, WHO estimates that the cure rate for the standard chemotherapy treatment in the public sector is 35%, implying that 480,000 patients are cured each year. The expected cure rate from the RNTP regimen supported through the proposed project is 85%, implying that 1.2 million would be cured annually if the RNTP covers the entire country. These rough figures suggest that if the RNTP was effectively adopted across the country, an additional 720,000 patient cures would be achieved each year. Many, but not all, of these patients would have died directly from the illness without proper treatment. WHO estimates that 200,000 deaths per year would be averted if RNTP was adopted throughout the country.

4.12 The current project would not cover the whole country because some districts are being covered by other donors. Treatment under the RNTP would be provided comprehensively across 102 districts. The project would also provide partially for smear-positive patients in a further 203 districts and would provide drugs for the conventional treatment of smear-positive patients in the final 154 districts. Estimations suggest that by the final year of the project, over 840,000 patients would be cured annually through treatment in the public sector.

4.13 Estimates of lost output due to TB must be very approximate. For the purposes of this exercise, annual average earnings are estimated at Rs. 5,200 a year (the daily rate for agricultural laborers of Rs. 20 a day for 260 days). It is also assumed that, on average, the disease is contracted 20 years prior to the normal end of working life. Discounting at 10% a year, the present value of lost outputs resulting from the deaths and continued disability of TB patients is estimated at around Rs. 40 billion. WHO estimates of the outcome of the project in terms of reduced deaths and patients remaining alive but debilitated suggest that this will fall to Rs. 31 billion, saving US$257.0 million; and with full coverage of the RNTP across the country to Rs. 23 billion. Savings in lost output from reduced deaths alone would be over Rs. 5 billion, or US$142.0 million each year. As a result of the project, an almost Rs.9 billion (US$260.0 million) would be saved following full implementation of the present project.

4.14 Cost Effectiveness. The 1993 World Development Report argued that the costs per death averted and per year of life saved make short-course chemotherapy for smear positive TB patients the cheapest known health intervention available in developing countries. Cost per year of life saved was estimated at between US$1 and US$4. Other highly cost-effective health interventions including immunizations for measles and tetanus, ORT for diarrhea and BCG vaccinations, cost between $5 and $10 per life saved. There are, however, alternative methods of treatment. In this project, short course chemotherapy with directly observed treatment (DOT) is to replace the standard longer term treatment. The effectiveness of each depends on (a) the cure rate; (b) the acquired drug resistance; and (c) the impact on the trend of the risk of infection. Of these, the cure rate is the most important. Ideally, administered courses of both treatments have high cure rates (around 95 percent); therefore compliance with the treatment is the most
important determinant of the cure rate. The social assessments undertaken for the project suggest that poverty is a main reason for non-compliance. However, duration of treatment also generally appears to be important. This is a major advantage of short course chemotherapy. A third determinant is the degree of supervision and the overall strength of the delivery system. A crucial aspect of the project (as in most programs of short course chemotherapy) is the inclusion of DOT - directly observed treatment - three times a week for the first 2/3 months with observed treatment once a week thereafter. DOT is more crucial to the success of short term than standard chemotherapy since incomplete treatment results in greater possibilities for developing resistance to the drugs in the short course regimen. Supervision increases costs. In addition, the drugs required for short course chemotherapy often are more expensive. The central issue arises of whether the higher costs of the short course treatment compared to those of the standard course are compensated for by increased effectiveness.

4.15 Preliminary data from the India pilot projects and more robust data from elsewhere, in particular East Africa, have demonstrated that costs per cure and death averted are higher for standard treatment than for short course chemotherapy. In one set of estimates the costs per life saved were over twice as high for the standard treatment. These conclusions resulted from intensive case studies over a lengthy period of time. In many respects the results will be robust across other developing countries, including India. For instance, the transmission rates and the age structure of patients is likely to be similar - hence the benefits in terms of deaths averted and years of life saved from a single cure will not be greatly different. Similarly, the results from the pilot projects suggest cure rates for the short term regimen to be around the same as those in East Africa (85-90 percent). However, since the cure rate for standard treatment is much lower in India (20-35 percent) than in East Africa (60-65 percent) and much lower than in the pilot projects areas, the improvement in deaths averted and years of life saved per treated case as a result of the project would be greater in India. In addition, the cost of drugs in India would be significantly below the US$40 per case used in the African calculations. The current estimate is around US$13. Overall, several factors suggest that the costs per year of life gained would be lower than the estimates for East Africa, which themselves demonstrated the highest returns on investments in health interventions. In addition, the difference in the cost effectiveness of the short course regimen compared to the standard approach is also expected to be larger in India.

4.16 Financial Sustainability. During the project, the incremental expenditures for both drugs and other inputs would be funded 100% by the Central Government. At the end of the project, it is expected that the responsibility for funding the drug component will revert to 50:50 share. Hence financial sustainability would be an issue for both the central and state governments. In the final year of the project, incremental expenditures on drugs would be US$7.0 million, half of which would be subsequently borne by the central government. Expenditures on TB in 1993/94 constituted 4.4% of total central government health expenditures, which in turn was equal to just 0.5% of its total expenditure. Growth in expenditures on TB over the past seven years has been below that of other centrally-sponsored schemes such as leprosy, blindness, both IDA supported.
Given the experiences of the central government in maintaining higher expenditures across other disease programs in recent years and its stated intention to give increased priority to social sectors, and tuberculosis control in particular, the program would not be difficult to sustain. State governments would bear responsibility for the other half of the incremental drug expenditures and for other recurrent costs. Overall, however, the incremental recurrent costs of the project for each state are a very small part of the total budget, and in principle, should easily be sustained. Taking Gujarat as an example, drugs for the NTP currently form 0.13% of the health department expenditures; even doubling of the drugs budget would still result in a very small share which should be easily sustainable. In practice, the reduced unit cost of drugs could well lead to only relatively small increases in the drugs bill.

4.17 The (non drugs) incremental recurrent costs of the RNTP strategy, however, would increase. For example, around five supervision teams consisting of a laboratory technician and treatment supervisor would be required in each district. For the 102 districts covering 30 percent of the population the incremental recurrent costs are anticipated to be around Rs. 383 million a year. Once the whole country is covered by the Program the incremental recurrent cost would be around Rs. 1,283 million. It is envisaged that these costs would then be the responsibility of the states. Part of this may be financed through savings. Currently the states are required to fund half the cost of drugs. In 1995/96 this totaled Rs. 400 million. Under the new RNTP Program GOI may continue to fund drugs. The savings to the states would be equivalent to almost one third of the incremental recurrent costs. The remaining costs, around Rs. 800 million, would be spread across all states, implying Rs. 53 million for each of the major states. Current health expenditures average around Rs. 5,700 million in the major states. In ten years time, assuming an annual growth rate of 4%, they would be around Rs. 8,500 million. Maintaining the TB program, therefore, implies an increase of around 0.6 percent in each state’s health budget. Even if the financing of the drugs bill did revert to a 50:50 share the total increase in states’ expenditures would not exceed one percent of their health budget. This should not provide a problem.

4.18 The experiences in recent years, however, indicate the need for some caution. Taking Gujarat as an example, drugs for the national TB program form 0.13 percent of current health department expenditures. In principle, there should be no problem of sustainability. In practice, the decrease in real expenditures on drugs in 1992/93 and 1993/94 suggests a constraint in that state. Similarly, of the seven states whose expenditures have been analyzed, only Karnataka and Maharashtra significantly increased their expenditures on TB drugs between 1991/92 and 1993/94. In the others, real expenditures fell. To secure the necessary budgetary allocations by the state, several provisions are being made, including linking eligibility for receiving drugs and other inputs to previous inputs provided by the state (see para. 4.17 above). In addition, to reduce the burden on the State, the Government of India may consider allowing District TB Societies charter to raise their own funds for TB Control Program. A detailed analysis on the financial sustainability of the project is given in Annex 13. During
negotiations, the Government of India provided assurances that the Government of India and the RNTP States would allocate sufficient funds for the project each year.

4.19 **Sustainability through Private Sector Involvement.** It is estimated that as much as 60% of TB patients first consult a private physician when feeling ill with TB. Until recently, there has been very little contact between the National TB Program and private providers; however, it is expected that, if the project succeeds in promoting the adoption of the RNTP guidelines for TB treatment among private providers, patients would remain with these physicians instead of switching to the public sector as is often the case now because of treatment failure in private hands. It is therefore expected that, while in the short term, many patients from the private sector may switch to the government sector if the latter succeeds in achieving high cures, in the long term, patients who are able to pay for drugs would continue to use the services of the private physicians who offer other advantages, particularly privacy.

4.20 **Managerial Sustainability.** The introduction of the revised strategy with its requirement of directly observed treatment and rigorous recording and registration system, would require a commitment on the part of the Government of India to maintain a strong central Program Division and strengthen the role of the Central Institutes. It will require the commitment from the states to ensure the positioning of staff at all levels, particularly supervisory staff at the subdistrict level. This would be a critical requirement for the success of TB control in India in the long term. Similarly, managerial sustainability would depend largely on staff continuity at the district and sub-district levels and a continuous and strong training program. Provisions have been made in the project to ensure that these tasks are implemented in a timely manner.

4.21 **DOT Sustainability.** Regarding the sustainability of the DOT approach, the pilots have not required the use of additional staff to provide this service but have been able to rely on existing health paramedical staff. The same approach would be used throughout the project. Furthermore, it is expected that with the increasing role of the Panchayat system, the community would be able to provide the necessary support to carry out DOT through appropriately trained community volunteers.

D. **Project Implementation**

4.22 The project would be implemented in a decentralized fashion through the structure of the National Tuberculosis Control Program, the existing health system at the state level and below, and NGOs experienced with community participation and health sector activities. Annex 3 and paras. 3.28-3.37 above describe the organizational structure of the National Program and a description of the functions of each level. An Implementation Plan is included in Annex 14.

4.23 **Role of the Central TB Division:** (see para. 3.28 above). Project implementation would be coordinated by the Central Tuberculosis Division under the Director General for Health Services in the MOHFW with the support of the Central Training and
Research Institutes. From the administrative side of the Ministry, the project would be coordinated by an official at the level of Joint Secretary. The Division would be responsible for the management of the proposed project. This would include: coordinating the program with the states, ensuring flow of funds to States and District Societies, overseeing the implementation of the technical and operational policies, guidelines and procedures through frequent field visits and data analysis, coordinating the procurement and distribution of drugs, vehicles and selected equipment, reviewing media services and program evaluation proposals. It would also oversee implementation of training, IEC and outreach, monitoring and evaluation, MIS system, and operations research. A full-time Program Director dedicated solely to the management of the NTP has been appointed by the MOHFW and would be the primary manager of project implementation.

4.24 **Role of the National Tuberculosis Control Board.** This advisory Board would be chaired by the Union Health Secretary with the Director General of Health Services as the vice-chair. It would act as an apex body and would be responsible for policy formulation, approval of annual implementation plans, approval of budgets and allocation of resources, coordination with other GOI departments, and evaluation of program objectives and achievements. The purpose of this body would be to promote an integrated approach to TB control nationwide. The Board would include staff from the main TB Research and Training institutes, the private and NGO sectors and representatives of donor organizations as members.

4.25 **Role of the State Tuberculosis Control Cell.** (See para. 3.31 above.) The State Cell would be responsible for the implementation of the project at the state level and for ensuring coordination and integration of the program with relevant institutions, including medical colleges. The State TB Cell would be supported by a Tuberculosis Coordinating Committee responsible for periodic program reviews.

4.26 **Role of the District Tuberculosis Center (DTC).** (See para. 3.33 above.) The District Tuberculosis Center (DTC) is the most important implementation unit at the District level and is responsible for the overall success of the project in the district, including: (a) training and direct supervision of the staff of the sub-district Tuberculosis Units; (b) consolidating and maintaining patient records by cohorts; (c) providing technical assistance to all health facilities offering TB services; and (d) coordinating TB activities with NGOs and the private sector, maintaining quality control, and reporting project outcomes to the state cell.

4.27 **Role of the District Societies.** The District Tuberculosis Society (see para. 3.35 above) would be responsible for ensuring availability of funds for payment of honoraria, contractual services, laboratory supplies, selected IEC activities and maintenance expenses, including petrol, oil and lubricants (POL) for vehicles. It has been agreed that in those districts where a District Leprosy Society or other Health Society is in operation, the charter could be modified to expand its activities to include TB control. Alternatively, a new District TB Society would be formed. As already established, the
Societies would be chaired by the District Collector and the District TB Officer (DTO), assigned to the District TB Center would act as Secretary for the Society. Half of the Society's membership would be comprised of representatives from NGOs and the private sector. Both as Secretary of the Society and as the main officer for TB control, the DTO, under the District Chief Medical Officer, would be responsible for the appropriate implementation of the project at the district and sub-district levels and for integrating the TB activities in the district with general health services, including the involvement of the NGOs and the private sector. Annex 8 provides details on the District TB Societies.

4.28 **Role of the Tuberculosis Units (TUs).** (See para. 3.33 above.) The TB Units at the sub-district level comprised of a Senior TB Laboratory Supervisor (STLS) and a Senior TB Supervisor (STS), would play a critical role in ensuring project success as their key responsibility is to ensure quality control for laboratory work, case management, and patient registration and reporting at the peripheral level where treatment services would be provided.

4.29 **Role of the City Corporation.** (See para. 3.37 above.) In the City Corporations, project implementation would be the responsibility of the TB Officer of the Corporation with the technical support from the District TB Officer. They would have joint responsibility for the implementation of the project, with the MO providing the managerial supervision of the staff and the DTO providing the technical supervision and advice on the program.

4.30 **Role of WHO in the Project.** Starting with the 1992 Program Review, WHO has collaborated with the Government of India and with the IDA project team, having played a pivotal role in the design and preparation of the project. As a co-financer of technical assistance under the project, WHO's important role would continue during implementation. Specifically, WHO would assist the National Program by: (a) providing TB technical assistance through a TB Advisor stationed in Delhi; (b) facilitating the implementation of drug quality control; and (c) providing technical support and advice to IDA, GOI and the state governments in project management and evaluation.

E. **Status of Project Development**

4.31 The project is at an advanced stage of preparation having already initiated implementation through the pilot projects. The preparation of this project followed the 1992 Program Review conducted by the Government of India with support from WHO and the Swedish International Development Agency (SIDA) as described in Annex 4.

4.32 **Pilot Projects.** Project preparation has centered around the implementation of 15 pilot projects with financing from a Project Preparation Facility (PPF) advance approved by IDA on November 30, 1993 and launched in February, 1994. The purpose of the pilots was to test the revised strategy in different Indian settings and improve the capacity of the Central TB Division to implement a new TB control program. As indicated in para. 2.13 above, a first set of pilots (Phase I) was financed by SIDA with WHO technical
assistance and they demonstrated successful outcomes under the revised strategy; however, there were logistical and managerial obstacles that remained to be tested. The Phase II pilots under the PPF were initiated with the purpose of correcting the errors found during Phase I and pave the way for an expansion of the revised strategy in several states.

4.33 The results of the pilot projects have been promising having achieved cure rates of more than 80% and significant improvement in diagnosis, including increasing numbers of female patients, better case management, patient registration, and cohort analysis. Similarly, the Central TB Division has been considerably strengthened with the addition of new staff who have been actively involved both in the implementation of the pilots as well as in the preparation of the proposed project. Annex 11 provides a summary of the Pilot Projects.

4.34 Technical and Operational Guidelines, Training Modules and Procurement Packages. With the experience gained through the pilots, the Central Division staff made successive changes in the technical and operational guidelines, in training curricula and plans, monitoring and supervision strategies, technical specifications for inputs, procurement arrangements, and drug storage and distribution. The technical and operational guidelines have been reviewed by IDA and are ready to be issued; several of the training modules have been tested and are being finalized.

4.35 Comprehensive Project Proposal. Based on this accumulated experience and a series of joint field visits with IDA missions, the Ministry of Health submitted to IDA, a comprehensive project proposal on which most of this Staff Appraisal Report is based. The proposal was prepared in close consultation with the State government and District Administration and on the basis of other preparatory studies carried out during project preparation, including two social assessments, an operational research study on private physicians conducted by WHO with ODA funding, and a series of preparatory workshops with state and district officials, NGOs and representatives of the Indian Medical Association. The participatory approach used in the design of this project is described in Annex 22.

4.36 Social Assessments (SAs). Two social assessments of tuberculosis in India were carried out with support from a PHRD Japanese Grant and funds from the Dutch Trust Fund. The studies focused in urban areas and in selected tribal areas of five states, where TB has become a problem for the last few decades. The assessments provided a wealth of qualitative data regarding health providers and patients’ attitudes and behavior towards TB and other social factors that affect program success. They identified five major factors affecting program effectiveness. First, poverty appears to be the single most important determinant of poor treatment compliance; second, the social stigma attached to TB, which is more common in urban areas, promotes a culture of secrecy and misinformation both on the part of the physician and on the part of the patient; third, TB control is affected by the lack of a constituency; four, patients have a marked preference for private providers for a variety of reasons, including privacy; and fifth, the quality of
provider-patient interaction has a significant effect on the patient’s disposition to continue
treatment. The findings of the SAs were instrumental in the formulation of an effective
strategy for the information, education and communication component of the project and
for the development of the strategy to reach tribal populations. Annex 16 summarizes the
key findings of the two social assessments and their differences and similarities which
served as the basis for the Social Indicators described in Annex 17.

4.37 Building a Constituency: One of the major difficulties encountered in the
preparation of this project and shown by the social assessments was the lack of
constituency for tuberculosis control due in part to the stigma attached to it and the lack
of visible manifestations that may elicit compassion such as leprosy or blindness. The
successful implementation of the pilot projects and the participatory approach to project
development served to build enthusiasm and commitment toward the program which led
to a rise in demand for a rapid expansion of the revised strategy. As a result, the project
scope which was originally limited to 15 states was changed to allow for wider
participation of districts throughout the country provided they meet the eligibility criteria
to enter the RNTP.

4.38 An International Partnership. The preparation of this project benefited from a
joint international partnership with the Government of India and the IDA team. WHO
played a central advisory role, which was complemented by technical advice from
officials from the U.S. Center for Disease Control (CDC), the International Union
Against Tuberculosis and Lung Diseases (IUATLD), the U.S. National Institutes of
Health (NIH), the London School of Hygiene and Tropical Medicine and the New York
City TB Control program. The British Overseas Development Administration (ODA)
was a full partner in the project preparation both as co-financer of the Phase II pilots and
as technical advisor.

4.39 NGO and Private Sector Involvement. Project preparation included a series of
meetings and workshops with major NGOs in India to exchange views and develop a
joint plan of action to benefit from their involvement in the National Tuberculosis
Control Project. With support from the Japanese Grant, INMED (International Medical
Services for Health), an international NGO with extensive experience in building
partnerships with the NGO and private sector, worked closely with the Government of
India, IDA and key NGOs in developing a framework for NGO participation. The role of
NGOs in tuberculosis in India is quite varied and their participation would reflect those
differences. Discussions and workshops were also held with representatives from the
Indian Medical Association in Delhi and in different states. Both NGOs and some private
physicians are already participating in the pilot projects. Annex 23 provides a brief
summary of the initial plan of action developed by the MOHFW to facilitate the
participation of NGOs in the program. The plan was based on the conclusions of
workshops carried out with NGOs.

4.40 Environmental Aspects. The proposed project would not present any major
environmental concerns. The newly developed guidelines for disposal of medical waste,
which are being strictly followed in the pilot projects, would also apply to the proposed project. The laboratory guidelines seek to reduce the risk of individual and environmental contamination by detailing the proper and safe handling, collection, storage, transportation and disposal of sputum containers, sputum slides and other laboratory supplies. The guidelines are an integral part of the training manual for laboratory technicians.

4.41 Tribal Populations. Malnutrition is prevalent in tribal areas, posing increased risk of TB for tribal populations. Their general isolation and socio-cultural characteristics call for a special plan of action to make TB service accessible to tribals. The social assessment conducted in tribal areas served to develop the Action Plan to deliver services to the tribal populations in adherence to OD 4.20. A summary of the Plan of Action is included in Annex 15. The major feature of the plan is the emphasis on the development of local resources through training to carry out many aspects of the program and on promoting culturally-sensitive communication between patients and service providers. At negotiations, the Government of India provided assurances that it would implement the strategy in tribal areas in accordance with the Plan of Action for Delivery of Tuberculosis Services in Tribal Areas approved by IDA, and would furnish detailed plans to implement the strategy in tribal areas as part of the eligibility criteria for a district’s participation in the RNTP.

F. Project Monitoring

4.42 Measurable indicators for quality control, clinical outcomes, and operational effectiveness have been agreed with the Government and they are part of the operational and technical guidelines (Annex 1). They are also included in Table 4.4 on performance indicators on page 38 and would be the basis for project monitoring and evaluation. Annex 19 provides a summary of objectives, inputs, and expected outcomes of the project.

4.43 Project monitoring at the national level would be done through reviews of quarterly reports collected from the periphery by the District TB Center and through regular supervisory visits and spot checks by state, regional and central level officials. Regional consultants hired by the central division would provide quarterly reports from their field visits highlighting major obstacles for project progress. The supervisory and monitoring functions of the Central Division are described in Annex 20. In addition, the Central and the State Training Institutes would carry out regular supervisory visits of laboratory and treatment facilities for quality control. Similarly, annual drug quality control analysis would be carried out by independent laboratories as well as an independent annual audit of the drug procurement and distribution system. Annual social assessments to measure the social indicators described in Annex 17 would be carried out starting on the second year of the project.

---

3 "Tribal" is the formal term used in the Indian Constitution to refer to indigenous groups who are currently living or have emigrated from isolated and remote areas and have distinctive social, cultural and economic characteristics.
4.44 During negotiations, the Government of India provided assurances that it would carry out an annual assessment of the drug procurement, storage and distribution system through an independent agency acceptable to IDA.

4.45 At the state and city levels, monitoring would include monthly meetings with district program coordinators followed by immediate feedback to the service providers. The District TB Officers would supervise district activities according to pre-established schedules and indicators.

Table 4.4 - Technical and Managerial Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>RNTP</th>
<th>SCC</th>
<th>NON-SCC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Number of smears per chest symptomatic examined</td>
<td>2-3</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>B. Percent of new cases which are smear positive</td>
<td>50%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>C. Proportion of new smear positive patients found in Laboratory Register who are in TB Register as undergoing treatment</td>
<td>≥ 90%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>D. Quality control network for microscopy services in place</td>
<td>≥ 50% Districts</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>II. Treatment outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Proportion of new smear positive cases placed on DOTS</td>
<td>≥ 90%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>B. Sputum conversion at 2-3 months of all new smear positive cases begun on treatment</td>
<td>≥ 85%</td>
<td>60%</td>
<td>NA</td>
</tr>
<tr>
<td>C. Cure/completion percentage of new smear positive patients begun on treatment</td>
<td>≥ 85%</td>
<td>60%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>III. Training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Percent of DTOs, STOs trained in RNTP</td>
<td>80%</td>
<td>50%</td>
<td>NA</td>
</tr>
<tr>
<td>B. Percent of STS/STLS trained in RNTP</td>
<td>70%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>C. Percent of MPW/LT trained in RNTP</td>
<td>50%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>IV. Supervision</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Staffing of Central Division consultants</td>
<td>80%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>B. Staffing of regional consultants</td>
<td>80%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>C. Supervisory visits to each subdistrict by DTO:</td>
<td>≥ 4/year</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>D. Supervisory visits to Districts by STO/Central Units:</td>
<td>≥ 2/year</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>E. Quarterly reports received on or before deadline</td>
<td>≥ 95%</td>
<td>&gt; 60%</td>
<td>NA</td>
</tr>
</tbody>
</table>
Table 4.4 - Technical and Managerial Indicators (Continued)

V. Disbursement and Logistics

| Availability of drugs at the treatment center level (for smear positive & smear negative patients) | > 95% | >90% (smear positive only) | >90% (smear positive only) |

4.46 The proposed project would finance annual review workshops with state, city and District project officers. Operational research findings would help evaluate and improve program activities.

4.47 In addition to bi-annual project review missions, operational and technical reviews would be carried out every two years to assess project implementation and make the necessary adjustments. A comprehensive project review by a panel of international and national technical experts agreeable to IDA, including WHO Global Tuberculosis Program representatives, would be carried out within two and half years of the project to assess the progress made in the introduction of the revised strategy and make the necessary adjustments in the project design and determine the possibilities of expansion of the RNTP beyond the 102 districts, under a separate intervention. This review would serve as the basis for IDA’s mid-term review of the project.

4.48 During negotiations, the Government of India provided assurances that it would carry out an independent review of the Project within the first two and a half years of the Project and that the reviews would be conducted by a panel of national and international experts; and the findings of such review would be furnished to the Association, and that no later than December 31, 1999, the GOI and IDA would carry out a mid-term management review and thereafter will implement its recommendations.

4.49 IDA Supervision Plan. WHO, in collaboration with the World Bank, would assign a TB expert to Delhi. The main focus of the Advisor’s duties would be to provide guidance and advice to the program and facilitate project implementation. The work of the TB Advisor would be complemented with periodic project review missions by IDA which would be based on progress reports submitted by the TB division every six months. IDA supervision teams would seek collaboration from WHO, CDC, IUATLD and national technical experts for program review missions. A Bank local staff member assigned to the Delhi office would carry out periodic visits to project sites, in combination with other assignments, to identify major bottlenecks in project implementation and would do periodic follow up of issues regarding, procurement, disbursements and auditing. The planned schedule and skills required for project supervision are listed in Annex 21.

4.50 Supervision missions would focus primarily on specific benchmarks related to the Performance Monitoring Indicators described in Annex 19 and on the technical and operational indicators described in Table 4.4 above.
G. Disbursements

4.51 The principles on which disbursement arrangements have been developed include: (a) the adequate training of project staff in Bank procedures and the appropriate mechanisms in the project sites, states and cities and the Center to ensure that differentials between project implementation and disbursement performance are reduced; and (b) adequate and appropriate mechanisms to ensure the flow of funds from the Center to the project states and cities and the District Societies and to project sites and to ensure that project funds are used exclusively for agreed project-related expenditures and purposes.

4.52 Disbursement Percentages. The disbursement plan has taken into account the fact that purchases would be made to support the entire tuberculosis control activities as summarized in Table 3.1 on page 11, including those that would have been funded by GOI in any case. Accordingly, disbursement percentages have been set at levels necessary to ensure that the IDA credit provides funds amounting to 86% of the incremental cost only. Thus, The IDA credit would be disbursed in accordance with Table 4.5 below.

Table 4.5 - Disbursement Percentages

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount of IDA Credit Allocated</th>
<th>Percentage of Expenditures to be Financed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil works</td>
<td>US$3.5 million</td>
<td>80%</td>
</tr>
<tr>
<td>Drugs, equipment, other goods and vehicles</td>
<td>US$74.0 million</td>
<td>100% of foreign expenditures, 100% of local expenditures (ex-factory cost) and 80% of local expenditures for other items procured locally</td>
</tr>
<tr>
<td>Consultant services, training, workshops, fellowships</td>
<td>US$7.9 million</td>
<td>100%</td>
</tr>
<tr>
<td>Publicity and social marketing services</td>
<td>US$3.3 million</td>
<td>85%</td>
</tr>
<tr>
<td>Incremental salaries, honoraria for volunteer DOT workers, lab supplies and consumables, operation and maintenance costs</td>
<td>US$32.8 million</td>
<td>90% of local expenditures for the first and second years, 75% of expenditures for the third year, 60% of expenditures for the fourth year, and 40% of expenditures thereafter.</td>
</tr>
<tr>
<td>Project Preparation Facility (total authorized PPF for US$1.2 million)</td>
<td>US$1.2 million</td>
<td>Disbursed as above for equipment and drug purchases, and for training</td>
</tr>
<tr>
<td>Unallocated</td>
<td>US$19.7 million</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>US$142.4 million</td>
<td></td>
</tr>
</tbody>
</table>

4.53 Disbursement Profile. The proposed credit would be disbursed over five and a half years, generally consistent with the standard profile for PHN projects in India. The proposed project is expected to be completed on December 31, 2001, and the Credit closed on June 30, 2002. Table 4.6 on page 41 shows the forecasts of expenditures and disbursements.
Table 4.6 - Forecast of Expenditures and Disbursements

<table>
<thead>
<tr>
<th>IDA Fiscal Year</th>
<th>Semester</th>
<th>Cumulative</th>
<th>Disbursements /b</th>
<th>Cumulative as % of Total</th>
<th>Semester From Appraisal Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY98</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st (Jul 97 - Dec 97)</td>
<td>15.7</td>
<td>15.7</td>
<td>3.5</td>
<td>3.5</td>
<td>2%</td>
</tr>
<tr>
<td>2nd (Jan 98 - Jun 98)</td>
<td>15.7</td>
<td>31.4</td>
<td>13.6</td>
<td>17.1</td>
<td>12%</td>
</tr>
<tr>
<td>FY99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st (Jul 98 - Dec 98)</td>
<td>16.0</td>
<td>47.4</td>
<td>13.6</td>
<td>30.6</td>
<td>21%</td>
</tr>
<tr>
<td>2nd (Jan 99 - Jun 99)</td>
<td>16.0</td>
<td>63.5</td>
<td>13.8</td>
<td>44.4</td>
<td>31%</td>
</tr>
<tr>
<td>FY2000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st (Jul 99 - Dec 99)</td>
<td>17.8</td>
<td>81.3</td>
<td>13.8</td>
<td>58.3</td>
<td>41%</td>
</tr>
<tr>
<td>2nd (Jan 2000 - Jun 2000)</td>
<td>17.8</td>
<td>99.1</td>
<td>14.5</td>
<td>72.8</td>
<td>51%</td>
</tr>
<tr>
<td>FY2001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st (Jul 2000 - Dec 2000)</td>
<td>18.9</td>
<td>117.9</td>
<td>14.5</td>
<td>87.3</td>
<td>61%</td>
</tr>
<tr>
<td>2nd (Jan 2001 - Jun 2001)</td>
<td>18.9</td>
<td>136.8</td>
<td>14.2</td>
<td>101.5</td>
<td>71%</td>
</tr>
<tr>
<td>FY2002</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st (Jul 2001 - Dec 2001)</td>
<td>19.8</td>
<td>156.6</td>
<td>14.2</td>
<td>115.7</td>
<td>81%</td>
</tr>
<tr>
<td>2nd (Jan 2002 - Jun 2002)</td>
<td>19.8</td>
<td>176.4</td>
<td>13.3</td>
<td>129.0</td>
<td>91%</td>
</tr>
<tr>
<td>FY2003</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st (Jul 2002 - Dec 2002)</td>
<td>-</td>
<td>176.4</td>
<td>13.3</td>
<td>142.4</td>
<td>100%</td>
</tr>
</tbody>
</table>

Closing Date: December 31, 2002

a/: Including Special Account and PPF
b/: Figures may not appear to add due to rounding
c/: Disbursement projections take into account the Regional Profiles for similar type projects

4.54 **Required Documentation.** Disbursement for procurement of goods and works under contracts valued at less than US$200,000 and services under contracts valued at less than US$100,000 per firm (US$50,000 per individual contract), maintenance of equipment and vehicles and salaries of incremental staff would be made against Statements of Expenses (SOEs), with supporting documentation to be retained by each state government. This documentation would be subject to annual audit and made available for review by IDA supervision missions. All other disbursements would be made against fully documented withdrawal applications. During negotiations, the Government of India provided assurances that no disbursements would be made for expenditures incurred in, or by, any Project State unless that Project State has delivered to the Association, a Letter of Undertaking of such Project State, satisfactory to the
4.55 **Special Account.** In order to accelerate disbursements with respect to IDA’s share of expenditures pre-financed by GOI and the state governments, and to allow for the direct payment of other local and foreign expenditures, a Special Account would be maintained in the Reserve Bank of India in the amount of US$6.5 million equivalent to cover four months of estimated disbursements through the Special Account.

4.56 **Flow of Funds.** The direct disbursement of funds to the District Societies for operating expenses has been tested in the pilots and found to work. The items eligible for disbursement through the District Societies have been identified (e.g., honoraria, lab supplies and consumables, small civil works, operation and maintenance costs, training funds, and limited publicity expenses). Funds for salaries, and selected goods would be disbursed to the states and cities. GOI would monitor closely the use of funds by the states, cities and District Societies. No other funds would be disbursed to the District Societies as the MOH would be responsible for procurement of most drugs, equipment and supplies.

### H. Procurement

4.57 Table 4.7 on page 43 summarizes the project items, their related cost estimates and proposed methods of procurement. Project related procurement of goods, works and services would follow procedures acceptable to IDA using ICB and NCB documents acceptable to the Associations. Procurement of drugs and microscopes would be carried out by the Procurement Unit at the Ministry of Health and Family Welfare during the first year of the project and a review of its operational effectiveness would be made after the first year. Project-financed consultants and NGOs would be recruited according to Guidelines on the Use of Consultants by World Bank Borrowers. Procurement of laboratory equipment and drugs would be bulked to the extent possible and any individual contract exceeding US$200,000 equivalent would be procured under ICB procedures.

4.58 **Civil Works (US$4.8 million).** The civil works component is dominated by very small scale works scattered widely in the project districts. For example, the plans call for minor alteration work at 6,517 existing field laboratories, such as installation of electrical outlets for microscopes and mounting of exhaust fume hoods. The cost of the works at each laboratory site is estimated at approximately US$600. Collectively, these minor alteration works constitute over 60% of the civil works covered by the project. At least 90% of these small alterations would be procured by soliciting quotations from at least three contractors to ensure competitive pricing since the small scale and disbursed nature of the work does not lend itself to an advertised bidding process. Not more than 10% of the small works would be permitted through the use of Force Account. The bulk of the remaining civil works involves alterations to existing facilities to create adequate storage room at the District levels to accommodate several months supply of TB drugs. A total
<table>
<thead>
<tr>
<th></th>
<th>Procurement Method</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>International</td>
<td>Local</td>
<td>Competitive</td>
<td>Competitive</td>
<td>Other</td>
<td>Consulting</td>
<td>N.B.F.</td>
</tr>
<tr>
<td></td>
<td>Bidding</td>
<td>Bidding</td>
<td></td>
<td></td>
<td></td>
<td>Services</td>
<td></td>
</tr>
<tr>
<td><strong>WORKS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Civil Works</td>
<td>-</td>
<td>-</td>
<td>4.8</td>
<td>-</td>
<td>-</td>
<td>4.8</td>
<td>(3.8)</td>
</tr>
<tr>
<td><strong>GOODS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>72.4</td>
<td>8.2</td>
<td>1.0</td>
<td>-</td>
<td>-</td>
<td>81.6</td>
<td>(65.2)</td>
</tr>
<tr>
<td>(65.2)</td>
<td>(7.3)</td>
<td>(0.9)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Laboratory Equipment</td>
<td>10.9</td>
<td>1.3</td>
<td>0.6</td>
<td>-</td>
<td>-</td>
<td>12.9</td>
<td>(8.7)</td>
</tr>
<tr>
<td>(8.7)</td>
<td>(1.0)</td>
<td>(0.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other Goods or Equipment</td>
<td>-</td>
<td>2.0</td>
<td>3.0</td>
<td>-</td>
<td>-</td>
<td>5.0</td>
<td>(1.6)</td>
</tr>
<tr>
<td>(1.6)</td>
<td>(2.4)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Vehicles</td>
<td>-</td>
<td>-</td>
<td>3.1</td>
<td>-</td>
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<td>(2.5)</td>
</tr>
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<tr>
<td>Lab Supplies</td>
<td>-</td>
<td>2.4</td>
<td>21.7</td>
<td>-</td>
<td>-</td>
<td>24.1</td>
<td>(1.5)</td>
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<td>(1.5)</td>
<td>(13.6)</td>
<td></td>
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</tr>
<tr>
<td><strong>CONSULTANCIES &amp; TRAINING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Project Prep &amp; Implementation Support</td>
<td>-</td>
<td>-</td>
<td>2.0</td>
<td>4.1</td>
<td>-</td>
<td>6.1</td>
<td>(1.7)</td>
</tr>
<tr>
<td>(Includes Consultants, NGO Support and Social Marketing)</td>
<td></td>
<td></td>
<td></td>
<td>(3.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institutional Development (includes Training &amp; Workshops)</td>
<td>-</td>
<td>-</td>
<td>6.5</td>
<td>-</td>
<td>-</td>
<td>6.5</td>
<td>(6.5)</td>
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<tr>
<td>(6.5)</td>
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<td></td>
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</tr>
<tr>
<td><strong>MISCELLANEOUS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Project Preparation Facility</td>
<td>-</td>
<td>-</td>
<td>1.2</td>
<td>-</td>
<td>-</td>
<td>1.2</td>
<td>(1.2)</td>
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<td>(1.2)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Salaries of Additional Staff</td>
<td>-</td>
<td>-</td>
<td>17.4</td>
<td>-</td>
<td>-</td>
<td>17.4</td>
<td>(11.3)</td>
</tr>
<tr>
<td>(11.3)</td>
<td></td>
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**NOTES**

a) "Other" methods include International and Local Shopping, Force Account, Direct Contracting and such "non-procurement" funded activities such as salaries of incremental staff covered by the project.
b) Figures in parenthesis are the respective amounts financed by IDA.
of 104 such storage facilities is planned at a total cost of some US$300,000, or roughly US$2,900 at each site. Where possible, construction at these locations would be advertised and competitively bid, but when this is not practical, use of force account or quotations from three contractors to ensure competitive prices would be permissible.

4.59 **Drugs (US$81.6 million).** Procurement of drugs for the project would be primarily a centrally managed activity performed by the MOH, and phased on an annual basis throughout the life of the project in accordance with the requirements of the project activities as additional districts are brought into the TB Control Program. Details on drugs purchasing and distribution are described in Annex 24. Initial drug purchases would be through the use of Bank Standard Bidding Documents and ICB Procedures to supply multi-drug packs in blister pack containers. Technical and commercial specifications for this type of purchase have already been successfully tested during the Phase II Pilot. Commencing year two of the project, consideration would be given to introducing Combination Drugs. Technical specifications for Combination Drugs are still under review with GOI and WHO, however, any such large scale procurement would also be conducted using ICB procedures. Prior to the extensive use of Combination Drugs, some operational research is anticipated, and to support this activity a limited amount of International Shopping would be permitted, not to exceed US$1.0 million, to obtain the necessary combination of drugs from the relatively few manufacturers in the world who are known to be providers of these specialized drugs. All significant purchases of fixed combination drugs would be subject to bioavailability tests at independent WHO approved laboratories. In summary, the majority of purchases of the TB drugs would be procured by the Center in contracts valued over US$200,000 using ICB procedures for a total amount not exceeding US$72.4 million. Contracts for TB and supportive drugs valued at US$200,000 or less would be procured through NCB procedures acceptable to IDA for an aggregate amount not exceeding US$8.2 million, and an additional US$1.0 million in drug purchases would be permitted under international shopping procedures.

4.60 **Laboratory equipment (US$12.9 million).** Procurement of most of the laboratory equipment would be phased on an annual basis over the first three years of the project in accordance with the requirements of the project activities. Over 90% of the costs for laboratory equipment involves the purchase of binocular microscopes, with the remainder for centrifuge devices, refrigerators, or similar small scale laboratory appliances. Bulk purchases of the microscopes and other laboratory equipment would be procured by the Center in contracts valued over US$200,000 using ICB procedures for a total amount not exceeding US$10.9 million. Contracts valued at US$200,000 or less would be procured through NCB procedures acceptable to IDA for an aggregate amount not exceeding US$1.3 million. For purchases not exceeding US$100,000, procurement would be through rate contracts or local shopping procedures, comparing price quotations from at least three suppliers to ensure competitive prices up to an aggregate amount not exceeding US$0.6 million.

4.61 **Other goods or equipment (US$5.0 million).** Procurement of other equipment would be phased on an annual basis over the first four years of the project in accordance
with the requirements of the project activities as additional districts meet eligibility
criteria and initiate new activities. Over 60% of the costs for laboratory equipment
involves the purchase of small computers and peripherals, with the remainder for audio
visual equipment, photocopiers, FAX machines and other office equipment. Purchases of
this equipment would be bulked whenever possible and purchased at the State level.
Contracts valued at US$200,000 or less would be procured through NCB procedures
acceptable to IDA for an aggregate amount not exceeding US$2.0 million. For purchases
not exceeding US$100,000, procurement would be through rate contracts or local
shopping procedures, comparing price quotations from at least three suppliers to ensure
competitive prices up to an aggregate amount not exceeding US$3.0 million.

4.62 Vehicles (US$3.1 million). Procurement of vehicles would be phased on an
annual basis over the entire five years of the project in accordance with the requirements
of the project activities as additional districts are brought into the RNTP. Over 50% of
the costs for vehicles would be for the purchase of jeeps to be used at the state and
District Headquarters, and the bulk of the remaining costs for some 537 two wheeler
vehicles for transportation at the sub-District levels. Because the project involves more
than fifteen states spaced over a five year period, and the total requirement for jeeps is
roughly 237 vehicles, no contract is expected to contain more than ten vehicles. Such a
purchasing plan does not lend itself to ICB. Wherever possible, requirements would be
bulk ed at the state level and purchased through NCB procedures. For purchases not
exceeding US$100,000, procurement would be through DGS&D rate contracts or local
shopping procedures, comparing price quotations from at least three suppliers to ensure
competitive prices up to an aggregate amount not exceeding US$3.1 million.

4.63 Laboratory supplies (US$24.1 million). Procurement of laboratory supplies
would be phased on a quarterly or semi-annual basis throughout the life of the project in
accordance with the requirements of the project activities. The supplies required include
such items as glass microscope slides, slide storage cases, reagents, and sputum cups.
Efficient purchasing, storage, and distribution of this type of material to over 6,500 lab
sites does not lend itself to bulking of requirements for ICB. With the exception of
chemical reagents, where quality control is a concern, bulking requirements for purchase
through NCB is also not a practical solution. Nevertheless, purchases of laboratory
supplies would be bulked whenever possible and procured at the State level in contracts
valued at US$200,000 or less through NCB procedures acceptable to IDA for an
aggregate amount not exceeding US$2.4 million. For small purchases not exceeding
US$100,000, procurement would be through DGS&D rate contracts or local shopping
procedures, comparing price quotations from at least three suppliers to ensure competitive
prices up to an aggregate amount not exceeding US$21.7 million.

4.64 Consultancies, Support to NGOs and Social Marketing (US$6.1 million).
Consultants required under the project would be hired following procedures prescribed in
the Guidelines on the Use of Consultants by World Bank Borrowers. Documents used for
inviting proposals, terms of reference for all consultancies and single source contracts
would be subject to prior review for all contracts valued at US$100,000 or more awarded
to firms and US$50,000 or more to be awarded to individuals. Publicity services for mass media would be procured by GOI and the states from the Ministry of Information's radio and television stations. The rates that would be used would not exceed the standard rate of charges to other advertisers. Informational spots directed at the private sector health providers would also be provided in professional trade journals or similar publications through direct contracting at existing commercial rates.

4.65 Training, Workshops & Fellowships (US$6.5 million). This category includes expenses related to training of about 235,000 health and other project staff over the life of the project in respect of seminars, workshops, fellowships, travel and subsistence allowances.

4.67 Vehicle and Equipment Maintenance (US$3.2 million). Maintenance costs for vehicles, laboratory and other equipment items estimated to cost less than US$25,000 per contract up to an aggregate amount of US$3.2 million would be procured from local commercial suppliers of such services in accordance with procedures acceptable to IDA.

4.68 IDA Review. All procurement under ICB would be subject to IDA’s prior review; the first three NCB contracts for goods in each state, regardless of size, would also be subject to prior review. All other contracts for goods would be subject to random post review in the field by IDA visiting missions. Contracts for the hiring of consulting firms costing US$100,000 equivalent or more and contracts for hiring individual consultants costing US$50,000 equivalent or more would be subject to prior review and approval by IDA. Approximately 65% of the value of contracts covered by the IDA Credit would require prior review. During negotiations, the Government of India provided assurances that no equipment, drugs or vehicles purchased with proceeds of the credit would be provided to any state which has not furnished a Letter of Undertaking with the central government.

I. Accounting and Auditing

4.69 Expenditures incurred by the Center and by each participating state and city corporation, including the District TB Societies, would be audited annually in accordance with sound auditing standards consistently applied by independent and qualified auditors acceptable to IDA; District Societies are to be audited by independent chartered accountants; and certified copies of the annual financial statements and SOEs together with the auditor’s report, which would comment separately on the SOEs, would be submitted to IDA no later than six months after the close of each fiscal year. The Central Government would maintain a separate account for the IDA assisted Program. At the Center, State, District and city levels, a record of program transactions would be maintained with appropriate supporting documentation for the transactions.
V. Benefits and Risks

A. Benefits

5.1 It is expected that by introducing a new paradigm for TB control and focusing on the most infectious cases with appropriate diagnosis and treatment under direct observation, the project would begin to reverse the trend of several years of sub-optimal program results which has led to increased numbers of TB cases as well as the emergence of drug-resistant strains. It is estimated that the project would treat about three million TB cases in five years of which about 1.9 million would be treated under the revised strategy, including about 800,000 new smear-positive cases. If the project objective of 85% cure rate is achieved, approximately 1.5 million infectious TB patients would be cured. In addition, many more millions of non-infected individuals would potentially be freed from the risk of TB infection and the development of TB disease. The most concrete benefit of the project is that it would avoid an estimated 140,000 deaths from TB per year. This is especially important considering that the TB burden adversely impacts the most economically and socially productive members of Indian society, the 15-44 year old age group. Moreover, the changes introduced by the project are likely to improve awareness about TB among the community and improve detection and treatment among private physicians who play an important role in TB care.

B. Program Objective Categories

5.2 Poverty Aspects. TB is a disease of poverty, having higher prevalence among the undernourished, rural migrants and those living in crowded conditions. Improving the socio-economic status of the people may be the most effective way of preventing TB, but in the short term, the best prevention of TB remains the detection and cure of infectious cases. The project would benefit primarily the poor who are most susceptible to the disease. The social assessments demonstrated that a major barrier in TB control is the financial constraints of the poor to pay for the medicines, transportation or doctor's fees and the poor were the bigger users of government facilities. The proposed project would reduce these barriers by making diagnosis and treatment more accessible, by involving the community and by providing for free and uninterrupted supply of anti-TB medicines, thereby increasing the credibility of the Government's TB health care system. Because of its special focus on the poor, this project is classified as a Program of Targeted Interventions (PTI).

5.3 Gender Issues. Reported TB prevalence among women is lower than among men worldwide, but opinions vary among TB specialist as to whether this is an epidemiological factor or simply the result of under-diagnosis of female patients because of lack of access or because of the stigma associated with TB. In any case, TB mortality rate among women of child-bearing age is disproportionately higher than among men. The social assessments and other literature on TB in India show that women are the main victims of the stigma associated with TB. Women's seclusion and lower social status, particularly in poor rural areas, make it difficult for them to comply with treatment.
Similarly, women tend to seek treatment often at advanced stages of the disease, making treatment more complicated and sometimes unsuccessful. The proposed project would promote the formation of support groups at the community level, include special training and communication models to raise awareness of women's issues concerning TB among service providers and develop IEC interventions to reduce the stigma associated with TB in general. The results of the Phase II pilots are promising regarding the treatment of women but a frequent and structured approach is needed to keep the momentum and raise awareness of the issues of women's health and TB. The cohort analysis allows supervisors to monitor the effectiveness of the project in reaching women. After the second year of the project, bi-annual beneficiary assessments would be conducted to assess the effect of the project among the most disadvantaged groups and based on the social indicators described in Annex 17.

C. Risks and Safeguards

5.4 Most of the common risks associated with PHR projects in India such as procurement, late disbursement, inadequate maintenance of equipment, and the software aspects have been considerably minimized by the experience and commitment gained through the pilot projects. Nonetheless, the project presents other risks, most typically associated with TB control and the introduction of a new program. These include: (a) the risk of significant variation between the estimated number of cases and the actual cases due to the fact that firm information on TB incidence in India is not available; (b) the inherent risks of a shift in technological and behavioral practices, particularly the difficulties of persuading providers and patients to accept the practice of directly observed treatment and the rigorous features of the DOTS strategy; (c) the risk of poorly administered short-course chemotherapy drugs and of poor quality anti-TB drugs which would increase the probabilities of developing drug resistance; (d) the risk that the Central and State TB Cells would be unable to provide the leadership and services required to ensure proper implementation of the program given the scope, the managerial complexity of the revised strategy, and the need to maintain an active constituency for TB control in the government and the community; (e) the risk of an uneven supply of drugs in light of the spotty record of drug deliveries in India combined with the availability of large quantities of drugs which could be misused; (f) the risk that the project would not succeed in influencing the private providers in changing their TB practices and patients would continue to rely on their services for reasons of privacy if the public sector does not deliver as expected; and (g) the continuous challenge of dealing with mobile migrant populations, particularly in urban slum settings.

5.5 The estimates of TB incidence in India are based on the best information available at present; however, to ensure greater accuracy on the quantitative objectives, the midterm review would be used to make a readjustment of the project objectives, as needed, based on the actual experience of the project. This would reduce the risk associated with possible inaccuracies on case estimates.
5.6 The Phases I and II pilots implemented as part of project preparation have helped to identify the risks associated with the new approach and to find ways to mitigate them. They have also provided the Central Unit in the Ministry of Health (MOH) with hands-on experience in running the new program, understanding the demands and constraints involved and having the opportunity to make corrections as the project progressed. Although the Program's scope is large, the possibility of expanding the revised strategy to wider geographical areas has generated enthusiasm and greater commitment among government officials, the medical associations, and other groups. Similarly, the efforts to involve the private sector and the NGOs are beginning to pay off.

5.7 The introduction of an appropriate Management Information System (MIS) would help keep adequate control of registration and patient records, including mobile populations; and a decentralized approach to treatment with the involvement of the community would facilitate the implementation of DOT. Interruption in the drug supply would be minimized through buffer stocks and monitored through annual independent audits of the drug inventory, distribution and utilization. Quality control of anti-TB drugs would be monitored through independent scientific institutions in addition to the standard government procedures. The packaging of drugs in multi-drug blister packs and per-patient treatment boxes, as well as the introduction of multi-drug combination pills at a later stage would help reduce mishandling of medicines. Finally, it is expected that the collaboration planned between the government and the private practitioners would help improve the effectiveness of TB control in both the public and private sectors.
VI. AGREEMENTS REACHED AND RECOMMENDATIONS

6.1 During negotiations, the Government of India provided assurances that:

(i) it shall implement the Project and will cause the States to implement the project according to the policies and norms of the National Program for Tuberculosis Control including the revised strategy for Tuberculosis Control (RNTP) and they will not make changes to the Program policies or guidelines, which, in the reasonable opinion of IDA, would adversely affect the project (para. 3.11);

(ii) (a) the SCC treatment regimen provided for the SCC districts would not include rifampicin in the continuation phase; (b) the RNTP patient registration and reporting system would be utilized in those districts; and (c) the supply of SCC drugs by the Project to a district will be liable to be discontinued if the district fails to maintain an annual average of 60% cure rate after the first two quarters of implementation (para. 3.19);

(iii) drugs shall be provided on a regular basis by the Center for all smear-positive cases in the non-RNTP districts, and it would ensure that conventional drugs have been provided for smear-negative patients based on expected case load (para. 3.22);

(iv) the Ministry of Health and the Project States where RNTP is being carried out, would develop and implement (a) a strategy for involvement of NGOs and Associations such as the Indian Medical Association; (b) a strategy for qualified medical practitioners which could include medical education, information and communication on various aspects of TB and referral mechanisms for RNTP; and (c) a strategy to promote referral of symptomatic patients to RNTP by other health practitioners. It was also agreed that specific annual plans for such strategies would furnished to the Association no later than March 31 every two years (para. 3.24);

(v) the Central Unit and the RNTP units in the Project States will be adequately staffed and maintained for the duration of the Project and at least 50% of the additional staff at the Central and the RNTP State Cells will be in position by July 1, 1997, and 90% of the staff shall be in place by December 31, 1997. It was also agreed that a full time State TB Officer would be in position by July 1, 1997 in all RNTP states, and District TB Officers will ordinarily remain in their posts for a minimum of two years (para. 3.34);

(vi) District TB Societies or equivalent societies would be established in the first 39 RNTP districts by March 31, 1997; by January 31, 1998 in the
following 39 RNTP districts; and by January 31, 1999 in the remaining 24 RNTP districts; and no RNTP activities can be initiated prior to the establishment of a District TB Society (para. 3.36);

(vii) (a) the designated Central Institutions would adopt and promote RNTP in all activities relevant to the Project and will carry out their training, monitoring and quality control functions, including the development and maintenance of demonstration sites for field practice, in accordance with agreed procedures; (b) an annual report on the Central Institutions’ performance and recommendations for action will be furnished to IDA by December 31 of each year during the first three years of the Project, and continued involvement of these institutions in the activities of the Project will be determined by mutual agreement between IDA and MOHFW based on their performance. (para. 3.39);

(viii) (a) only such districts which have met the eligibility criteria for each level of participation would participate in the RNTP; (b) the first two appraisals of the districts eligible to enter the RNTP will be submitted to IDA for review prior to MOHFW’s approval; and (c) the borrower would provide IDA a sample of 20% of district project appraisals approved by the borrower for review by IDA on an ex-post basis (para. 3.41);

(ix) it would establish an appropriate information system no later than November 30, 1997; and by December 31, 1998, an information system to allow electronic reporting, based on technical specifications to be agreed with IDA (para. 3.44);

(x) the new RNTP curricula, including the new curricula for participatory training in interpersonal skills, would be used in training of all categories of staff no later than September 30, 1997 (para. 3.50);

(xi) it would allocate and cause the Project States to allocate sufficient funds for the Program each year (para. 4.18);

(xii) it would implement the strategy in tribal areas in accordance with the Plan of Action for Delivery of Tuberculosis Services in Tribal Areas approved by IDA, and would furnished detailed plans to implement the strategy in tribal areas as part of the eligibility criteria for a district’s participation in the RNTP (para. 4.41);

(xiii) it would carry out annual assessments of the drug procurement, storage and distribution system through an independent agency and with terms of reference acceptable to IDA (para. 4.44);
(xiv) (a) it would carry out an independent review of the Project within the first two and a half years of the Project and that the reviews would be conducted by a panel of national and international experts, and (b) the findings of such review would be furnished to the Association; and (c) no later than December 31, 1999, the GOI and IDA would carry out a midterm management review and thereafter will implement its recommendations (para. 4.48); and,

(xv) no equipment, drugs and vehicles purchased with the proceeds of the credit would be provided to any State which has not furnished a Letter of Undertaking with the Central Government (para. 4.68).

6.2 **Condition of Disbursement.** During negotiations, the Government of India provided assurances that no disbursements would be made for expenditures incurred in, or by, any Project State unless that Project State has delivered to the Association, a Letter of Undertaking of such Project State, satisfactory to the Association (para. 4.54).
INDIA: Tuberculosis Control Project

SUMMARY FROM THE TECHNICAL AND OPERATIONAL GUIDELINES
REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAM

Diagnosis

1. Diagnosis is done through passive case finding, i.e., patients who present themselves to a tuberculosis clinic, and through sputum examination, i.e., three sputum samples per patient, one taken on the day of the visit, a second overnight and a third on the following day.

2. For diagnostic purposes, Pulmonary Tuberculosis is classified into Pulmonary Smear Positive, Pulmonary Smear Negative and Extra-Pulmonary Tuberculosis.

3. Pulmonary Smear Positive patients are those with at least two sputum specimens positive for the Acid Fast Bacilli (AFB) by microscopy; or those with one positive sputum specimen and radiographic abnormalities consistent with active pulmonary tuberculosis.

4. Pulmonary Smear Negative patients are those with three sputum specimens negative for the AFB by microscopy and radiographic abnormalities consistent with active pulmonary tuberculosis (i.e., a changing chest radiograph) and decision by a physician to treat with a full curative course of anti-tuberculosis chemotherapy. In case of pediatric tuberculosis, the decision of the physician to treat with full course of chemotherapy is sufficient.

5. Extra-Pulmonary Tuberculosis patients are those with a history and/or clinical evidence consistent with active tuberculosis and a decision by a physician to treat with a full curative course of anti-tuberculosis chemotherapy.

Treatment History

6. To determine the treatment regimen to be followed, tuberculosis patients are classified according to their treatment history: new, relapse, failure, default, or chronic.

7. A new case is a patient who has never taken anti-tuberculosis drugs in the past, or one who has had less than four weeks of treatment.

8. A relapse case is a patient, who was previously treated and declared cured by a physician, but is found to be smear positive.

9. A failure case consists of four sub-categories: (a) a new smear positive pulmonary tuberculosis patient on short course chemotherapy (SCC) who remains sputum smear positive after 5 months, or more, of SCC; or (b) a retreatment case in which a patient remains smear positive after completing a full course of chemotherapy; or (c) a smear negative patient, at the start of treatment, becomes smear positive at two months from start of treatment.
Annex 1

10. A **default case** is a patient who interrupts treatment for two months or more.

11. A **chronic case** is a patient who remains smear positive after completing a retreatment regimen.

**Short Course Chemotherapy Treatment Regimen**

12. **Category I** patients are new cases of smear positive pulmonary tuberculosis and other newly diagnosed smear negative but seriously ill patients with severe forms of tuberculosis. These have the highest priority in SCC due to infectiousness.

13. The initial intensive phase is 2(HRZE)3, i.e., isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) in a blister pack, administered three (3) times a week for two (2) months, under Directly Observed Therapy (DOT).

14. If after the two months initial intensive phase the patient is smear negative, then the 4 months continuation phase follows. If after the two months initial intensive phase the patient is smear positive, the two month intensive phase is extended to another month of thrice a week DOT of HRZE, after which the continuation phase will commence regardless of sputum test results. If the patient remains smear positive at three months and is put on the continuation phase, his/her sputum is examined after two months, i.e., month 5, and if still smear positive, the patient is categorized as a failure case and started on the retreatment regimen.

15. The continuation phase is 4(HR)3, i.e., isoniazid and rifampicin in a blister pack, administered three times a week for four months. A blister calendar pack for one week treatment is given to the patient and at least the first dose should be directly observed at the time of collection. On the next collection, the patient should return the empty blisters.

16. **Category II** or **Retreatment patients** are those who have received anti-tuberculosis treatment for more than one month in the past. They are at an increased risk of developing multi-drug resistant (MDR) tuberculosis. These include smear positive, relapse and failure cases. These are also of high priority in SCC because they are still infectious and under suspicion of MDR.

17. The initial intensive phase is 2(HRZES)3/1(HRZE)3, i.e., isoniazid, rifampicin, pyrazinamide and ethambutol, in a blister pack, supplemented with streptomycin (S), administered three times a week, for the first two months, followed by the same drugs, without streptomycin, administered three times a week, through DOT, for one month.

18. If the patient is smear negative at three months, then the continuation phase is started. If the patient is smear positive at three months, then HRZE is continued for another month, administered three times a week. If the patient is still smear positive at the end of the fourth month, and there is a facility to undertake culture test, then, after stoppage of the drugs for three days, sputum samples should be sent for culture and drug sensitivity tests. In any case, the patient should begin the continuation phase with a blister calendar pack for weekly treatment in which the first dose shall be directly observed at the time of collection.
19. The continuation phase is 5 (HR)3, i.e., isoniazid, rifampicin and ethambutol, in a blister calendar pack, administered three times a week under observation one in three doses for five months and with the patient returning the empty blister pack. If the patient remains smear positive after the completion of the continuation phase, the patient is no longer eligible for the retreatment regimen and is managed as a chronic case.

20. Concerning treatment after default, if the patient is smear positive while returning to treatment, he/she is put on a retreatment regimen as described above. If smear negative, then he/she should complete the course of treatment that the patient was on prior to default.

21. Concerning chronic cases, they should be suspected of having MDR to both isoniazid and rifampicin and should be referred for review to specialists.

22. Category III patients are new cases of smear negative pulmonary and extra-pulmonary tuberculosis. These have a lower priority in SCC.

23. The initial intensive phase is 2(HR)3, i.e., isoniazid, rifampicin and pyrazinamide, in a blister pack, administered three times a week, for two months, under DOT. If smear negative at two months, then the patient starts the continuation phase. The continuation phase is 4(HR)3, i.e., isoniazid and rifampicin in a blister pack, administered three times a week, for four months. If the patient is smear positive at two months, then he/she is categorized as a failure case and is put on a retreatment regimen as described above.

Treatment Evaluation

24. Treatment evaluation is done on quarterly cohorts of patients, using two sputum samples per patient each time at 2/3 months, 4/5 months and at the end of the treatment regimen. A cohort would include all patients registered in a sub-district/ward during a quarter. The sub-district/ward Tuberculosis Register is used to determine these cohorts.

25. Treatment results are classified into cure, completed treatment, defaulted, failed, died and transferred out. Cured are SCC patients who convert to smear negative at 4-5 months and at end of the chemotherapy. Completed treatment are those who have incomplete smear results but have completed their chemotherapy. Defaulted are those who interrupted their treatment for more than two months. Failed are those who remain smear positive at five months or later during chemotherapy or those who are smear negative at the start of the chemotherapy and become smear positive at the second month of smear examination. Died are patients who die while on chemotherapy due to any cause. Transferred Out are those patients who transferred to any other health unit.

Delivery of Health Care Against Tuberculosis

26. The Revised National Tuberculosis Program (RNTP) of the Government of India (GOI) is responsible for the delivery of health care against tuberculosis. At the Center, the RNTP is responsible for the technical and operational norms and procedures; planning, monitoring and evaluation; ensuring regular supplies of drugs and other inputs and adequate training of personnel; quality assurance, surveillance and program monitoring; ensuring sufficient financial resources for the tuberculosis control program and coordinating the
activities of different institutions. At the State, the RNTP is supported by a State Tuberculosis Officer (STO) and the State Tuberculosis Training Centers. The STO is responsible for planning, training, implementing, supervising and monitoring of the RNTP at the State level, and coordinating Tuberculosis Control activities with other health institutions involved in TB control.

27. Diagnosis is made by medical staff (Government, Non-Governmental Organizations or NGOs and private clinicians). Patients diagnosed with tuberculosis may be referred to government facilities for treatment which is free of charge. Once the patient has been diagnosed, treatment is provided by trained health staff at all levels, including the village level.

28. Upon the advice of health staff, patients may choose their most convenient place to receive treatment, e.g., a hospital, a District Tuberculosis Center (DTC), a Community Health Center (CHC), a Primary Health Center (PHC).

29. Drugs are taken by the patient under DOT during the intensive phase of the treatment regimen. During the continuation phase of the treatment regimen, drugs are supplied, in blister packs, weekly for self administration, with the dose of the collection day taken under DOT.

30. The service delivery is decentralized at the District level and below.

(a) The District Tuberculosis Center or DTC acts as a tuberculosis unit for its geographical catchment area and as a specialized reference center for tuberculosis diagnosis and case management for the whole district. It is also responsible for training of staff and for the supervision and support of the Tuberculosis Units in the entire district. The District Tuberculosis Officer (DTO) is in charge of the DTC and responsible for the implementation of the Program at the district level.

(b) The Sub-District or Subdivision is part of a district or a municipal corporation, with a population of approximately 500,000, with a TB unit responsible for supervision and maintaining the Tuberculosis Register under the DTC.

(c) The TB Unit is a team of one Senior Tuberculosis Supervisor (STS) and one Senior Tuberculosis Laboratory Supervisor (STLS) at a Taluk (sub-district) Hospital, CHC or Block PHC. It has the organizational functions of a DTC at the sub-district level and operates under the guidance and support of the District TB Officer. A medical officer of the facility in which the TB unit is based is designated to support the team in clinical aspects.

(d) An STS is responsible for (a) organizing DOT and case finding in the sub-district; (b) supervising each PHC, CHC and hospital in the area at least once a month; (c) randomly checking on patients to ensure that chemotherapy is carried out according to the guidelines; (d) maintaining a list of all government health facilities in the area, and of government and NGO facilities which carry out TB activities, including distribution (map), and staff
(name, position, location) responsible for TB activities; (f) coordinating training of general staff at the health facilities in TB case detection and case management; (g) ensuring that patients are correctly classified, appropriate treatment indicated and provided, laboratory controls carried out and patient discharge done appropriately; ensuring that TB activities are carried out according to the technical and operational guidelines; (h) maintaining the Tuberculosis Register and preparing and sending to the DTO quarterly reports on cases detected and treatment results (sputum conversion and treatment outcome) and on health services implementing TB activities; (i) facilitating patient referral to the DTC or other health facilities for diagnosis, drug toxicity, or complications; (j) providing on-going staff training; (k) liaising with private practitioners and NGOs to promote compliance with national norms, facilitate referral and ensure registration and notification; and (l) ensuring adequate drugs and supplies by reporting supply problems to the DTO.

(e) An STLS is responsible for (a) maintaining a list of all microscopy centers in the sub-district which carry out TB activities, including distribution (map) and staffing (name, position and location) in collaboration with the STS; (b) training of laboratory staff in TB smear examination; (c) supervising the microscopy centers at the CHCs once a month and at the PHCs once every two months, including registering the number of slides checked and the proportion of discordance for positive and negative; (d) ensuring internal adjustments in the assignment of microscopists; (e) monitoring of laboratory records, including comparing the workload for case finding with the attendance of adults to the health facilities; (f) ensuring quality control of smears, proper storage and transport of sputum and safety of laboratory staff; (g) ensuring adequate supplies and proper maintenance of microscopes; and (h) preparing, in collaboration with the STS, and forwarding, to the DTO reports on laboratory implementation, quality control, supervision and management of supplies.

(f) The designated medical officer in the TB unit is responsible for (a) history taking and examination of patients reporting to the TB unit; (b) investigating TB suspects; (c) diagnosing TB patients and prescribing correct regimen; (d) checking of cases diagnosed and of treatment prescribed by the Medical Officer in charge of peripheral centers; (e) referring problem cases to DTO; (f) supervising STS and STLT; (g) sending back treatment cards with the appropriate medicines to the peripheral centers; requisition receipt and monitoring of supplies; (h) continuing medical education of staff; (i) participation in operational research; specifically see patients with drug reactions, or who refuse to take drugs, or with drug failure, or with non-conversion after intensive phase and identify the reason, or to define treatment outcome (i.e., cured, completed, etc.); and (j) any further assignments as may be needed by the project.

(g) A Microscopy Center is located at the CHC or Block PHC level, serving a population of 100,000. This is the diagnostic and treatment evaluation
component of the RNTP. It provides general health service and is capable of sputum smear examination for diagnosis of tuberculosis and treatment evaluation, with a trained microscopist, microscope and supplies, and a tuberculosis microscopy register.

(h) **Peripheral Level Workers,** attached to a PHC/CHC, would be responsible for drug delivery and DOT. These workers would include male and female multi-purpose workers (MPWs), trained “Dais” and Anganwadi workers at the sub-center, and village health guides or community volunteers at the village level.

(i) In addition, at the sub-centers and/or at the villages, the MPWs and/or TB Health Visitors would: (a) verify the address of new patients and instruct patients and their families on providing sputum specimens for diagnosis and treatment evaluation and on the importance of treatment completion; (b) administer DOT three times a week; (c) ensure the maintenance of tuberculosis treatment cards and patient identity cards; and (d) take the necessary steps for the immediate restoration of defaulters to treatment regimen.

**Recording and Reporting**

31. The accurate keeping of records on all individual patients under treatment and quarterly reporting of treatment results of all registered new patients and retreatment cases by means of a cohort analysis, is essential for reliable continuous evaluation of the RNTP at the sub-district, district, state and national levels. The number of documents used in the RNTP is limited as much as possible and they are clear and simple. The following records are recommended for the revised RNTP:

(a) **Tuberculosis Treatment Card.** A tuberculosis treatment card is filled as soon as a diagnosis of tuberculosis is made. It is kept at the health institution where the patient receives treatment (either at a TB clinic, DTC, district hospital, CHC, PHC, Health Post, etc.). A duplicate of this card is given to the most peripheral health functionary who is directly supervising the drug administration of the patient who cannot or failed to visit the designated treatment health unit at a given time. Information on administration of drugs during the initial intensive phase is to be entered on this card and transferred on to the main card kept at the health institution by the most peripheral health functionary. The Senior Tuberculosis Supervisor (STS) of the Tuberculosis Unit (TU) transfers the relevant data, in particular the results of smear examinations on entry, at two (three) months, at five months (in retreatment cases) and at the end of treatment, from the Tuberculosis Treatment Card to the TB Register kept at the sub-district or sub-divisional level.

(b) **Tuberculosis Identity Card.** This card is filled as soon as the diagnosis of tuberculosis is made and the Tuberculosis Treatment Card completed. It is kept by the patient. The TB Identity Card contains disease classification, date treatment started, type of tuberculosis, type of the RNTP regimen...
Annex 1

(Category 1, II or III), type of a blister pack for the initial intensive phase to be closely supervised (DOT), and type of blister pack for the continuation phase. Appointment dates for blister packs collection during the continuation phase and following examinations are entered on page 2 of the Card.

(c) **Tuberculosis Register.** The Tuberculosis Register is one of the basic documents since it contains all essential data on the patient, treatment unit, classification of the disease and bacteriological status on entry, type of the regimen, date of the start of treatment, type of the patient (new, relapse, transferred in, returned after defaulting, failure case), and smear examination results during treatment and at its completion. It is kept by the STS who is responsible for entering all the required data on all patients enrolled in chemotherapy in the sub-district or sub-division. The TB Register is the basic document for reporting results of case finding of new cases and relapses and treatment results to the DTC by means of the respective quarterly reports. It is also necessary for collection of the data as reported in the Quarterly Report on Management of the RNTP.

(d) **Laboratory Register.** This Register is kept at all laboratories in the sub-district performing sputum smear examinations for AFB. Important information is contained in columns "Reason for Examination" and "Results of Specimen". The laboratory technician should tick carefully whether the sputum was collected for diagnosis (both new patients and relapses) or for follow-up of treatment. For diagnosis, three sputa are required, and two sputum specimens for follow-up of patients. For follow-up, the patient’s TB Register Number is written in the column provided. All results of diagnostic examination should be entered in the same line.

(e) **Request Form for Sputum Examination.** It is essential that the person who completes the form indicates whether the sputum is sent for diagnosis or for follow-up. In the former case a detailed address should be given for the patient in case he does not return to the health institution and the sputum is found to be smear-positive, so that the patient can be traced. This form is kept at all health institutions (peripheral, intermediate, central).

(f) **Tuberculosis Culture/Sensitivity Test Request Form.** Request Form for culture/sensitivity tests will be sent to central laboratory by Medical Officer in case of failure to respond to short course chemotherapy.

(g) **Tuberculosis Referral/Transfer Form.** This form is used when transferring patients from one area to another or when referring patients to a referral center. It is to be filled in triplicate: one is given to the patient (to hand over at the next health institution), one is sent to the health institution directly and the other retained for records. The receiving health institution will fill the bottom half of the form and return it to the referring or transferring institution, as soon as the patient comes to them.
32. **Quarterly Reporting.** All sub-district/subdivisions or ward STSs must submit reports on case-finding, and results of treatment to the District TB Officer. The forms to be used are:

(a) Quarterly Report on New Cases and Relapses.

(b) Quarterly Report on the Results of Treatment of Pulmonary Tuberculosis Patients registered 12-15 months earlier.

(c) Quarterly Report on Program Management.

33. These forms are to be completed in triplicate by each sub-district/ward STS: one will be sent to the DTO, one to the State TB Officer and the other retained by the STS for the records. The forms will be checked by the DTO and submitted promptly to the State TB Officer, where the forms are to be collected for prompt submission to the Director TB Control at the National level for easy retrieval and production of country reports.

34. The two quarterly reports are made in a manner to permit cohort analysis. A cohort refers to a group of individuals with a common characteristic; in this case, the cohort includes all patients registered in a sub-district/ward during a quarter. The sub-district/ward STS is to be trained to be able to prepare accurately these reports. Reliable reports can only be produced if the register is kept up to date.

35. Quarterly reports No. 1 and 2 will be computerized at the State and Central level for all districts.

(a) Quarterly report No. 1 contains information on new cases and relapses of tuberculosis. Block 1 refers to all patients registered during the last quarter by disease classification and bacteriological status (smear-positive, smear-negative and extra-pulmonary), and Block 2 refers to only smear-positive new cases by age groups and sex.

The State/Corporation TB officer will analyze the results of case-finding, and produce explanatory remarks concerning all districts, in particular the detection-rate of new smear-positive cases, the percentage of smear positive cases from the total number of detected pulmonary cases, the detection rate of smear-positive relapses, and the percentage of extra-pulmonary tuberculosis cases. In the report covering all four quarters, rates (per 100,000) by age and sex will be calculated for new smear-positive cases. The figures per district will be compared with the previous years. The reports will be distributed to all districts and sub-districts in the division as a feedback of case-finding, activities, and will be important background information for supervisory visits.

(b) Quarterly report No. 2 shows results of treatment of new smear-positive cases, smear-negative cases, smear-positive relapses and other re-treatment cases in each sub-district/ward, quarterly. The most important index is the cure rate (and treatment completion rate) in new smear-positive cases and, separately, smear-positive relapses, and other retreatment cases. It is expected that in India, with the regimens used, the success rate (the cure plus
completion rates) would be 85% (or more) of new smear positive cases. The
dates for preparing the Quarterly reports indicating the results of the
treatment (Treatment Outcomes) of patients who started treatment during e.g.
1997 would be as follows:

<table>
<thead>
<tr>
<th>Start of Treatment</th>
<th>Date of Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st January to 31st March 1997</td>
<td>1st week of April 1998</td>
</tr>
<tr>
<td>1st April to 30th June 1997</td>
<td>1st week of July 1998</td>
</tr>
<tr>
<td>1st October to 31st Dec. 1997</td>
<td>1st week of January 1999</td>
</tr>
</tbody>
</table>

36. **Reporting on Program Management.** Quarterly Report No. 3 deals with various
aspects of program management at the sub-district, district and state level, and national level.
Draft Quarterly Report No. 3 for the three levels include:

- Program Management at the Tuberculosis Unit level;
- Program Management at the DTC/Chest Clinic level; and
- Program Management at the State level.

37. The most important of the three reports is Program Management at the Tuberculosis
Unit level, since it contains the essential data on sputum conversion at two (three) months
per quarter, consumption of drugs and other items, payments made to Community Health
Volunteers and others, supervisory activities, number of sputum smear examinations, and
number of X-ray films taken in the last quarter.

38. **At the Tuberculosis Unit (Sub-District/Sub-divisional) Level.**

Quarterly Report on Management contains the following 8 items:

(a) Number of TB cases registered during the last quarter by treatment status.

(b) Payments made to Community Health Volunteers and others for case detection
and supervision of drug administration during the last quarter.

(c) Sputum conversion rate at two (three) months in smear-positive patients
enrolled on SCC one quarter previously (four to six months ago).

(d) Distribution of drugs during the last quarter.

(e) Distribution of other items during the last quarter.

(f) Supervisory activities to the peripheral health units during the last quarter.

(g) Examination of sputum of tuberculosis suspects by microscopy and
monitoring treatment results by microscopy examination during the last
quarter.

(h) Examination of TB suspects by X-ray during the last quarter.
39. **At the DTC/Chest Clinic (District) Level.**

The Report is based on the data provided by the Tuberculosis Units. It summarizes information on five items:

(a) Number of Tuberculosis Units involved in the revised RNTP.

(b) Number of Quarterly Reports No. 3 received from Tuberculosis Units.

(c) Supervisory activities by the state staff to the Tuberculosis Units during the last quarter.

(d) Consumption of anti-tuberculosis drugs during the last quarter (blister packs and loose drugs).

(e) Consumption of other items during the last quarter.

40. **At the State Level.**

The Report contains the same information as Quarterly Report No. 3 at the district level except that the Report is based on the data provided to the state level by DTCs. Supervisory activities of the state level are focused on DTCs.
India: Tuberculosis Control Project

Summary of Drug Regimens to Be Used Under the Project

1. Based on the proposed project, the project districts are classified into three groups, each using a different drug regimen based on the TB Control strategy operating in their respective areas. These three groupings are: (a) the 102 RNTP Districts; (b) the 203 non-RNTP, SCC districts; and (c) the 154 non-SCC districts.

RNTP Districts

2. **Category I** patients are new cases of smear positive pulmonary tuberculosis and other newly diagnosed smear negative but seriously ill patients with severe forms of tuberculosis. These have the highest priority in Short Course Chemotherapy (SCC) due to infectiousness.

3. The initial intensive phase is 2(HRZE)3, i.e., isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) in a blister pack, administered three (3) times a week for two (2) months, under Directly Observed Therapy (DOT).

4. The continuation phase is 4(HR)3, i.e., isoniazid and rifampicin in a blister pack, administered three times a week for four months. A blister calendar pack for one week treatment is given to the patient and at least the first dose should be directly observed at the time of collection. On the next collection, the patient should return the empty blisters.

5. **Category II** or **Retreatment** patients are those who have received anti-tuberculosis treatment for more than one month in the past. They are at an increased risk of developing multi-drug resistant (MDR) tuberculosis. These include smear positive, relapse and failure cases. These patients also have a high priority in SCC due to infectiousness and suspicion of MDR.

6. The initial intensive phase is 2(HRZES)3/1(HRZE)3, i.e., isoniazid, rifampicin, pyrazinamide and ethambutol, in a blister pack, supplemented with streptomycin (S), administered three times a week, for the first two months, followed by the same drugs, without streptomycin, administered three times a week, through DOT, for one month.

7. The continuation phase is 5(HRE)3, i.e., isoniazid, rifampicin and ethambutol, in a blister calendar pack, administered three times a week under observation of one in three doses and with the patients returning the empty blister pack for five months. If the patient remains smear positive after the completion of the continuation phase, the patient is no longer eligible for the retreatment regimen and is managed as a chronic case.

8. **Category III** patients are new cases of smear negative pulmonary and extrapulmonary tuberculosis. These have a lower priority in SCC.
9. The initial intensive phase is 2(HRZ)3, i.e., isoniazid, rifampicin and pyrazinamide, in a blister pack, administered three times a week, for two months, under DOT. If smear negative at two months, then the patient starts the continuation phase.

10. The continuation phase is 4(HR)3, i.e., isoniazid and rifampicin in a blister pack, administered three times a week, for four months. If the patient is smear positive at two months, then he/she is categorized as a failure case and is put on a retreatment regimen as described above.

Non-RNTP, SCC Districts

11. There are two types of TB patients in the non-RNTP, SCC districts: (a) the smear positive and the seriously ill smear negative TB patients; and (b) the non-seriously ill smear negative TB patients.

12. For the Smear Positive, the Seriously Ill Smear Negative TB Patients, the drug regimen would be:

- 2(EHRZ)/6(EH). The initial intensive phase is 2(EHRZ), i.e., ethambutol, isoniazid, rifampicin and pyrazinamide, administered daily, for two months.
- The continuation phase is 6(EH), i.e., ethambutol and isoniazid, administered daily, for six months, and self-administered by the patient.

13. For Non-Seriously Ill Smear Negative TB Patients, the drug regimen could take either of two forms:

- 12(TH) or 12(EH). There is only one phase of 12 months. The drug regimen is 12(TH)/12(EH), i.e., thiacetazone and isoniazid or ethambutol and isoniazid, self-administered daily for 12 months.

Non-SCC Districts

14. For Sputum Positive and Seriously Ill patients:

- The initial intensive phase is 2(STH), i.e., streptomycin, thiacetazone and isoniazid, administered daily, for two months, or 2(SEH), i.e., streptomycin, ethambutol and isoniazid, administered daily for two months.
- The continuation phase is 10(TH), i.e., thiacetazone and isoniazid, administered daily, for ten months, and self-administered by the patient, or 10(EH), i.e., ethambutol and isoniazid, administered daily, for ten months, and self-administered by the patient.
15. For Sputum Negative and Non-seriously Ill patients:

- The drug regimen is 12(TH)/12(EH), i.e., thiacetazone and isoniazid or ethambutol and isoniazid, self-administered daily for 12 months.
1. The chart on page 2 of this Annex depicts the revised structure that is proposed for the National Tuberculosis Control Program and the implementation of the RNTP. These changes respond to the rapid population growth and the increase in TB incidence since 1962 when the current structure was introduced, and to the demands of the revised strategy.

2. The structure of the National Program, including the RNTP has four levels, all of which will be strengthened as part of the project:
   
   (a) the Central Unit at MOHFW;
   
   (b) the State TB Officer at the state level;
   
   (c) the District TB Center at the district level; and
   
   (d) a small TB unit at the subdistrict or equivalent intermediate level.

Central Level

3. The Central Unit will include, in addition to the Program Director, posts for a Technical Adviser, an Accounts Specialist, a Logistics and Operational Supervisor, a Procurement Specialist, an Operations Research Officer, a Training Officer, a Supervision and Monitoring Officer and a Community Relations Officer.

4. The Central Unit will be responsible for the overall implementation of the revised strategy. This will include setting policies and procedures, ensuring, compliance with such policies, providing technical leadership to the State and the districts, coordinating training, activities and strengthening community relations. More specifically, the Division's main responsibilities will be to prepare, disseminate and enforce technical and operational policies and guidelines, ensure compliance with the program policies, provide technical assistance to the states and districts, ensure quality control and monitor program implementation. The office of the Joint Secretary in the administrative side of the Ministry of Health is responsible for the financial and administrative matters related to TB and will be strengthened by adding one new official at the level of Under Secretary, and two Assistants. The training, IEC and staff recognition activities of the project will be a joint responsibility with the technical unit. In addition, the Central Division will identify areas and mechanisms of coordination with the National AIDS Program to ensure adequate inter-program support.
Organizational Structure
National Tuberculosis Control Programme

Central Institutions

Designation and number of Central Institutions as mutually agreed between IDA and GOI. List will be reviewed from time to time.

Central Institutions

National TB Control Board/
National Coordination Committee

National Level
TB Cell
Deputy Director
General (TB)

Designated
Joint Secretary

Operational Divisions in MOH

Technical & Operations
Training
Operations Research
Logistics
IEC & NGOs

State Level
(State TB Officer)

District Level
(District TB Officer)

District TB Center
(one per district)

Other Health Facilities
(e.g. District Hospitals)

Sub-District Level
(Designated MO)

Technical Unit
(several per district)

Metropolitan City
(TBO)

Borough/Ward
(Chest Clinic)

PHC
(MO)

Sub-Center
(MPW)

Actual number of units at each level will vary

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Annex 3
State Level

5. The State Cell would be responsible for the supervision and monitoring of the program throughout the state, including metropolitan cities, and for ensuring the integration of the revised strategy throughout the health system. To respond to these demands, the existing State TB cells would be strengthened with additional staff and equipment. The position of TB State Program officer would be upgraded to give the program the prominence required. The State TB Officer would be assisted by a Medical Officer, an IEC officer, a Secretary/Assistant and an Accountant.

6. More specifically, the State Tuberculosis Control Cell would be responsible for (i) ensuring adequate supply of inputs to the service facilities, including drugs and laboratory supplies; (ii) ensuring district compliance with eligibility criteria for participating in the proposed project; (iii) overseeing the functioning of the District TB Centers; iv) identifying and correcting bottlenecks in implementation; (v) overseeing implementation of staff training plans; and (vi) ensuring quality control and appropriate recording for monitoring of project outcomes.

District Level

7. The establishment of the sub-district Tuberculosis Units (TUs) will alter the tasks of the District Tuberculosis Center (DTC) and the District Tuberculosis Officer (DTO). The tasks of the DTC in the RNTP can be summarized as follows:

(a) coordinating and supervising tuberculosis control activities in the respective district and working closely with the state level of the RNTP;

(b) training or re-training all Senior Tuberculosis Supervisors and Senior Tuberculosis Laboratory Technicians and other key peripheral workers;

(c) serving as a referral center to the staff of the TUs and other health workers involved in the NTP, in all aspects of tuberculosis control;

(d) compiling and analyzing tuberculosis data for the district;

(e) procuring supplies: drugs, laboratory reagents, sputum containers and forms, for the district and distributing them to the TUs; and

(f) implementing the NTP in the administrative area around the DTC.
Sub-District Level

8. A supervisory and managerial team at the peripheral level as a Tuberculosis Unit (TU) would operate at the subdivision (block or Taluka) level in all RNTP districts. The TU would cover a population of about 500,000 and would consist of two persons: a Senior Tuberculosis Supervisor (STS) and a Senior Tuberculosis Laboratory Technician (STLT).

9. The STS will keep the Tuberculosis Register and record all cases of tuberculosis diagnosed or transferred in the administrative area covered by the TU. The diagnosis of tuberculosis and the regimen prescribed will be the responsibility of a designated medical officer of the health institution to which the TU is attached, for instance, a Taluka hospital. The designated doctor will refer patients with any queries to the DTC. The main responsibilities and tasks of the STS are found in the Technical and Operational Guidelines.

10. The Senior Tuberculosis Laboratory Technician (STLT) is usually a senior lab technician responsible for microscopy examination in a subdivision (district) general laboratory (e.g. at a Taluka hospital). The responsibilities of the STLT are detailed in the Technical and Operational Guidelines.

11. **Main Duties and Tasks of Senior Tuberculosis Supervisor (STS) at the Tuberculosis Unit (TU).**

   (a) To keep an up-to-date and accurate Tuberculosis Register and check that reports and TB Treatment Cards are properly filled in by supervisors at CHCs and other PHCs, or by Community Health Volunteers (CHVs).

   (b) To implement the RNTP in the subdistrict, through the staff of the primary health facilities, under the technical guidance of the DTO and the designated doctor at the TU.

   (c) To supervise treatment delivery to every patient in the designated TU area and to ensure that:

   (1) the RNTP regimens are appropriately prescribed;

   (2) patients under treatment are treated under direct-observation (DOT);

   (3) drugs are given for the required period and cured patients are discharged from treatment;

   (4) sputum is examined for tubercle bacilli at the required intervals; and
Annex 3

(5) patients are referred to the DTO or the designated doctor for consideration for retreatment following the failure of chemotherapy for any reason, or if side effects of drugs occur, or the patient needs medical attention for any other reason.

(d) To assist health workers in the introduction and extension of TB case-finding, in all existing health facilities of the subdivision (subdistrict).

(e) To regularly visit all Primary health facilities under his/her jurisdiction once every two or three months. Also, to make detailed programmes for such visits, at least three months in advance and send these to all PHCs.

(f) To compile Quarterly Reports on Case-finding of New Cases and Relapses, and Results of Treatment of smear-positive cases, under the supervision of the designated doctor and/or DTO.

12. The STS is appointed as per the State Government rules and should have had formal training for the post. He is responsible to the Subdivision Medical Officer and to the DTO who supervise him in the implementation of the DTP in the TU area.

13. Main Responsibilities and Tasks of the Senior TB Laboratory Technician (STLT).

(a) To closely cooperate with the STS.

(b) To supervise all microscopy centres in CHCs and PHCs of the TU area in which smear examination of sputum for AFB has been carried out (microscopy centres in CHCs: once every month, the remaining laboratories once every two or three months):

(1) proper collection of sputum specimens;

(2) storage and transport of sputum specimens;

(3) safety of laboratory technicians and coworkers;

(4) techniques of smear preparation and reading;

(5) maintenance of microscopes;

(6) recording of the results of sputum examination in the Tuberculosis Laboratory Book; and

(7) keeping two slides of smear-positive patients and three slides of every smear-negative patient who had been labeled, by the doctor, as smear-negative on clinical symptoms and x-ray appearances.
(c) To train or retrain laboratory technicians either in the DTC Laboratory or in the subdistrict general laboratory.

(d) To organize, in cooperation with the DTC Laboratory Technician, a quality control system of sputum examination within the TU laboratories.
INDIA: Tuberculosis Control Project

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS OF THE 1992 REVIEW OF THE NATIONAL TUBERCULOSIS CONTROL PROGRAM (NTP) OF INDIA

NTP's Organizational Structure.

1. The NTP has a very weak central structure, which, for a long time, has not provided leadership in establishing and updating policy and technical procedures and assuming program direction. As a result, program procedures have stagnated and the original philosophy of the NTP has not been fully implemented, nor revised to make full use of the PHC system.

2. The functions and resources of the States, particularly in training, have not been developed and properly utilized.

3. In most large urban centers, the coordination of activities among different institutions, under the guidance of the STOs and STDTCs, have not yet been implemented.

4. Curative services (hospitals and the like) and preventive services are not coordinated at the District level, in a single network for TB control, and the lines of authority of the DTO are not clearly established.

5. The extension of TB diagnosis and treatment to the community through the MPHW has been slow and valuable human resource is not sufficiently utilized to enhance access to care and patient compliance to the drug treatment.

6. There is no technical and policy advisory body to provide support for the NTP in the preparation and periodic updating of national policies, technical and administrative procedures, and monitoring and evaluation of the NTP.

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1/ This review was carried out by a joint team comprised of representatives from the Government of India (GOI), the World Health Organization (WHO) and the Swedish International Development Agency (SIDA) from September 1-17, 1992. Please see India: Tuberculosis Program Review, World Health Organization, September 1992, pp.3 and 7.

2/ Ibid., p.19.
Case Finding and Diagnosis

7. A major weakness in the NTP is that usually only one or no sputum smear is obtained before a TB diagnosis is made. The primary aim in case finding should be the identification of sputum smear-positive cases. Before the diagnosis of TB and decision to treat are made, the results of at least two sputum smears should be available.

8. Another major weakness is that diagnosis is primarily based on chest x-ray results. The role of sputum-smear examination in TB diagnosis should be greatly emphasized and the role of radiological examination should be reconsidered. For differential diagnosis, the ODELCA cameras and miniature films for diagnostic chest x-rays may be phased out and replaced with equipment based on the specifications for the WHO Basic Radiological System, after carefully working out the cost considerations. For screening of symptomatic attendees in hospitals of large urban areas to select patients for bacteriology, small size x-rays may be useful.

9. The NTI laboratory manual should be revised, used for training at the state level and distributed as a reference to the laboratory staff of the peripheral health services (PHIs).

10. Wall posters with the basic procedures for microscopy should be made available to all peripheral microscopy centers.

11. Acceptable quality binocular microscopes should be made available.\(^3\)

Treatment

12. NTP policies and procedures on treatment do not reflect the WHO recommended emphasis on short-course chemotherapy and patient registration systems which facilitate the monitoring of completion and cure rates of patients on anti-tuberculosis treatment.

13. The NTP at the delivery level does not adequately emphasize the importance of treatment completion as the main index for program evaluation. Service delivery focuses on case finding activities and not on treatment completion and cure.

14. NTP policies and procedures should ensure the use of effective and current treatment regimens, including fewer regimens and short-course chemotherapy, where appropriate.

15. Registration systems should solicit data to monitor completion and cure rates, with particular focus on smear-positive TB patients.\(^4\)

\(^3\) Ibid., p.21-22.
Case Notification

16. The current NTP reporting and recording system does not monitor the cure rate among smear-positive cases of TB.

17. Cohort analysis does not cover all smear-positive cases diagnosed and is not done at the peripheral health institutions, i.e., CHCs and PHCs that are designated as such.

18. The NTP system of registration and notification should record essential data, such as previous history of TB treatment, and emphasize the collection and cohort analysis of treatment results as the main indicator of the effectiveness of the NTP.

19. Printed copies of the laboratory and patient TB registries should be kept by the PHI staff trained in record keeping and supervised by the District TB Center (DTC) supervisor.

20. Quarterly standardized reports from the PHIs should be sent to the DTCs indicating treatment results and cure rates. The DTCs, in turn, will consolidate these reports and send them to the state TB office.5

21. Ensuring the uninterrupted supply of anti-TB drugs to the TB patient is the responsibility of the Center and the states.

Drug Supplies

22. The State TB Officer (STO) should closely monitor the usage patterns, drug purchase projections and stocks of anti-TB drugs.

23. A buffer stock at the state level should be established, sufficient to ensure at least a six month supply of uninterrupted drug supply to the districts.

24. Districts and PHIs should maintain buffer stocks sufficient for three months.

25. It is the responsibility of the Center and the states to monitor the quality of the anti-TB drugs through a scientific institution of their choice.6

5/ Ibid., p.27.
6/ Ibid., p.28.
Supervision, Monitoring and Evaluation

26. In order to address the increase in population and health care facilities at the periphery, additional staff (e.g., a medical officer or treatment organizer and a laboratory supervisor) should be included in the DTC team at the sub-divisional level (500,000 population) in order to facilitate decentralization of supervision, staff training, monitoring and evaluation, and management of the DTP at the PHI level.

27. PHI management staff should be trained to analyze their own facilities' performance indicators and to take corrective action promptly, particularly in the areas of case findings and treatment results.

28. DTC, State and National staff should analyze the monthly, quarterly and annual reports received and provide feedback to the PHIs on the priority indicators of DTP efficacy.7

Education and Training

29. The needs for training of TB personnel for DTCs, PHIs and the like exceeds the present training capacity of the NTI in Bangalore. The current NTP training should be decentralized by using the existing state training facilities, medical colleges, public health institutions and TB-oriented voluntary agencies. They should receive NTP training materials and "train the trainer" courses to maintain standardization of training efforts.

30. The NTP manuals should be revised to reflect the recommendations of the GOI-WHO-SIDA review enumerated below.

31. NTP should develop standardized educational materials for different categories of personnel involved in TB control, including medical students, general practitioners and others involved in private practice.

32. NTP should develop standardized educational materials for patient motivation.8

The Private Sector

33. About half of new cases of TB seek care in the private sector. Although many of these later avail of the health services in the public sector, private practitioners continue to

7/ Ibid., p.30.

8/ Ibid., p.31.
play a major role in the NTP and their management of TB cases influence the outcomes of the NTP.

34. Private physicians practice a variety of regimens and do not adhere to any set drug regimen. Often their regimen is more costly than the one recommended by the NTP. Patients are usually given a prescription and sent to a pharmacy for drug purchase, with very little monitoring of patient compliance. Defaulter action is rarely taken.

35. The training of private practitioners is currently not adequate and has not been updated to incorporate recent advances in knowledge and strategies of the NTP.

36. The capacity and organization of medical associations, like the Indian Medical Association (IMA) and the Anti-TB Associations, have not been tapped to provide continuing education and awareness of the NTP to the private sector.

37. The use of health education messages targeted towards both the private physician and the consumer regarding correct treatment regimens and the importance of completing treatment should be tested as a method to standardize care provided by the private sector.

38. There is need for the NTP to clarify the role of the private sector in the care of TB patients. If a large share of TB patients do seek care in the private sector, then improved training in medical schools and the education of private physicians should be done in order to ensure proper diagnosis and treatment and augment cure rates for patients under private care.\(^9\)

Research

39. Research can be undertaken to analyze the functioning of the NTP and to test alternatives to improve NTP results, in particular the organization of treatment delivery service to increase the cure rate.

40. Operational research should be integral to the NTP to test the feasibility and results of different technical and organizational strategies adopted by the NTP.

41. The research potentials of the various research institutes, such as the Tuberculosis Research Center (TRC) in Madras, the National Tuberculosis Institute (NTI) in Bangalore, the Indian Council of Medical Research (ICMR) in Delhi, the Institute of Thoracic Medical Association in Madras and other such research institutes should be harnessed to bring about paras.39 and 40 above.\(^10\) In addition to the TRC and NTI, other institutes could be tapped to

\(^9\)/ Ibid., pp.31-32.

\(^10\)/ Ibid., pp.32-33, 38 and 39.
provide support to the NTP for research. Two of these institutes are the National Institute of Communicable Diseases (NICD), in Delhi, and the All India Institute of Hygiene and Public Health (AIHHPH) in Calcutta. Both the NICD and the AIHHPH are national public health institutes and have expertise and capabilities in epidemiological studies of TB. Both could complement the efforts of the NTI and the TRC in operational research.

**Recommendations**

42. Strengthen the organizational structure of the NTP by: (a) establishing an apex policy making authority and an executive task force with managerial functions to implement the reorganization of the NTP; and (b) upgrading the central TB control unit (researcher’s note: this upgrade has already been undertaken by making the TB section of the Directorate General for Health Services (DGHS), which supervises the technical aspects of the NTP, into a division headed by a Deputy Director (TB), when formerly it was headed by an Assistant Director General, and by having a senior officer, with the rank of Director (TB), assist the joint secretary in the Ministry of Health and Family Welfare who is in charge of the financial and administrative aspects of the NTP).

43. Improve quality of patient diagnosis by: (a) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment; (b) ensuring quality of microscopic examinations with adequate equipment, training and quality control; and (c) establishing criteria for diagnosis by radiological and clinical methods.

44. Direct national and state resources to ensure cure of TB patients, giving priority to infectious TB cases, by: (a) adopting short-course chemotherapy; (b) establishing criteria for treatment completion, cure and discharge from the TB registry; and (c) ensuring the uninterrupted supply of quality anti-TB drugs.

45. Revise current NTP system of registration and notification by emphasizing cohort analysis of treatment results, viz., completion and cure, transfers, defaulters, died and treatment failures, as the main indicators of the effectiveness of the NTP.

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12/ Ibid., p.52.

13/ Ibid., p.36.

46. Develop policies to decentralize treatment services closer to the community level to ensure access to care and patient compliance to recommended drug regimens.

47. Implement pilot projects at the block level to test capacity to implement paras. 43 through 46 above.

48. Add a medical officer or treatment organizer and a laboratory supervisor at the sub-district level (500,000 population) to strengthen NTP management and facilitate decentralization of supervision.

49. Develop training materials that incorporate changes proposed by the joint review in the NTP’s policies and procedures. Use not only the State TB Training and Demonstration Centers (STTDCs), but also medical colleges, public health institutes and TB-oriented voluntary agencies as venues for training. Make available international and national training opportunities for different levels of NTP staff.

50. Undertake operational research as an integral part of the NTP to: (a) evaluate NTP performance; (b) improve service delivery; (c) increase problem solving capacity; and (d) obtain baseline epidemiological information to measure reduction in the risk of infection.
INDIA: Tuberculosis Control Project

LESSONS LEARNED FROM EXPERIENCE

Worldwide.

1. The proposed project would benefit from lessons learned worldwide on Tuberculosis control interventions, experiences from Bank lending for TB control and the Indian experience of the two Pilot Phases.

2. The Tuberculosis control strategy advocated by the World Health Organization (WHO) and to be adopted by the proposed project, is based on the lessons learned from rigorous evaluations by notable TB experts of TB control experiences worldwide. These lessons have been incorporated in the five key elements of the WHO policy for TB control: (a) the need for government commitment to an effective TB program; (b) a focus on case detection through predominantly passive case finding; (c) administration of standardized short-course chemotherapy to at least all sputum-positive cases, preferably under directly observed therapy (DOT) or similar case management conditions; (d) establishment and maintenance of a system of regular drug supply, and (e) establishment and maintenance of an effective monitoring system for program management and evaluation.

3. The background to this approach is based on the following findings from previous experience on TB control.

4. Domiciliary Treatment vs. Hospitalized Treatment. Prior to the establishment of domiciliary treatment and the development of anti-TB drugs, TB patients were placed in sanatoria. It was in the late 1950’s that the Tuberculosis Research Center (TRC) in Madras, India, showed the effectiveness of the domiciliary treatment of TB. In general, the treatment of TB is now ambulatory; only in exceptional situations is long-term hospitalization recommended.

5. Short-term vs. Long Term Chemotherapy. The production of powerful anti-Tuberculosis Drugs has shortened the treatment period from 12-18 months (Long-Course or Standard Chemotherapy) to 6-8 months (Short-Course Chemotherapy or SCC). Although Standard Therapy (ST) drugs are cheaper than SCC drugs, the length of treatment often discourages completion and complicates case management. The reduced mortality, morbidity and disability resulting from a successful use of SCC make this course of treatment more cost effective than LCC drugs. It has been shown that SCC treatment is more cost effective than oral rehydration and measles immunization when reduction in risk of infection is taken into account. Annex 13 provides an

economic analysis of TB treatment as proposed. SCC drugs are considered the best regimen for Tuberculosis control technologically, economically and socially. Under SCC, however, rigorous adherence to treatment, particularly during the initial phase, is critical to prevent the development of drug resistance.

6. **Sputum Examination and Culture Tests vs. X-rays in Diagnosis and Evaluation of Treatment Outcome.** TB control means reducing to manageable levels the TB incidence and the annual risk of TB infection in the community. Since it is the sputum-positive TB patients who are capable of transmitting the disease, they have to be identified, treated and made non-infectious. X-rays do not distinguish between sputum-positive and sputum-negative TB patients and has therefore limited capacity. Furthermore, X-rays are expensive to procure and maintain. Microscopy and culture tests are able to identify sputum-positive and sputum-negative patients and can therefore isolate the source of infection and treat it appropriately. Furthermore, in addition to being effective in diagnosing infectious cases of TB, sputum examinations and culture tests are also effective in evaluating treatment effectiveness of the drug regimen. Sputum tests can determine whether a patient has converted to sputum-negative, or non-infectious, status and is cured of TB. Culture tests can determine if retreatment or relapse TB cases have developed drug resistant TB and to which drugs they are resistant, so that a more effective treatment regimen can be mounted to effectively render these patients non-infectious. X-rays, on the other hand, cannot do any of these. Therefore, sputum examination and culture tests are the most effective ways to diagnose and evaluate TB treatment outcomes.

7. **Directly Observed Therapy vs. Unsupervised Case Management.** Directly-Observed Therapy or DOT refers to a case management system whereby the patient swallows the prescribed drugs in the presence of a health care worker or another person designated for that purpose. Studies have shown that most defaults (TB patients who don't take their regular supply of drugs), occur within the first several weeks of the start of treatment. The six-month short-course chemotherapy regimen, although shorter in duration than the standard chemotherapy, is no assurance of treatment completion. Moreover, with the intermittent regimen prescribed under SCC (when drugs are taken every other day or at intervals), each day missed can make the treatment regimen less effective. DOT has been adopted in developed and developing countries as a sure-proof method to achieve cure with a success rate of over 80%. However, DOT is not without controversy and needs to be addressed within the context in which the program is implemented. Fully supervised or directly-observed treatment for intermittent drug-taking have proved feasible and successful in urban areas. In rural areas, however, where patients live far from the nearest health center, problems of directly supervising intermittent drug-taking have been found less effective. More creative ways of undertaking DOT have to be developed and introduced in the rural and remote settings, e.g., through community leaders, traditional healers and Familial Care Givers.

8. **Vertical vs. Integrated Approach.** Experience with both approaches have led to the WHO recommendation that tuberculosis control programs should involve both the vertical and the integrated approach, recognizing the need for a specialized TB health care workforce to provide the
technical guidance and supervision, and the generalized health care to bring the knowledge and technology to the periphery.

9. **The Role of the Private Sector.** Recent studies of service providers in several countries, particularly India, have shown that private physicians are actively involved in the treatment of tuberculosis, but are often unacquainted with the most recent developments in the field; as a result, TB treatment in the private sector is also deficient. Over 60% of the patients in India tend to visit first a private doctor; they switch to the government service when their finances to pay for private care run out. The systematic involvement of this sector in TB control is emerging as an important priority for a successful TB control.

10. **Limited Effectiveness of BCG Vaccination.** The vaccine, which is given to most infants, does not prevent TB infection, but it prevents the spread of TB infection within the lungs and to other parts of the body. The vaccine has been found effective in young children in preventing the spread of TB in the blood stream (Miliary Tuberculosis) and in the brain and spinal cord (Tuberculosis Meningitis). Miliary TB and TB Meningitis are the primary source of TB morbidity and mortality in young children. The effect of the vaccine lasts 10 to 15 years.

11. Because the BCG vaccine does not provide real protection against pulmonary TB infection, nor does it reduce the pool of infectious, sputum-positive, TB patients, the BCG vaccine is not used as a technological measure to control the spread of TB. The best way to protect children against TB infection is by having the TB control program concentrate on reducing the risk of TB infection by reducing the number of infectious, sputum-positive TB in the families and communities where these children live.

**Experiences from Bank Lending for TB Control.**

12. Bank experience with TB control has been exclusively in projects that do not focus on TB control alone, e.g., Lesotho's Health and Population Project (Report No. 5437-LSO, 1985); China's Infectious and Endemic Disease Control Project (Report No. 9894-CHA, 1991); and Zimbabwe's Sexually Transmitted Infections Prevention and Care Project (Report No. 11730-ZIM, 1993). The China and Bangladesh projects offered the best example for India as they have strictly followed the WHO strategy, and, in the case of China, it represented a problem of somewhat similar magnitude as in India. Indian TB officials visited the project to become acquainted with the details of project implementation. The proposed project in India would be the first Bank lending operation that would focus only on Tuberculosis Control. Such an approach is justified, given the magnitude of the problem in India and its weak TB infrastructure.

13. The main lessons learned from these projects relate to the use of passive case finding, government charges for TB services, and issues of sustainability for DOT.
14. **Passive Case Finding vs Active Case Finding.** The passive case-finding approach emphasizes successful cure rather than number of TB patients who have been actively found. The passive case finding approach ensures rigorous program management that can later respond to increased demand. Moreover, by emphasizing cure, more attention is given to treatment completion which greatly reduces the risk of TB infection and the development of acquired drug-resistant strains of TB. According to WHO, passive case finding is advisable until a cure rate of 85% is achieved. Only then can active case finding be recommended particularly to reach isolated groups and other areas of the population.

15. **Free vs. Paid TB Care.** While payment of TB care will help in efforts at cost recovery, especially in terms of beneficiary contribution to the cost of SCC drugs, it has been found that paid TB care has had adverse effects in China. When the Chinese authorities introduced payment for TB care in the 1980s, after providing it free of charge in the 1960s and 1970s, the TB incidence and the risk of infection rose dramatically, forcing the Chinese authorities to revert back in the 1990s to their original practice of providing free TB care.$^{2}$

16. **Sustainability of Directly-Observed Therapy.** One of the concerns with the use of DOT is the potential cost it represents to the government if extra payments need to be made for this service. Because DOT is labor-intensive and requires considerable manpower for an extended period of time, it is important that provisions be made ahead of time to reduce the burden this approach may create to the government budgetary system.

**Findings from the Pilot Projects - Phases I and II.**

17. The findings of the Phase I and Phase II pilots constitute valuable experiences for the proposed project. The pilots provided critical information in defining the roles of the management units at each level, the amendments needed in the technical and operational guidelines, the technical specifications of certain medical inputs, and the procurement and distribution systems. They also pointed to the need for: (a) a strong Central Management Unit that would provide clear and decisive leadership and management direction; (b) a broader project scope in order to elicit the political will needed for successful TB control; (c) an effective and rigorous training program that would facilitate the transfer of knowledge needed to implement the new technical approach; (d) creative institutional arrangements to help promote the adoption of the revised strategy not only within the existing TB structure but most importantly throughout the health system; and (e) the involvement of the private and NGO sector given the important role private physicians play in TB treatment in India. (Annex 11 describes the implementation and outcomes of the project.)

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2. Ibid., p. 58.
INDIA: Tuberculosis Control Project

RECOMMENDATIONS OF THE INDIAN CENTRAL COUNCIL OF HEALTH - 1995

On September 1995, the Council reviewed the National Tuberculosis Control Programme (NTCP) and was concerned about the increasing threat of TB-HIV co-infection, emergence of multi-drug resistant strains of Tuberculosis and low cure rates under the NTCP. The Council expressed an urgent need to strengthen the program in order to prevent further deterioration in the Tuberculosis situation. The following resolutions were passed by the Council:

1. **Notifiable Disease:** The Council felt that Tuberculosis should be made a notifiable disease so that all TB cases detected by different institutions (Government and Private) are reported to the NTCP.

2. **Increase Budget Allocation:** The Council recommended the Central and State Governments to increase the budget allocation for Tuberculosis, at least to the extent of providing Standardized Short-Course Chemotherapeutic drugs to all patients put on treatment under the NTCP.

3. **Early Detection and Cure:** The Council desired that efforts must be made to cure at least 85 percent of all sputum-positive cases and to detect at least 70 percent of the estimated incidence through the primary health care approach, involving the peripheral health functionaries.

4. **Infrastructure:** The Council recommended the States/UTs to fill up all vacant posts in the State TB Training Centres, District TB Centres and the staff in the Peripheral Health Institutions doing Tuberculosis work on a priority basis and appropriately train them at the State and National Training Institutes.

5. **Logistics:** The Council recommended the Centre and State Governments to ensure timely, adequate and uninterrupted supply of anti-TB drugs to the most peripheral areas by simplifying and gearing up the administrative procedures involved in their procurement and supply.

6. **NGOs and Private Sector:** Efforts should be made to involve the NGOs and Private Sector in the NTCP. The Council desired that necessary steps must be taken in this direction by the Centre/States.

7. Short-Course Chemotherapy should be introduced in each district expeditiously to cover at least all sputum positive patients.

8. IEC activities should be further intensified.
INDIA: Tuberculosis Control Project

ELIGIBILITY CRITERIA FOR THE SELECTION, IMPLEMENTATION AND EXPANSION OF RNTP DISTRICTS

1. There are currently a total of 496 districts in India. District TB Centers are operating in 446 districts. In some of the remaining 50 districts, tuberculosis control activities are being undertaken by TB clinics (total 330) and TB hospitals (total beds: 47,600). Out of 446 districts, 292 are currently undertaking Short-Course Chemotherapy (SCC), while the remaining 154 districts are still using Long-Course Chemotherapy (LCC). Out of 292 SCC districts, four districts in Orissa are likely to be covered by DANIDA, and one district in Andhra Pradesh is functioning under ODA. Out of the remaining 287 districts, 84 are designated project or RNTP districts and also include the districts covered by the two sets of pilots during project preparation. The remaining 18 districts included in the 102 proposed RNTP districts are out of 154 non-SCC districts. While the project seeks to fully implement the RNTP in these 102 SCC districts, the project will also include partial financing of TB activities in the remaining 203 SCC districts in preparation for adoption of the RNTP. In addition, the project would fund the drug requirement for all sputum positive patients throughout the country. The project would not fund TB control expenditures in districts covered by other donors.

2. In order to be eligible to participate in the RNTP, a district would need to meet the following criteria:

   a. **Selection of Initial Districts.**

      (1) The State TB Unit has been strengthened as required by the project. District Tuberculosis Control Societies (DTCS) have been established.

      (2) District TB Officer/Medical Officer, Laboratory Technician, Statistical Assistant and Treatment Organizer are in place in the District TB Center and functioning.

      (3) Additional staff to be recruited have been identified, specifying the number of staff per staff category.

      (4) Sites for TB Units and Microscopy Centers have been identified.

      (5) Training centers have been identified and the Training Plan for all categories of staff have been completed.
(6) State trainers have been trained in Central Institutes, State Training & Demonstration Centers (STDCs), TB Hospitals (in states where there are no STDCs), or District level training facilities, or other comparable training or demonstration sites.

(7) Directly Observed Therapy (DOT) providers have been identified.

b. **Starting Service Delivery.**

(1) The following staff training should have been completed:
   
   (a) all key staff at the district and sub-district level;
   
   (b) 80% of the Medical Officers from the General Health Services;
   
   (c) 80% of the Laboratory Technicians from the Microscopy Centers; and
   
   (d) 50% of Peripheral Health Staff (Multi-Purpose Health Supervisors and Multi-Purpose Workers).

(2) Tuberculosis Units have been established at the sub-district level with staff in position.

(3) The following inputs are in place, namely:
   
   (a) microscopes (may be monocular initially);
   
   (b) drugs;
   
   (c) drug storage area/inventory system; and
   
   (d) registers and formats.

(4) Key staff of the district and sub-district have visited the demonstration.

(5) At least 50% of the sub-centers are ready for DOT (i.e., centers identified, staff in position, etc.)

(6) Plan of action for implementation of the strategy for tribal populations has been developed for tribal areas, if they exist in the district.

(7) The Central Division has appraised the status of preparation and finds it fully satisfactory

c. **Criteria for Expansion of RNTP in a State.**

(1) The proposed districts should have fulfilled all the criteria for Initial Districts.
(2) Achievement in Initial Districts:

(a) Ratio of sputum positive/sputum negative diagnosed cases is at least 1:1.2;

(b) Sputum conversion at three months in new smear positive cases is at least 80% on the aggregate for two quarters; and

(c) Case detection of new smear positive patients would be at least 15 per lakh population (15 per 100,000).
INDIA: Tuberculosis Control Project

DISTRICT TUBERCULOSIS CONTROL SOCIETIES (DTCS)

1. District Tuberculosis Control Societies (DTCS) will be established in all of the project districts. In the districts where there are already District Leprosy Societies or another equivalent Health Society, their charters would be revised to transform them into District Leprosy/Health Cum Tuberculosis Societies.

2. **Rationale.** DTCS are important structures in the Revised National Tuberculosis Control Program (RNTP). Since the GOI's 8th Year Plan, districts have become the implementing foci of various development programs. With an average population of 15 to 20 lakhs (i.e., 1.5 to 2.0 million people), districts have also become the most viable fora for coordinating the activities of the government, private and voluntary sectors. DTCS are likewise important vehicles for ensuring the uninterrupted flow of funds to project districts. Finally, while it is possible to frame policies, guidelines, norms and broad strategies for action at the national and state levels, it is only the district officials and citizens who best know their district and are the most appropriate people to decide how to effectively implement the RNTP based on local conditions in the district in terms of diverse socio-economic status, population size, geographical terrain, etc.

3. **Membership.** The DTCS would consist of a maximum of 20 members equally divided between the government (10) and the non-government/private sectors (10). The chairman would be the District Officer (e.g., Collector, Magistrate, Deputy Commissioner) and the member secretary would be the District TB Control Officer (DTO).

4. **Funding and Activities.** While the DTCS would receive funding from project funds through submission of reimbursement claims in terms of audited Statements of Expenses (SOEs) to the Government of India (GOI), the Government of India may consider allowing District TB Societies to raise their own funds for TB Control. These funds, whether from project or private sources, would be used to finance various activities including (a) the payment of district contractual staff and honoraria of those who conduct Directly-Observed Therapy (DOT); (b) Information, Education and Communication (IEC) activities; (c) active involvement of the private and Non-Government Organization (NGO) sectors in the RNTP; (d) the running and maintenance of project vehicles; and (e) minor civil works such as additions or alterations required in establishing microscopy centers. In terms of providing honoraria to non-government DOT workers, such honoraria would be paid AFTER proof or certificate has been acquired from the DTO that such a person was undertaking DOT to such TB patient(s) whose names and addresses are specified during the intensive phase and continuation phase of the drug regimen and that, as a result of such DOT, the patient(s) was able to complete treatment and cured of TB.

5. **Functions of the DTCS.** These would include: (a) situational analysis and planning (e.g., periodic assessment of the magnitude of the TB problem in the district, district needs, status of available district facilities and resources such as infrastructure and manpower; and preparation of an annual district action plan); (b) resource mobilization (e.g., receive and monitor the use of funds, equipment and materials); (c) coordination among government,
inter-government, private and NGO sectors; and (d) implementation (e.g., strengthen existing and potential facilities and resources; undertake IEC; collect, compile and report information concerning the RNTP in the district on a quarterly basis; upgrade the knowledge and skills of service providers through IEC activities, training programs and sponsorship in conferences and workshops).

6. **Term of Office.** The term of office of both ex-officio and nominated members of the DTCS is two years. Re-nomination is on a yearly basis.

7. **Powers and Functions of the Executive Body/Governing Council.** The Executive Body/Governing Council would be comprised of the Chair, the Vice-Chair and member secretary of the DTCS and those members attending the Council Meetings. Its powers and functions would be to: (a) approve an annual budget; (b) consider and approve the annual account with the audit report; (c) inspect and supervise the implementation of RNTP schemes under the guidance and advice of State and Central governments; (d) undertake activities consistent with the aims of the Society; and (e) take decision on any matters referred to it by the Central or State government, or the chairman.

8. **Powers of Member Secretary.** These would include: (a) all executive and financial powers consistent with the Member Secretary’s responsibility for the planning, implementation and monitoring of time bound activities; (b) supervision of the Society’s activities; (c) provision and distribution of needed drugs, medical consumables, equipment, other supplies and health education materials; (d) submission of periodic reports to central and state authorities; and (e) exercise and discharge such duties delegated by the Executive Body/Governing Council.

9. **Meeting of the Governing Council.** The Council is to meet at least once in six months, or as often as necessary to transact Society business, and the date and time of such meetings shall be set by the member secretary in consultation with the Chair. Two weeks, or, in case of emergency, 48 hours notice of the meeting shall be given to the members either personally or by post by the member secretary. A quorum would consist of at least five members and decisions shall be taken by a majority vote of the members present in the meeting.

10. **Emergency Powers.** These are vested on the Chair and member secretary, who, acting together, shall exercise all powers of the Governing Council in case of emergencies and whose emergency actions shall be reported in the next meeting of the Governing Council and its approval sought.

11. **Registration and Office.** The DTCS shall be formed and registered under the Societies Registration Act of 1860 and any other similar act by the state government. The registered office of the DTCS is the District Headquarters.
INDIA: Tuberculosis Control Project

TRAINING ACTION PLAN IN THE REVISED NTP (RNTP)

Criteria for Selection of Training Institutes

1. Institutes fulfilling the following criteria would be eligible to become training institutes under the project:

   (a) **Curricula**: Formal commitment that they would adopt the strategy, policy, technical and operational guidelines of the RNTP in its training curricula;

   (b) **Building**: Adequate space for lecture/class room, laboratory and bio-culture facility and hostel facilities;

   (c) **Training Staff**: Availability of faculty members, especially for Health Management, Epidemiology, Microbiology, Health Education, Statistics, etc.;

   (d) **Support Staff**: Availability of (i) office staff for managing finance and coordinating training; and (ii) technical staff for providing theoretical and field training;

   (e) **Other Facilities**: Availability of teaching aids like overhead and slide projectors, public address system, audio-visual aids, and transport facilities for training;

   (f) **Teaching Material**: Capacity for development of teaching materials for training and provision of translation into the vernacular of materials provided by the Central TB Division; and

   (g) **Teaching Experience**: Institutes with previous experience in training especially in relation to the TB Control program would be ideally suitable.

State Trainer Trainees

2. The trainee selected to be trained as a trainer would ideally be a person already working in the TB Control program with experience in training activity. The candidates would therefore be chosen from persons working in STDCs, State TB units, TB hospitals, medical colleges in the vicinity of the STDCs, project officers in the RNTP, District TB Officers and the neighboring Family Welfare Training Institutes. Trainers must be given practical field experience in RNTP training and demonstration areas. Responsibility for training and monitoring the results of training will be assigned to Central and State Institutions by the Central Unit, with periodic evaluation of performance.

3. Based on the type of training they have received, the state candidates would be designated as (i) Trainers for Medical Officers (MO); (ii) Trainers for Senior TB Supervisors (STS); and/or (iii) Trainers for Senior TB Laboratory Supervisors (STLS).
State Training Institutes

4. There are 16 STDCs in 15 states already established for training of NTP staff. They are shown in the table below.

<table>
<thead>
<tr>
<th>State Where STDC Located</th>
<th>Name of City</th>
<th>States under STDC where Training is Proposed to be Undertaken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andhra Pradesh</td>
<td>Hyderabad</td>
<td>Andhra Pradesh</td>
</tr>
<tr>
<td>Bihar</td>
<td>Patna, Darbhanga</td>
<td>Bihar, Bihar, D&amp;N Haveli</td>
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<tr>
<td>Delhi</td>
<td>Delhi</td>
<td>Delhi</td>
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<tr>
<td>Gujarat</td>
<td>Ahmedabad</td>
<td>Gujarat, D&amp;N Haveli</td>
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<tr>
<td>Jammu &amp; Kashmir</td>
<td>Srinagar</td>
<td>Jammu &amp; Kashmir</td>
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<td>Karnataka</td>
<td>Bangalore</td>
<td>Karnataka</td>
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<td>Kerala</td>
<td>Trivandrum</td>
<td>Kerala, Lakshadweep</td>
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<td>Madhya Pradesh</td>
<td>Bhopal</td>
<td>Madhya Pradesh</td>
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<td>Maharashtra</td>
<td>Nagpur</td>
<td>Maharashtra, Goa Daman &amp; Diu</td>
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<td>Cuttack</td>
<td>Orissa</td>
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<td>Punjab</td>
<td>Patiala</td>
<td>Punjab, Haryana, Chandigarth</td>
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<td>Ajmer</td>
<td>Rajasthan</td>
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<td>Tamil Nadu</td>
<td>Madras</td>
<td>Tamil Nadu, A&amp;N Islands, Pondicherry</td>
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<td>Uttar Pradesh</td>
<td>Lucknow</td>
<td>Uttar Pradesh</td>
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<tr>
<td>West Bengal</td>
<td>Calcutta</td>
<td>West Bengal, Sikkim</td>
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</tbody>
</table>

5. Other States which do not have STDCs could provide training in TB hospitals. These states with TB hospitals are given below.

<table>
<thead>
<tr>
<th>State Where TB Hospital is Located</th>
<th>Name of City</th>
<th>Name of City/States Under TB Hospital Where Training is to be Imparted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assam</td>
<td>Guwahati</td>
<td>Assam, Arunachal Pradesh, Meghalaya, Manipur, Mizoram, Nagaland, Tripura</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>Tanda (Kangra Sub-District) Dharampur (Solan district)</td>
<td>Himachal Pradesh</td>
</tr>
</tbody>
</table>

District Level Training Facilities

6. All District TB Centers (DTCs) and adjacent TB hospitals and Medical Colleges would be utilized as District Training Centers throughout the country.

7. At the Sub-District Level, existing Community Health Centers (CHCs) or Block Primary Health Centers (BPHCs) would be utilized as institutes for training general staff in the RNTP after the concerned Medical Officer (TB Control) and other supervisory staff like STLS and STS have been trained in the State Institutes.

8. Training facilities would be identified at the district level out of the existing institutes which may be the DTC, Sub-District/Taluk Hospital, Medical College, Family Welfare Training Center, etc.
9. There are 47 Regional Family Welfare Training Centers imparting training to various categories of grassroot level health worker for Family Welfare. The same training centers can be used for imparting training in the RNTP to the same category of grassroot level health workers.

**Identification of Trainers**

10. Trainers for the RNTP would be selected from any of the following categories:

| Trainer for Medical Officer | The States of Andhra Pradesh, Karnataka, Madhya Pradesh, Maharashtra, Gujarat, Punjab, Rajasthan, Uttar Pradesh, Bihar and West Bengal                                      | (i) State TB Officer  
|                            |                                                                 | (ii) Director, STDC  
|                            |                                                                 | (iii) Microbiologist, STDC  
|                            |                                                                 | (iv) Epidemiologist, STDC  
|                            |                                                                 | (v) Chest Physician, STDC  
|                            |                                                                 | (vi) DTO in same District as STDC  
|                            |                                                                 | (vii) 2nd MO of DTC in same District as STDC  
|                            |                                                                 | (viii) Teachers of PSM, Microbiology  
|                            |                                                                 | (ix) Chest Medicine of nearby Gov’t  
|                            |                                                                 | (x) Medical College, preferably in same station as STDC  
| The States of Delhi, Haryana, Himachal Pradesh, Jammu & Kashmir and Assam | (i) State TB Officer  
|                            |                                                                 | (ii) Director, STDC/Superintendent of TB Hospital  
|                            |                                                                 | (iii) DTO in same District as STDC  
|                            |                                                                 | (iv) Medical Officer of STDC/TB Hospital or Project Officer in on-going RNTP of the State  
|                            |                                                                 | (v) & Teachers of PSM, Microbiology  
|                            |                                                                 | (vi) Chest Medicine of nearby Gov’t Medical College, preferably in same station as STDC/TB Hospital, OR  
| For the States of D&N Haveli, Daman & Diu, Goa, Lakshadweep, Chandigarh, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura | (i) State TB Officer  
|                            |                                                                 | (ii) DTO of same District/Superintendent of TB Hospital  

**Trainer for Senior Treatment Supervisor/Treatment Organizer**

For all States and Union Territories (Uts)  
(i) BCG Team Leader posted in State HQ  
(ii) Senior Treatment Organizer of STDC  
(iii) Senior Treatment Organizer of DTC of same District  
(if no staff available, any of the above two can be selected)

**Trainer for Senior Laboratory Technician/ Laboratory Technician**

For all States and Union Territories (Uts)  
(i) Senior Laboratory Technician of STDC/TB Hospital  
(ii) Laboratory Technician of DTC of same District  
(iii) 2nd Laboratory Technician of DTC of same District  
(if no staff available, any of the above two can be selected)
District Trainers

11. At the District level, the training of workers supervising grassroot level workers would be undertaken by the DTC staff.

12. At the Tuberculosis Unit level, the Medical Officer (TB Control) would be responsible for the training of grassroot level workers.

Staff to be Trained

<table>
<thead>
<tr>
<th>Category</th>
<th>Number Trained</th>
<th>Number Per Batch</th>
<th>Number of Batches</th>
<th>Duration (in Days)</th>
<th>Training Days</th>
<th>Training Sites</th>
</tr>
</thead>
<tbody>
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<td>DO</td>
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<td>20</td>
<td>15</td>
<td>10</td>
<td>145</td>
<td>4</td>
</tr>
<tr>
<td>MO</td>
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<td>20</td>
<td>749</td>
<td>5</td>
<td>3,747</td>
<td>122</td>
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<tr>
<td>STLS</td>
<td>501</td>
<td>6</td>
<td>84</td>
<td>5</td>
<td>418</td>
<td>30</td>
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<tr>
<td>LT</td>
<td>5,062</td>
<td>8</td>
<td>633</td>
<td>10</td>
<td>6,333</td>
<td>135</td>
</tr>
<tr>
<td>STS/TO/SA</td>
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<td>20</td>
<td>38</td>
<td>6</td>
<td>228</td>
<td>123</td>
</tr>
<tr>
<td>MPHS</td>
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<td>1,181</td>
<td>3</td>
<td>3,543</td>
<td>1,149</td>
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<tr>
<td>MFW/TBH</td>
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<td>25</td>
<td>1,991</td>
<td>2</td>
<td>3,982</td>
<td>1,654</td>
</tr>
</tbody>
</table>

Training Curricula

13. **Center.** The task of developing, field testing and revising training materials and curricula for all levels of health staff to be trained in the Project will be undertaken by DGHS in collaboration with Central Institutes and other technical institutions. Coordination of this effort would be improved to speedily produce materials of the quality desired.

14. To make the curricula consistent with the program, agreement would be reached on a uniform format, use of illustrations and attractive easy-to-read typeface. A range of training methods would be included to ensure that participants think, act and practice skills during training.

15. **NGOs and the Private Sector.** While the current involvement of experienced staff from the four central training institutions is appropriate, NGO staff would also be asked to contribute to developing modules for MPWs and CHVs. Private medical associations such as the IMA would be involved to offer ways to communicate crucial information to their members regarding drug use and the RNTP operations.

16. **Information, Education and Communication (IEC).** The IEC component would be integrated into the training program for each cadre of worker.

17. **DO and MO.** The core curricula for the training of doctors would be the series of WHO modules Managing Tuberculosis at the District Level comprising of:

   A1 Introduction

   A2 Administering Treatment
A3 Registering Cases
A4 Ensuring Identification of Tuberculosis Suspects
A5 Monitoring Treatment
A6 Quarterly Reporting on Case Finding
A7 Quarterly Reporting on Treatment Results
A8 Maintaining Regular Drug Supplies and Other Materials

18. There would be need to correct discrepancies with the RNTP guidelines such as:
(a) daily regimens (WHO) vs thrice weekly regimens (RNTP); and (b) advice about side effects whereby it is suggested that patients immediately stop treatment and see the closest health staff if there is a red/orange discoloration of the urine when this is a common and harmless side effect of taking rifampicin.

19. While it is reported that trainers and participants often agree to skip the role play exercises in Module A2 (pp. 95-99) on Communicating With Patients, this would be avoided as lack of training in this area threatens to weaken compliance with therapy if patients have a poor basic understanding of TB and do not comprehend the importance of their medications, frequency, side effects, sputum exams, and/or dangers of developing resistance.

20. Skills in conducting supervisory visits, using the TB register workbook and interacting with the supporting laboratory services would be included in the curriculum.

21. STLS. The content of the curricula would include at least all of the Laboratory Technician Training, WHO Module A5, orientation to the quality control system and supervision skills.

22. LT. The Manual for Laboratory Technicians Training (Mycobacteriology) by the L.R.S. Institute in Delhi would need to be reviewed and revised to include content and exercises on microscope repair, record keeping in the laboratory and maintaining stocks of reagents, slides, etc.

23. STS/TO/SA. The draft Module for Senior Tuberculosis Supervisor/TB Health Visitor by the L.R.S. Institute in Delhi would be supplemented with the IEC component, as well as training objectives and instructions for organizing the field work on supervising Directly-Observed Therapy (DOT).

24. MPW. There is a draft Module for Training of Health Workers on Tuberculosis (Revised Strategy) by the Gandhigram Institute of Rural Health and Family Welfare Trust. The draft would be revised to incorporate the IEC component and be consistent with the RNTP technical and operational guidelines.

25. MPHS/TBHV, CHV/ Anganwadi HW and Storekeeper/ Pharmacist. Curricula and training materials would need to be developed for these levels.
26. **Trainers Experience in the RNTP.** All the trainers would need at least a few days observing the RNTP at the district level. They would need to have hands-on experience managing, supervising and providing services under the revised technical and operational guidelines.
INDIA: Tuberculosis Control Project

OPERATIONS RESEARCH

1. **Goal.** The goal of Operations Research is two-fold: (a) to build local capacity for Operations Research in India, including establishing an operations research network among various public, private and NGO institutions, both local and international; and (b) to generate appropriate and continuous flow of information to make Tuberculosis control in India more efficient and effective.

2. **Central Steering Committee.** A steering committee would be established at the national level with the Director General of Health Services as Chairman. The Member-Secretary would be the Central TB Division officer responsible for operations research. The members would be one representative each from major research institutions such as the NTI, TRC, LRS Institute, IMA, and national level NGOs and representatives from concerned international organizations such as WHO, ODA and DANIDA.

3. **Protocol Development Workshops.** Research Institutions within India, including NTI, TRC, LRS and NICD, that are interested in undertaking programs of work in specified areas of tuberculosis operations research would be identified through Protocol Development Workshops. These workshops would be organized to finalize area-wise priorities of operations research and develop skeletal outlines of protocols. Attendees in these workshops would include: (a) noted researchers from research institutions; (b) international experts; and (c) program managers of pilot areas where the revised NTP (RNTP) is being implemented.

4. **Approval Process.** During the Protocol Development Workshops, investigators would be asked to submit protocols on allotted priorities and agreed program work for operations research in particular geographical areas. The protocols that have been submitted would be screened by the Central TB Division and would then be reviewed by the Steering Committee for selection and approval of specific studies for implementation. The Central TB Division would then provide funds for such studies. These operations research studies would be monitored and periodically reviewed by the Central TB Division and the Steering Committee. The Central TB Division would develop mechanisms to transfer the results of the different operations research studies into the Tuberculosis Control Program in order to make the services more efficient and effective.

5. **District Program Managers.** The District Program Managers (DPMs) would be expected to: (a) interact with researchers and inform them of the problems faced in implementation of the RNTP; (b) attend the Protocol Development Workshops, symposia and meetings in order to assist in the selection of operations research priorities and protocol formulation; and (c) assist, in terms of logistical support, the research institutions conducting operations research studies in their respective areas.
6. **Sample Operations Research Priorities.** Major responsibilities of the central division and the steering committee would be to coordinate the different sources of support to operational research to ensure that the studies are processed, executed and reported rapidly and that the results are applied to guide policy decisions and programme implementation. The following major areas for study would be refined and prioritized by the steering committee and recommendations on the four areas of research to be carried out under the project would be submitted to IDA by January 1, 1998.

(a) **Effectiveness of Individual elements of the RNTP strategy.** The RNTP package incorporates several elements of TB control. The recording and reporting system and a regular drug supply would be introduced into all SCC districts at the start of the program, the rest of the RNTP package will be introduced into districts in a phased manner over subsequent years. It would be feasible and ethical to investigate the impact of different individual components on TB control: outcome measures in full RNTP districts can be compared with others without decentralisation of care, without direct observation of therapy, without improved diagnosis and without short course chemotherapy, etc.

(b) **Operational studies on TB service delivery.** Detection and management of TB cases depends on the coverage of general health services and their capacity to provide high quality, affordable care to the community. Studies on the real proportion of outpatients with respiratory symptoms (productivcough), the proportion of smear-positive cases among them according to the duration of cough, access for women and special groups to health services and to specific TB diagnosis and treatment, and hospital/health centre organization are required, to monitor TB management by health facilities.

(c) **Public/private mix of TB treatment sources.** Currently a substantial proportion of TB patients do not first seek professional health care from government-run services. Much of the TB treatment given by private providers (including for-profit providers) has been achieving palliation instead of documented cure. Therefore it is necessary to: (a) develop and test methods to achieve a better public/private mix of TB treatment sources in various ways, including methods to improve the image and share of government-run services; (b) develop options for involvement of the various health care providers in delivering documented TB cure; and, establish contractual arrangements, incentives and disincentives to engage private providers in delivery of documented TB cures.

(d) **Perceived importance of TB and of documented cure.** High-quality technical strategies can succeed to the extent that a wide range of potential stakeholders consider them important and useful. Support for the RNTP depends partly on socio-behavioral studies, including analysis of
stakeholders and their interests; design and pilot testing of communications strategies; and assessment of the perceptions about TB and about the RNTP held by various sectors (including the health professionals, NGOs and general public) at periodic intervals during implementation.

(e) **Economic and social impact of TB and benefits of the RNTP.** There is growing recognition of the burden imposed by TB and the benefits of TB cure to individuals, households, and the society. However, documentation of these impacts in India has been rare. Such documentation is useful to help sustain the momentum of the RNTP and to justify investments for sustainability. In particular, it would be useful to document the burden imposed by TB on marginalized groups, and the benefits of TB cure to them at the level of individuals, households and the society.

(f) **Cost-effectiveness of the RNTP and alternative approaches to TB treatment.** Although the consistency of TB cure in a well-functioning RNTP makes it hard to match in terms of cost-effectiveness, there is a scarcity of data documenting costs and analysing cost-effectiveness ratios. This needs to be remedied by a series of careful cost-effectiveness analyses, and computation of important parameters including the average and marginal cost per cure.

(g) **User-friendliness of the RNTP for special populations.** Studies of the costs and inconveniences borne by the TB patient in the course of treatment should help to fine-tune the programme to achieve greater success. This is likely to be particularly important in the case of marginalized and disempowered groups, as the more accessible groups are covered. This includes studies on accessibility and adequacy of TB management strategies to mobile populations, tribal groups, refugees, etc.

(h) **Improving household and community participation in assisting TB cure (including educational materials development).** Pilot trials of innovative arrangements for involving the community in helping to achieve documented TB cure are needed, especially the development and testing of educational materials for lay people; as well as development and testing of locally appropriate communication strategies.

(i) **Monitoring drug resistance.** The true magnitude of the antituberculosis drug resistance problem in India is not well described, and the trend will be an important indicator of programme effectiveness. In early 1994 the WHO/GTB and the IUATLD started a global project to utilize drug resistance as an indicator to measure the performance of TB programs and, in certain settings, improve the NTP performance by contributing to policy recommendations on treatment. The strategy to achieve this aim consists of the implementation of standardized drug resistance surveillance in new and re-treatment cases (in order to distinguish between primary and acquired
drug resistance), representative of the population studied, under the guidance of a network of supranational reference laboratories (SRL). Drug resistance studies should be carried out during project implementation, both in RNTP fully implemented districts and in districts to be implemented, following the standard procedures of the network.

(j) **TB/HIV surveillance**: Measuring the HIV seroprevalence among tuberculosis patients is important to the tuberculosis programme, as it allows to plan resource allocation and strengthening of the local program where the HIV prevalence is high. Areas with high HIV prevalence are those where inevitably the tuberculosis burden is going to increase rapidly, due to the immunosuppression induced by HIV infection, reactivation of latent tuberculosis infection and rapid progression of a new infection to disease. WHO has produced guidelines on anonymous unlinked HIV surveillance among tuberculosis patients. They could be adopted in India to have a precise understanding of the extent, distribution and trends of the problem.

(k) **Fixed-Dose Combination Therapy**: Fixed dose combination therapy has significant advantages in promoting adherence to TB treatment, and in decreasing drug resistance. Their widespread introduction into the RNTP would be considered during the mid-term review. There is at present remarkably little hard research data to base such decision in India. Fixed drug combinations can be introduced on a pilot basis in selected districts, following well designed research protocols, to measure the advantages in operational management and acceptability of treatment.

(l) **Drug Quality**: There is concern about the quality and bioavailability of TB drugs available in India, and the inadequacies of the current monitoring systems. There is a need to describe the scale and scope of the problem, and to develop a system to sample the drugs available, test their quality, and disseminate the results. While quality is an important issue when using single drugs, there is an increasing trend towards the use of combination pills, which are far more prone to variations in quality. There is a need to develop effective systems whereby the bioequivalence of large purchases of fixed dose combination drugs can be measured, and the bioavailability of the drugs that are used in the market place can be monitored.

(m) **Baseline for measuring the trend of the TB epidemic**: The risk of infection is the best indicator of the long-term trend of tuberculosis transmission, and therefore the indicator for the major public health objective of the programme. Although it cannot measure the impact in the short five year period of this project, baseline data is required to measure the impact of the programme and future of the epidemic, particularly as the expansion of HIV will eliminate the usefulness of incidence and mortality for this
purpose. Representative studies of prevalence of infection in children should be carried out for this purpose.

(n) Other areas of study may include:

1. the value of in-built quality control for sputum smear microscopy, incorporating facilities for proper maintenance and repair of microscopes;

2. the factors attributable to patients and health services which are responsible for delaying case-detection;

3. the development of methods which will enhance treatment adherence Short Course Chemotherapy (SCC) and behavioral studies for understanding the reasons for post-treatment compliance;

4. Knowledge, Attitude and Practice (K.A.P.) studies among medical professionals, para-medical workers, tribal population and urban slum dwellers to improve program delivery;

5. alternative simplified procedures for procurement and supply of drugs; and

6. strategies for involving major hospitals and academic institutions in the RNTP.
INDIA: Tuberculosis Control Project

PHASES I AND II PILOT PROJECTS

Initial transition from the NTP to the RNTP

1. In preparation for a shift of strategy to control TB in a more effective way, the GOI carried out two sets of pilot projects. The main purpose of the Phases I and II pilot projects was to test a new paradigm for TB control in the Indian context based on the 1992 recommendations of the joint GOI-WHO-SIDA review of the NTP. In summary, the review found the following inter-connected problems in India's 30-year-old National Tuberculosis Control Program (NTP): (a) a weak central unit; (b) poor quality of diagnosis, based mainly on X-rays; (c) multiple treatment regimens; (d) lack of sufficient funds for regular supplies of drugs, particularly the SCC drugs recommended for smear-positive patients; (e) treatment completion rate of 25% on average; (f) low proportion of infectious cases among the estimated 1.5 million cases reported per year; (g) lack of monitoring of program performance and quality; (h) irregularity in the supply of drugs; and (i) frequent transfer of patients between the public and private sectors, contributing to default and drug resistance (see Annex 4 for details on the Program Review).

Phase I Pilots

2. With the findings and recommendations of the joint review, a task force was created to develop the pilots. In February 1993, the technical guidelines and a plan of activities to implement the pilots were prepared and approved. Financial assistance came from SIDA. The pilots were implemented in two taluks in the Mehsana district of Gujarat (population 400,000), one ward in Bombay (population 350,000) and one Chest Clinic area in Gulabi Bagh in Delhi (population one million) in October 1993 and in Calcutta and Bangalore in early 1994.

3. The basic principles of the project included: (a) use of intermittent, Directly-Observed SCC (DOTS) during the initial phase for smear-positive cases and a strengthened regimen for re-treatment cases; (b) use of multi-purpose health workers to administer DOTS and provide drugs; (c) registration, monitoring and evaluation of program results based on WHO guidelines; (d) establishment in rural areas of a TB unit for program supervision at the sub-district level (population about 500,000); and (e) strengthened laboratory services to form the basis for diagnosis.

4. Training for the pilot areas started at the national level in July 1993. Training was undertaken at the National Tuberculosis Institute (NTI) in Bangalore using the WHO modules and at the WHO regional office (SEARO) in New Delhi.

5. By October 1993, the pilot sites (Delhi, Bombay and Gujarat) had started registering cases, the central team had been reinforced and GOI had committed increased financial resources for the Tuberculosis Program. Calcutta and Bangalore started the pilots in early 1994.
6. Although the basic principles of the pilot were maintained in all the pilot sites, adjustments were made to respond to local circumstances. Delhi established specialized TB units in ten existing general dispensaries, each staffed with a treatment supervisor and a microscopist. Bombay maintained DOTS for the whole duration of treatment and developed a computerized system for registration instead of hand-written books and cards. Gujarat implemented treatment supervision mainly through existing multi-purpose health workers at the village level (population 3,000).

7. The Phase I pilots showed that the RNTP was feasible and could produce satisfactory results. In the evaluation carried out in April 1994, 83% of the cohort of smear positive cases registered in the first quarter of the pilots were smear negative at three months. Furthermore, the quality of diagnosis improved, with the proportion of smear negative pulmonary cases diminishing rapidly to around 50%.

8. In an evaluation of the pilot sites from data from October 1993 through December 1994, 3,777 cases were registered, two-thirds of which were males. 1,343 were new smear positive cases (Category I) and 468 smear positive relapses (Category II). The results of sputum conversion at three months among new smear positive cases varied from 64.4% in Calcutta to 96.8% in Delhi, for an average of 86.1%. 79.3% of these cases were cured or completed treatment. Through September 1996, the pilot projects have treated a total of 15,821 patients in a population base coverage of roughly 12 million with cure rates as high as 92% and 80%, on average, for all the sites.

Lessons Learned from Phase I

9. Below are clusters of valuable lessons learned from the Phase I pilot projects:

(a) Central planning needed to be done much earlier to ensure that essential resources were available when required. Guidelines and forms needed to be reproduced at the central level for uniformity. Frequent supervision by trained staff with experience in the pilot project strategy was necessary. The officers responsible for new areas need to be trained in visits to already implemented projects.

(b) Active case finding should not have been done. Manual records (registry books) were necessary, even when the system was computerized, to ensure quality of data. Detailed mapping of existing health facilities and population centers ought to have been available before starting implementation.

(c) Multi-purpose health workers could provide effectively supervised treatment and this extra work did not interfere with other activities. In fact, it stimulated other programs and increased their status.
Areas for Improvement in Phase I

10. While the results of Phase I in terms of sputum conversion and cure were very good and they demonstrated the feasibility of patient registration and DOT and justified extension of the RNTP to larger populations, there were areas that needed improvement such as:

(a) Phase I did not provide sufficient information on the expected case load (incidence) nor on the feasibility and effectiveness of a sub-district TB supervision unit for rural areas, nor on methods to involve NGOs and private practitioners.

(b) Frequent changes of the national program manager produced delays in project implementation and in the consolidation of the national program management team.

(c) Implementation was undertaken under significant constraints of resources and equipment and without all the required inputs from the central government such as printed guidelines, record books, regular supervision, funding and drugs.

Phase II Pilots

11. In order to build on the lessons learned and areas for improvement in Phase I, and as an immediate preparation for a proposed Tuberculosis Control Project to be financed with IDA assistance, a second series (Phase II) of demonstration pilots was prepared through an IDA Project Preparation Facility (PPF) credit advance. The British Overseas Development Administration (ODA) provided co-financing.

12. As part of preparation for Phase II, the technical and operational guidelines were revised on the basis of the experience acquired in Phase I. The Phase II pilots comprised TB Centers in five states and ten cities (total population 12 million) and were launched in February 1994. Phase II was implemented only in those sites which had received the necessary resources to undertake the RNTP and had completed site preparations. One of the criteria whereby a site could demonstrate that it completed site preparations was the participatory drafting of a specific RNTP plan of action, including objectives, activities and inputs. Eventually, all 15 sites entered the program.

13. The Phase II pilots demonstrated the feasibility of expanding the RNTP to a much larger population and at the same time getting the same results as in the Phase I pilots. From data through December 1995, out of 2,858 new smear positive cases, 85.1% had converted by the third month of treatment. Of the initial 1,546 new smear positive cases put on treatment, 80.0% had completed treatment successfully. The Central Division was likewise strengthened further with additional new staff actively involved in both the implementation of the pilots and the preparation of the proposed Tuberculosis Control project. Phase II implemented the recommendations emerging from Phase I and validated the areas requiring improvement, which are expected to be corrected with the proposed project.
### INDIA: Tuberculosis Control Project

**Project Cost, Financing & Disbursement Tables**

**Cost By Component**

<table>
<thead>
<tr>
<th>Component</th>
<th>Local (Rs Million)</th>
<th>Foreign (Rs Million)</th>
<th>Total (Rs Million)</th>
<th>Local ($ Million)</th>
<th>Foreign ($ Million)</th>
<th>Total ($ Million)</th>
<th>% Foreign Exchange</th>
<th>% Total Costs</th>
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<tbody>
<tr>
<td>Improve Quality, Access &amp; Outcomes of TB Treatment</td>
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<td>2,374.8</td>
<td>4,512.3</td>
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<td>Institutional and Operations Research Capacity Building</td>
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<td>Enhancing Technical &amp; Managerial Skills</td>
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<td>Develop IEC and Community Involvement</td>
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<td>204.4</td>
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<td>-</td>
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<td>Physical Contingencies</td>
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<td>Total PROJECT COSTS</td>
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### India: Tuberculosis Control Project

Cost by Expenditure Accounts

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<tr>
<th></th>
<th>(Rupee Million)</th>
<th>(US$ Million)</th>
<th>% Exchange Costs</th>
<th>% Total Base Costs</th>
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<tr>
<td><strong>Investment Costs</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Civil Works</td>
<td>144.5</td>
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<td>4.2 .2 4.4 5% 3%</td>
</tr>
<tr>
<td>Laboratory Equipment</td>
<td>116.5</td>
<td>271.9</td>
<td>388.4</td>
<td>3.4 7.8 11.2 70% 7%</td>
</tr>
<tr>
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<td>23.8</td>
<td>158.7</td>
<td>3.9 .7 4.6 15% 3%</td>
</tr>
<tr>
<td>Vehicles</td>
<td>83.8</td>
<td>14.8</td>
<td>98.6</td>
<td>2.4 .4 2.8 15% 2%</td>
</tr>
<tr>
<td>Drugs</td>
<td>222.9</td>
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<td>2,228.7</td>
<td>6.4 57.8 64.2 90% 42%</td>
</tr>
<tr>
<td>Publicity Services</td>
<td>136.6</td>
<td>-</td>
<td>136.6</td>
<td>3.9 - 3.9 - 3%</td>
</tr>
<tr>
<td>Training and Workshops</td>
<td>204.9</td>
<td>4.2</td>
<td>209.0</td>
<td>5.9 .1 6.0 2% 4%</td>
</tr>
<tr>
<td>Support to NGO's</td>
<td>67.8</td>
<td>-</td>
<td>67.8</td>
<td>2.0 - 2.0 - 1%</td>
</tr>
<tr>
<td>Project Preparation Facility</td>
<td>8.3</td>
<td>33.3</td>
<td>41.6</td>
<td>.2 1.0 1.2 80% 1%</td>
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<tr>
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<td>1,120.2</td>
<td>2,361.4</td>
<td>3,481.6</td>
<td>32.3 68.1 100.3 68% 66%</td>
</tr>
</tbody>
</table>

| **Recurrent Costs**   |                 |               |                  |                   |
| Salaries of Additional Staff | 581.5       | -             | 581.5            | 16.8 - 16.8 - 11% |
| Incremental Operating Costs | 270.9       | 14.3          | 285.2            | 7.8 .4 8.2 5% 5% |
| Lab Supplies          | 708.3          | 53.3          | 761.6            | 20.4 1.5 21.9 7% 14% |
| Honorarium to DOT Workers | 64.7        | -             | 64.7             | 1.9 - 1.9 - 1%    |
| Vehicle Maintenance   | 71.0           | 7.9           | 78.9             | 2.0 .2 2.3 10% 1% |
| Equipment Maintenance | 22.7           | 4.0           | 26.7             | .7 .1 .8 15% 1%   |
| **Total Recurrent Costs** | 1,719.0       | 79.5          | 1,798.5          | 49.5 2.3 51.8 4% 34% |

| **Total BASELINE COSTS** | 2,839.2       | 2,440.8       | 5,280.1          | 81.8 70.3 152.2 46% 100% |

| Physical Contingencies | 244.6          | 440.0         | 684.6            | 7.0 12.7 19.7 64% 13% |
| Price Contingencies   | 694.9          | 833.1         | 1,528.0          | -.6 5.1 4.5 113% 3%  |
| **Total PROJECT COSTS** | 3,778.8       | 3,714.0       | 7,492.8          | 88.3 88.1 176.4 50% 116% |
INDIA: Tuberculosis Control Project
Expenditure Accounts by Years - Base Costs
(Costs in Rs. Millions)

<table>
<thead>
<tr>
<th></th>
<th>Base Cost in IDA Fiscal Year (July 1-June 30)</th>
<th>Foreign Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1998</td>
<td>1999</td>
</tr>
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<td><strong>Investment Costs</strong></td>
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<tr>
<td>Civil Works</td>
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<td>27.4</td>
</tr>
<tr>
<td>Laboratory Equipment</td>
<td>66.0</td>
<td>69.9</td>
</tr>
<tr>
<td>Other Goods or Equipment</td>
<td>47.6</td>
<td>47.6</td>
</tr>
<tr>
<td>Vehicles</td>
<td>34.5</td>
<td>19.7</td>
</tr>
<tr>
<td>Drugs</td>
<td>468.0</td>
<td>468.0</td>
</tr>
<tr>
<td>Publicity Services</td>
<td>23.2</td>
<td>24.6</td>
</tr>
<tr>
<td>Training and Workshops</td>
<td>50.2</td>
<td>62.7</td>
</tr>
<tr>
<td>Support to NGO's</td>
<td>8.1</td>
<td>10.2</td>
</tr>
<tr>
<td>Project Preparation Facility</td>
<td>41.6</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total Investment Costs</strong></td>
<td>765.2</td>
<td>730.1</td>
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<td><strong>Recurrent Costs</strong></td>
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<td></td>
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<td>87.2</td>
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<td>42.8</td>
</tr>
<tr>
<td>Lab Supplies</td>
<td>76.2</td>
<td>83.8</td>
</tr>
<tr>
<td>Honorarium to DOT Workers</td>
<td>7.8</td>
<td>9.7</td>
</tr>
<tr>
<td>Vehicle Maintenance</td>
<td>9.5</td>
<td>11.8</td>
</tr>
<tr>
<td>Equipment Maintenance</td>
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<td>4.0</td>
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<td>239.3</td>
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<td><strong>Total BASELINE COSTS</strong></td>
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<td>969.4</td>
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<td>Physical Contingencies</td>
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</tr>
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<td>Price Contingencies</td>
<td>77.0</td>
<td>179.1</td>
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<td>1,282.8</td>
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<td>670.3</td>
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INDIA: Tuberculosis Control Project

Expenditure Accounts by Years - Total Costs
(Costs in Rs. Millions)

<table>
<thead>
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<th>Total Cost (Including Contingencies) in IDA FY (July 1-June 30)</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>Total</th>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Civil Works</td>
<td>29.7</td>
<td>33.9</td>
<td>54.5</td>
<td>47.3</td>
<td>36.5</td>
<td>201.9</td>
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<tr>
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<td>90.4</td>
<td>146.9</td>
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<td>100.2</td>
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<td>24.1</td>
<td>204.1</td>
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<td>24.6</td>
<td>26.4</td>
<td>18.3</td>
<td>18.0</td>
<td>127.1</td>
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<td>692.2</td>
<td>707.2</td>
<td>760.4</td>
<td>3,440.5</td>
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<td>46.5</td>
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<td>31.1</td>
<td>172.3</td>
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<td>16.3</td>
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<td>29.0</td>
<td>87.9</td>
</tr>
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<td>45.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>45.0</td>
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<td>995.7</td>
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<td>1,041.8</td>
<td>1,036.8</td>
<td>5,092.3</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>102.6</td>
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<td>248.4</td>
<td>754.2</td>
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<td>50.5</td>
<td>68.7</td>
<td>92.4</td>
<td>122.5</td>
<td>371.5</td>
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<tr>
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<td>87.5</td>
<td>103.8</td>
<td>192.4</td>
<td>302.3</td>
<td>366.6</td>
<td>1,052.6</td>
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<td>8.5</td>
<td>11.4</td>
<td>15.5</td>
<td>20.9</td>
<td>27.6</td>
<td>83.9</td>
</tr>
<tr>
<td>Vehicle Maintenance</td>
<td>10.4</td>
<td>14.0</td>
<td>19.1</td>
<td>25.7</td>
<td>34.1</td>
<td>103.3</td>
</tr>
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<td>Equipment Maintenance</td>
<td>3.5</td>
<td>4.8</td>
<td>6.5</td>
<td>8.7</td>
<td>11.6</td>
<td>35.1</td>
</tr>
<tr>
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<td>287.1</td>
<td>441.6</td>
<td>637.4</td>
<td>810.9</td>
<td>2,400.5</td>
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<td>1,174.2</td>
<td>1,282.8</td>
<td>1,508.9</td>
<td>1,679.2</td>
<td>1,847.7</td>
<td>7,492.8</td>
</tr>
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# Annex 12

## INDIA: Tuberculosis Control Project

### Expenditure Accounts by Years - Base Costs

(Costs in Rs. Millions)

<table>
<thead>
<tr>
<th></th>
<th>Base Cost in IDA Fiscal Year (July 1-June 30)</th>
<th>Foreign Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1998</td>
<td>1999</td>
</tr>
<tr>
<td>Investment Costs</td>
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<td></td>
</tr>
<tr>
<td>Civil Works</td>
<td>25.9</td>
<td>27.4</td>
</tr>
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<td>66.0</td>
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</tr>
<tr>
<td>Other Goods or Equipment</td>
<td>47.6</td>
<td>47.6</td>
</tr>
<tr>
<td>Vehicles</td>
<td>34.5</td>
<td>19.7</td>
</tr>
<tr>
<td>Drugs</td>
<td>468.0</td>
<td>468.0</td>
</tr>
<tr>
<td>Publicity Services</td>
<td>23.2</td>
<td>24.6</td>
</tr>
<tr>
<td>Training and Workshops</td>
<td>50.2</td>
<td>62.7</td>
</tr>
<tr>
<td>Support to NGO's</td>
<td>8.1</td>
<td>10.2</td>
</tr>
<tr>
<td>Project Preparation Facility</td>
<td>41.6</td>
<td>-</td>
</tr>
<tr>
<td>Total Investment Costs</td>
<td>765.2</td>
<td>730.1</td>
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<tr>
<td>Recurrent Costs</td>
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<td></td>
</tr>
<tr>
<td>Salaries of Additional Staff</td>
<td>69.8</td>
<td>87.2</td>
</tr>
<tr>
<td>Incremental Operating Costs</td>
<td>34.2</td>
<td>42.8</td>
</tr>
<tr>
<td>Lab Supplies</td>
<td>76.2</td>
<td>83.8</td>
</tr>
<tr>
<td>Honorarium to DOT Workers</td>
<td>7.8</td>
<td>9.7</td>
</tr>
<tr>
<td>Vehicle Maintenance</td>
<td>9.5</td>
<td>11.8</td>
</tr>
<tr>
<td>Equipment Maintenance</td>
<td>3.2</td>
<td>4.0</td>
</tr>
<tr>
<td>Total Recurrent Costs</td>
<td>200.6</td>
<td>239.3</td>
</tr>
<tr>
<td>Total BASELINE COSTS</td>
<td>965.8</td>
<td>969.4</td>
</tr>
<tr>
<td>Physical Contingencies</td>
<td>131.4</td>
<td>134.2</td>
</tr>
<tr>
<td>Price Contingencies</td>
<td>77.0</td>
<td>179.1</td>
</tr>
<tr>
<td>Total PROJECT COSTS</td>
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<td>1,282.8</td>
</tr>
<tr>
<td>Taxes</td>
<td>71.8</td>
<td>78.9</td>
</tr>
<tr>
<td>Foreign Exchange</td>
<td>670.3</td>
<td>697.1</td>
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</tbody>
</table>
INDIA: Tuberculosis Control Project

Disbursement Accounts by Financiers
(Total Cost in US$ Million)

<table>
<thead>
<tr>
<th>Item</th>
<th>GOI Amount</th>
<th>GOI %</th>
<th>IDA Amount</th>
<th>IDA %</th>
<th>Total Amount</th>
<th>Total %</th>
<th>For. Excl. (Excl. Duties)</th>
<th>Duties &amp; Taxes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil Works</td>
<td>1.0</td>
<td>20%</td>
<td>3.8</td>
<td>80%</td>
<td>4.8</td>
<td>3%</td>
<td>0.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Vehicles</td>
<td>0.6</td>
<td>20%</td>
<td>2.5</td>
<td>80%</td>
<td>/a</td>
<td>3.1</td>
<td>2%</td>
<td>0.5</td>
</tr>
<tr>
<td>Equipment &amp; Other Goods</td>
<td>3.6</td>
<td>20%</td>
<td>14.3</td>
<td>80%</td>
<td>/a</td>
<td>17.8</td>
<td>10%</td>
<td>10.0</td>
</tr>
<tr>
<td>Drugs</td>
<td>8.2</td>
<td>10%</td>
<td>73.4</td>
<td>90%</td>
<td>/a</td>
<td>81.6</td>
<td>46%</td>
<td>73.6</td>
</tr>
<tr>
<td>Publicity &amp; Social Marketing</td>
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<td>15%</td>
<td>3.5</td>
<td>85%</td>
<td>/a</td>
<td>4.1</td>
<td>2%</td>
<td>-</td>
</tr>
<tr>
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<td>6.5</td>
<td>100%</td>
<td>-</td>
<td>6.5</td>
<td>4%</td>
<td>-</td>
</tr>
<tr>
<td>Project Preparation Facility</td>
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<td>1.2</td>
<td>100%</td>
<td>-</td>
<td>1.2</td>
<td>1%</td>
<td>-</td>
</tr>
<tr>
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<td>-</td>
<td>-</td>
<td>2.0</td>
<td>100%</td>
<td>-</td>
<td>2.0</td>
<td>1%</td>
<td>-</td>
</tr>
<tr>
<td>Salaries</td>
<td>6.2</td>
<td>35%</td>
<td>11.3</td>
<td>65%</td>
<td>/b</td>
<td>17.4</td>
<td>10%</td>
<td>-</td>
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<td>Honorarium</td>
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<td>1.3</td>
<td>65%</td>
<td>/b</td>
<td>1.9</td>
<td>1%</td>
<td>-</td>
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<td>Operational Expenditures</td>
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<td>5.5</td>
<td>65%</td>
<td>/b</td>
<td>8.6</td>
<td>5%</td>
<td>0.5</td>
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<tr>
<td>Lab Supplies</td>
<td>9.1</td>
<td>38%</td>
<td>15.1</td>
<td>62%</td>
<td>/b</td>
<td>24.1</td>
<td>14%</td>
<td>1.8</td>
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<td>Equipment &amp; Vehicle Maintenance</td>
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<td>35%</td>
<td>2.1</td>
<td>65%</td>
<td>/b</td>
<td>3.2</td>
<td>2%</td>
<td>0.4</td>
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<tr>
<td><strong>Total</strong></td>
<td>34.0</td>
<td>19%</td>
<td>142.4</td>
<td>81%</td>
<td>176.4</td>
<td>100%</td>
<td>88.1</td>
<td>77.2</td>
</tr>
</tbody>
</table>

Calculation of IDA Share = 142.4
(Net of Tax and Duties) 176.4 - 11.1 = 86.1%

NOTES:

/a Percentages shown are the estimated overall disbursement rates based on the following disbursement criteria:
For Drugs, Equipment, Goods & Vehicles - 100% of foreign expenditures, 100% of local expenditures (ex-factory cost), and 80% of local expenditures for other items procured locally.

/b Disbursements on Recurrent Costs are on a declining basis: Years 1-2 at 90%, Year 3 at 75%, Year 4 at 60%, Year 5 at 40%
INDIA: Tuberculosis Control Project

Expenditure Accounts by Project Components
(Costs in US$ Millions)

<table>
<thead>
<tr>
<th></th>
<th>Improve Quality, Access &amp; Outcomes of TB Treatment</th>
<th>Capacity Building</th>
<th>Institutional Research</th>
<th>Enhancing Technical &amp; Managerial Skills</th>
<th>Develop IEC and Community Involvement</th>
<th>Total</th>
<th>Physical Contingencies %</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Investment Costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Civil Works</td>
<td>3.8</td>
<td>0.5</td>
<td>0.1</td>
<td></td>
<td></td>
<td>4.4</td>
<td>10%</td>
<td>0.4</td>
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<td>9.6</td>
<td>0.2</td>
<td>1.4</td>
<td></td>
<td></td>
<td>11.2</td>
<td>10%</td>
<td>1.1</td>
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<td></td>
<td></td>
<td>4.6</td>
<td>10%</td>
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<td>10%</td>
<td>0.3</td>
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<td></td>
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<td>20%</td>
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<td></td>
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<td>3.9</td>
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<td>6.1</td>
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<td>176.4</td>
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## INDIAN Tuberculosis Control Project

### Expenditure Accounts by Project Components (Costs in Rs. Millions)

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<tr>
<th>Capacity Building</th>
<th>Improve Quality, Institutional and Access &amp; Operations of TB</th>
<th>Improve Research Capacity Building</th>
<th>Enhance Technical Outcomes</th>
<th>Enhancing Training &amp; Managerial Skills</th>
<th>Develop IEC Outcomes</th>
<th>Total</th>
<th>Physical Contingencies %</th>
<th>Amount</th>
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<td>-</td>
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<td>Drugs</td>
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<td>Publicity Services</td>
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<tr>
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<td><strong>204.4</strong></td>
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### Recurrent Costs

<table>
<thead>
<tr>
<th></th>
<th>Salaries of Additional Staff</th>
<th>Incremental Operating Costs</th>
<th>Lab Supplies</th>
<th>Honorarium to DOT Workers</th>
<th>Vehicle Maintenance</th>
<th>Equipment Maintenance</th>
<th><strong>Total Recurrent Costs</strong></th>
<th><strong>Total BASELINE COSTS</strong></th>
<th><strong>Total PROJECT COSTS</strong></th>
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</thead>
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<td>93.0</td>
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<td>-</td>
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<td>-</td>
<td>1,618.1</td>
<td>1,618.1</td>
<td>4,512.3</td>
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<td>-</td>
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<tr>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>820.0</td>
<td>820.0</td>
<td>2,228.7</td>
</tr>
<tr>
<td>Honorarium to DOT Workers</td>
<td>64.7</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>64.7</td>
<td>64.7</td>
<td>187.1</td>
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<td>Vehicle Maintenance</td>
<td>37.8</td>
<td>36.6</td>
<td>4.4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>79.9</td>
<td>79.9</td>
<td>223.7</td>
</tr>
<tr>
<td>Equipment Maintenance</td>
<td>10.3</td>
<td>3.8</td>
<td>12.6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>26.7</td>
<td>26.7</td>
<td>72.0</td>
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<tr>
<td><strong>Total Recurrent Costs</strong></td>
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<td><strong>1,618.1</strong></td>
<td><strong>24.0</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>1,798.5</strong></td>
<td><strong>1,798.5</strong></td>
<td><strong>4,512.3</strong></td>
</tr>
</tbody>
</table>

### Physical Contingencies

- Physical Contingencies: 627.1
- Price Contingencies: 1,358.0

### Taxes

- Taxes: 433.3
- Foreign Exchange: 3,620.9

### Total BASELINE COSTS

- Total BASELINE COSTS: 4,512.3

### Total PROJECT COSTS

- Total PROJECT COSTS: 6,497.4

### Price Contingencies

- Price Contingencies: 1,358.0
## INDIAN: Tuberculosis Control Project

Project Components by Year
(Base Costs in Rs. Millions)

<table>
<thead>
<tr>
<th>Component</th>
<th>Base Cost in IDA Fiscal Year (July 1-June 30)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1998</td>
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<tr>
<td>Improve Quality, Access &amp; Outcomes of TB Treatment</td>
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<td>Capacity Building</td>
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</tr>
<tr>
<td>Institutional and Operations Research Capacity Building</td>
<td>48.7</td>
</tr>
<tr>
<td>Enhancing Technical &amp; Managerial Skills</td>
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<td>Develop IEC and Community Involvement</td>
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<td><strong>Total BASELINE COSTS</strong></td>
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<td>Taxes</td>
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<tr>
<td>Foreign Exchange</td>
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INDIA: Tuberculosis Control Project
Project Components by Financiers
(Total Costs in US$ Million)

<table>
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<th>Local Exch.</th>
<th>Total</th>
<th>For.</th>
<th>Local (Excl. Dedies &amp; Taxes)</th>
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</thead>
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<td>Amount</td>
<td>Amount</td>
<td>Exch.</td>
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<td><strong>Improve Quality, Access &amp; Outcomes of TB Treatment</strong></td>
<td>30.3 19.9%</td>
<td>122.4 80.1%</td>
<td>152.8 86.6%</td>
<td>85.9 56.7 10.2</td>
</tr>
</tbody>
</table>

**Capacity Building**

- Institutional and Operations Research Capacity Building
  - 2.3 29.0% 5.7 71.0% 8.0 4.5% 0.8 6.8 0.4
- Enhancing Technical & Managerial Skills
  - 0.7 7.5% 8.8 92.5% 9.5 5.4% 1.4 7.9 0.2

**Develop IEC and Community Involvement**

- 0.6 10.0% 5.5 90.0% 6.1 3.5% - 5.8 0.3

**Total Disbursement**

- 34.0 19.3% 142.4 80.7% 176.4 100.0% 88.1 77.2 11.1
**Annex 12**

**INDIA: Tuberculosis Control Project**

**Procurement Arrangements /a**

(Total Costs in US$ Millions)

<table>
<thead>
<tr>
<th>Procurement Method</th>
<th>International Competitive Bidding</th>
<th>National Competitive Bidding</th>
<th>International Shopping</th>
<th>Local Shopping</th>
<th>Direct Contracting</th>
<th>Force Account Services</th>
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<td>CIVIL WORKS</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>(3.4)</td>
<td></td>
<td></td>
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<td>(3.8)</td>
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<tr>
<td>GOODS</td>
<td>Drugs</td>
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<td>(7.3)</td>
<td>-</td>
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<td>(73.4)</td>
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<td>-</td>
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<td>12.9</td>
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<td>(10.3)</td>
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</tr>
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<td>(13.6)</td>
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<td></td>
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<td>(15.1)</td>
</tr>
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<td>CONSULTANCIES &amp; TRAINING</td>
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<td>4.1</td>
<td>6.1</td>
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<td>(5.5)</td>
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<td>Institutional Development (includes Training &amp; Workshops)</td>
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</tr>
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<td>1.9</td>
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<td>(2.1)</td>
</tr>
<tr>
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<td>32.3</td>
<td>4.1</td>
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<td>(11.5)</td>
<td>(0.9)</td>
<td>(27.9)</td>
<td>(24.0)</td>
<td>(3.8)</td>
</tr>
</tbody>
</table>

**NOTES:**

/a This table is an "expanded" version of Table 4.6 to show breakdown of all procurement categories

/a Figures in parenthesis are the respective amounts financed by IDA
INDIA: Tuberculosis Control Project
Disbursement Profiles

US$ Millions

Semester End Date

South Asia Health Profile  Bank-wide Health Profile  Expected Project Profile
INDIA: Tuberculosis Control Project

ECONOMIC AND FINANCIAL ANALYSES

I. Cost Effectiveness and Monetary Benefits of Tuberculosis Treatment

Cost Effectiveness

1. The 1993 World Development Report argued that the costs per death averted and per year of life saved make chemotherapy for smear-positive tuberculosis (TB) patients the cheapest known health intervention available in developing countries. Cost per year of life saved was estimated at between US$1 and US$4. Other highly cost-effective health interventions including immunization for measles and tetanus, ORT for diarrhea and BCG vaccinations, cost between $5 and 10 dollars per year of life saved. The results for TB assume that the treatment is efficiently administered. Since in practice it often is not, the actual cost:benefit ratio may be larger. In addition, different treatments are available. Consequently, cost effectiveness analysis needs to emphasize alternative forms of treatment and focus not only on their potential cure rates but also on the likely cure rates.

2. The large benefits resulting from the cure of smear positive cases of TB (in particular) mainly result from the infectious nature of the disease and the consequent reduced level of transmission. Each untreated case causes roughly one additional case. Over an 18 year period, it is estimated that each untreated case leads to 5.2 deaths. Of all deaths ultimately attributable to a set of smear positive cases, 18 percent are due to direct mortality and 82 percent to secondary mortality.

3. Application of chemotherapy for curing TB can have large benefits relative to the costs. There are, however, alternative treatments which can be followed. In this project, short term chemotherapy with directly-observed treatment (DOT) is to replace standard chemotherapy. Several of the determinants of both the costs and benefits of these two approaches differ significantly. It is important, therefore, to provide estimates of the relative cost effectiveness of each.

4. TB is generally regarded as an illness of middle age adults with the highest incidence among the 25-44 year age group. This is the age group not only parenting but also at the peak of its labor productivity. Most of the burden of disease resulting from TB comes from mortality. Of all avoidable adult deaths in developing countries, 26 percent are due to TB. Children in households in Bangladesh where one parent is suffering from a debilitating disease, such as TB, are two and a half times more likely to be severely malnourished. The economic and social cost of TB is very high.

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5. Prior to discussing the relative cost effectiveness of alternative regimens of chemotherapy for the treatment of TB, a brief description is provided of two major strategies for preventing the disease: BCG vaccination and isoniazid chemoprophylaxis. BCG is given at birth in most developing countries. However, given that TB is transmitted by sputum positive cases and the age distribution of these cases, it is clear that even complete BCG coverage will have little effect on the annual risk of infection - reducing total TB mortality by under 10 percent. A second preventative approach would be to administer isoniazid chemoprophylaxis to individuals with the tuberculosis infection. However, since only 6-8 percent of these cases evolve into clinical TB, the cost per death averted would be very high. No studies have been made in developing countries. One for developed countries produced estimates of US$1700 per case averted in developed countries.  

6. The project focuses on passive case detection using sputum examination. The alternative approaches of active case detection and radiology would each be very expensive and the latter has been shown to be often unreliable in developing countries as the system cannot respond to the generated demand. In addition the approach does not allow for differentiation between infectious and non-infectious cases.

7. The alternative treatment regimens are conventional or chemotherapy (roughly a 12 months course of a particular drug combination) and short course chemotherapy (roughly a six month course of a more potent drug combination ). The effectiveness of each depends on (a) the cure rate, (b) the acquired drug resistance, and (c) the impact on the trend of the risk of infection. Of these, the cure rate is the most important. Ideally administered courses of both treatments have high cure rates (around 95 percent) - therefore compliance with the treatment is the most important determinant of the cure rate. The social assessments undertaken for the project suggest that poverty is a main reason for non-compliance. In addition, duration of treatment generally appears to be important. This is a major advantage of short course chemotherapy. A third determinant is the degree of supervision and the overall strength of the delivery system. A crucial aspect of the project (as in most programs of short course chemotherapy) is the inclusion of DOT - directly-observed therapy - three times a week for the first 2/3 months with observed treatment once a week thereafter. DOT is more crucial to the success of short term than standard chemotherapy since incomplete treatment results in greater possibilities for developing resistance to the drugs in the short course regimen. Supervision increases costs. In addition, the drugs required for short-course chemotherapy often are more expensive. The central issue arises of whether the higher costs of the short-course treatment compared to those of the standard course are compensated for by increased effectiveness.

Existing Studies

8. Cost-effectiveness studies of TB treatment have been made only for Indonesia and, more recently and in more detail, for three countries of East Africa. The former set reported

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3 D. Snider and others (1986) Preventive therapy with isoniazid. Cost effectiveness of different durations of therapy. JAMA 255,12
cost per case treated while the latter also considered cost per death averted. The East African studies are particularly thorough and provide a base for the economic analysis of the proposed project in India. In addition, data resulting from the Indian pilot projects have been incorporated in the analysis.

9. Aside from the patient's opportunity cost of time and the cost of transport incurred in receiving treatment, the costs of a TB program is comprised of various types: fixed costs associated with the use of facilities outside of the program, e.g., hospitals; fixed costs associated with the program itself, e.g., salaries, vehicles, equipment; and variable costs, depending on the number of patients treated and monitored, e.g., sputum tests and drugs. The average incremental costs, defined as variable costs plus fixed costs directly attributable to the program, are focused on here.

10. Cost estimates based on detailed analysis were made for four types of treatment - short-course and standard chemotherapy, with and without an initial two month period of hospitalization.

11. The benefits of chemotherapy for smear positive patients include those for the patient treated and those resulting from reduced transmission. As described above, based on the stable transmission pattern, these have been calculated as the aversion of 5.2 deaths (or 3.8 deaths using a discount rate of 3% a year) using life tables for treated and untreated subjects and allowing for a spontaneous cure rate of 30 percent. Effective cure rates were calculated (from detailed records) at 90 percent for the short course treatment and 65 percent for standard programs.

12. The results of the cost-effectiveness calculations are shown below. They cover cost per cure, death averted and year of life saved for each of the four alternative programs (short and standard course chemotherapy, with and without hospitalization) averaged across the three East African countries (US$):

<table>
<thead>
<tr>
<th></th>
<th>Short Course</th>
<th>Standard Course</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital</td>
<td>Ambulatory</td>
</tr>
<tr>
<td>Per cure</td>
<td>US$188</td>
<td>US$96</td>
</tr>
<tr>
<td>Per death averted</td>
<td>US$46</td>
<td>US$23</td>
</tr>
<tr>
<td>Per year of life saved</td>
<td>US$2.1</td>
<td>US$1.0</td>
</tr>
</tbody>
</table>

13. On the basis of the cost estimates, the reported cure rates and the pattern of disease transmission in these countries, treatment of TB appears to be highly cost-effective when effectiveness is measured in terms of deaths averted and years of life saved. When effective supervision can be designed and implemented in a way which does not require inpatient
services in hospitals, the costs are particularly low. In both situations (with hospitalization and without), the cost effectiveness of the short-course regimen is highest.

14. A more recent study of cost effectiveness of health care interventions has been undertaken by the World Bank across five East African countries. Results for the treatment of TB in Ethiopia indicate lower levels of cost effectiveness than the studies reported above. Cost per life year saved was estimated at US$7.6 for short course treatment and US$19 for the standard course. Treatment involving hospitalization was significantly more costly per life year saved - US$21.8 for short course treatment. These estimates, while higher than previous ones, should be compared to those made by the same authors for other health interventions e.g. AIDS preventive US$198 and curative US$45,394; malaria preventive US$1,106 and curative US$48; cardiovascular disease preventive US$637 and curative US$283.

15. Summarizing, on the basis of the most detailed studies currently available:

(a) chemotherapy for sputum positive TB patients is the cheapest of all health interventions available in developing countries per death averted and per year of life saved;

(b) short course chemotherapy is even more cost effective than the standard course; and,

(c) the short course is also preferable since the effectiveness cure rate is higher and fewer patients will require the higher cost retreatment program in the future.

Cost Effectiveness in India

16. The cost-effectiveness calculations reported above for three East African countries resulted from intensive case studies over a lengthy period of time. In many respects the results will be quite robust across other developing countries, including India. For instance, the transmission rates and the age structure of patients will be similar - hence the benefits in terms of deaths averted and years of life saved from a single cure will not be greatly different. However, the costs of the program in India may differ (for instance, the cost of drugs for the short course has fallen recently) while the effective cure rates of each regimen may also vary from those recorded in East Africa.

Effective Cure Rate

17. Cure rates in India are very low compared to those achieved, even by standard therapy, in East Africa. According to the National Tuberculosis Institute, cure rates for the standard treatment are 20 percent and for the short course (currently unsupervised) 30 percent. In a study of 18 districts in Tamil Nadu, the highest cure rate for (again virtually unsupervised) short-course chemotherapy was 50 percent and for the standard regimen, 35 percent. Provisional data from the pilot projects of DOT short-course treatment suggests
cure rates of around 80 percent. This should increase. The cure rate in China, with DOT short course chemotherapy, is 92 percent.

18. For India, neither the costs nor the cure rates, which will result from the new regimen, can be known in great detail. Current knowledge based on the pilot projects, however, suggests the following:

(a) On the basis of the early results from the pilot projects, cure rates of short-course chemotherapy are likely to be similar to those in East Africa (90%). Cure rates from standard treatment are lower in India (20-35 percent) than those in East Africa (60-66 percent). Consequently, the number of deaths averted and years of life saved per treated case will be similar for short course treatment as in East Africa, but the improvement in these measures resulting from a switch from standard therapy will be greater.

(b) The cost per case treated in East Africa included an estimate for drugs in the short course regimen of US$40. For the current project, the drugs package will be around US$12.80.

(c) The evidence strongly suggests that, mainly resulting from recent decreases in the price of drugs, the cost of death averted and year of life saved in India through the project's support for short course DOT chemotherapy will be lower than even the estimates for East Africa, which themselves are regarded as demonstrating among the highest returns on investments from health interventions. In addition, the difference in the cost effectiveness of the short course regimen compared to the standard approach is also expected to be larger in India - partly due to the reduced differential in the price of the short course and standard drug packages, and partly due to the poor results of the standard treatment in India relative to those recorded in East Africa.

**Monetary Benefits**

19. The Burden of Disease study for India, undertaken for the 1993 World Development Report, indicated that tuberculosis is responsible for 3.7 percent of the country’s total burden of disease. Seen in another perspective this is eleven times more than malaria, six times more than the tropical cluster of diseases and two and a half times more than AIDS. The incidence of TB tends to peak among those in mid adulthood. This age group has the highest level of labor productivity and is the group in which society has already invested the largest amounts of human capital. In addition, studies in Bangladesh indicate that children of parents with illnesses such as TB are two and a half times more likely to suffer severe malnutrition. The economic and social costs of TB are likely to be high.

20. Results from the more recent and detailed Burden of Disease study for the state of Andhra Pradesh provide more details of the destructive nature of the disease. Among the causes of death in rural areas 1988-93, TB was exceeded only by bronchitis and heart attacks for males, and by these illnesses plus fever, cancer and childbearing deaths among females. For 1993, TB was responsible for 10 percent of all DALYs for males and just over 5 percent
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for females. Among the 15-45 year age group, TB was the leading cause of death among both the urban and rural population. Twenty percent of all DALYs for males between 15 and 60 are caused by TB. For females the figure is 10 percent. TB is the major cause of death among the economically active population.

21. The population of India is roughly 920 million. Those regarded at risk (above five years of age) number 798 million. Applying the results of discussions of expert groups utilized for the burden of disease study in Andhra Pradesh across the whole country suggests that 20 million TB symptomatics (2.5%) exist annually. Of these, 16.4% or 3.27 million would develop the disease each year. Tuberculosis is not fatal for all those who contract the disease. The spontaneous cure rate is roughly 30%. Those requiring treatment would be 2.3 million. Sixty percent of these patients, or 1.4 million, are expected to seek treatment in the public sector. Currently, WHO estimates that the cure rate for the standard chemotherapy treatment in the public sector is 35%, implying that 480,000 patients are cured each year. The expected cure rate from the RNTP regimen supported through the proposed project is 85%, implying that 1.2 million would be cured annually if the RNTP covers the entire country. These rough figures suggest that if the RNTP was effectively adopted across the country, an additional 720,000 patient cures would be achieved each year. Many, but not all, of these patients would have died directly from the illness without proper treatment. WHO estimates that 200,000 deaths per year would be averted if RNTP was adopted throughout the country.

22. The current project would not cover the whole country. Treatment under the RNTP would be provided comprehensively across 102 districts. The project would also provide partially for smear-positive patients in a further 203 districts and would provide drugs for the conventional treatment of smear-positive patients in the final 154 districts. Estimations suggest that by the final year of the project, over 840,000 patients would be cured annually through treatment in the public sector.

23. Estimates of lost output due to TB must be very approximate. For the purposes of this exercise, annual average earnings are estimated at Rs.5,200 a year (the daily rate for agricultural laborers of Rs.20 a day for 260 days). It is also assumed that, on average, the disease is contracted 20 years prior to the normal end of working life. Discounting at 10% a year, the present value of lost outputs resulting from the deaths and continued disability of TB patients is estimated at around Rs.40 billion. WHO estimates of the outcome of the project in terms of reduced deaths and patients remaining alive but debilitated suggest that this will fall to Rs.31 billion, saving US$257.0 million; and with full coverage of the RNTP across the country to Rs.23 billion. Savings in lost output from reduced deaths alone would be over Rs.5 billion, or US$142.0 million each year. As a result of the project, an almost Rs.9 billion (US$260.0 million) would be saved following full implementation of the RNTP in the whole country.

II. Financial Sustainability

24. The National Tuberculosis Control Program is a centrally sponsored scheme. The current modality for its funding is an equal sharing of the cost of drugs between the central government and each state government. Salaries, transport and other related costs have been
borne by the state governments, in addition to the costs of other TB programs operated outside of the National Program. The Project will finance a time-slice of the National Program whose financial modality is planned to change. During the Project period, all drugs and other incremental inputs provided for RNTP districts (102) will be fully funded by the central government. In SCC districts (203), drugs for all sputum positive patients will be fully funded together with some institutional strengthening inputs and training while drugs for sputum negative patients will be financed by the state governments. In non SCC districts the same arrangements will be made for financing the drugs while other interventions will be more limited. The required state financing of part of the drug supplies in SCC and non SCC districts will act as an incentive for the states to establish the conditions for altering the treatment regime to the DOT one which entitles all drugs to be funded by GOI. This project will provide support for five years by which time almost one third of the population will be fully covered by the new regimen and a further 50 percent will live in districts which are partially covered and on track to adopt and implement the new regimen. It is anticipated that the time-frame to introduce the Revised Strategy for Tuberculosis Control across the whole country will be 8-12 years. In the final set of districts, some institutional and training programs will have begun to lay the base for further strengthening in the following years.

25. GOI expenditure on the TB National Programme in 1995/96 was Rs.460 million compared to Rs.160 million in 1991/92 when the initial preparations to alter the approach were begun. This constitutes 4.4 percent of total central government health expenditure, which in turn was equal to just 0.5 percent of its total expenditures. Currently, the GOI finances the central administration of the Programme and 50% of drugs. Under the project, drugs for all patients in the RNTP districts and for sputum positive patients in the SCC districts will be centrally financed. The conventional drugs for sputum negative patients in the SCC and non SCC districts will be financed outside of the project by GOI and the states. Adequate funding of these drugs by the states will be a condition for receiving additional support for the program. Overall, expenditures by GOI for continuing and strengthening those activities currently provided for Programme administration plus its shares of drug expenditures will result in the Government at least maintaining expenditures at pre project levels.

26. In the final year of the project, the total recurrent costs in the 102 RNTP project districts are projected at around Rs.366 million (base costs). For SCC districts the recurrent costs will be Rs.165 million. For non SCC districts there will be no recurrent costs under the project. Overall recurrent costs in the final year of the project are projected to be Rs.531 million. If responsibility for recurrent costs revert to the states, they would average Rs.35 million across each of the fifteen major states. The average expenditure by health departments across these states currently is around Rs.4,700 million. Assuming an annual average growth rate of 4 percent through the life of the project this would rise to around Rs.5,700. The additional expenditures required for the maintenance of the project would be equivalent to well under 1 percent of each state’s health budget.

27. At least during the implementation of the Revised Strategy to the whole country, the GOI will maintain full funding of drugs under the new regime in addition to funding 50 percent of conventional drugs. At the end of the project this would total Rs.830 million equivalent to double GOIs 1995/96 expenditure. Given the small share of total health
expenditures devoted to the TB program, the experiences of the central government in maintaining higher expenditure across other disease programs in recent years plus the stated intention to give increased priority to social sectors, it is not anticipated that the project will be difficult to sustain.

28. The project activities represent just the first phase in a National Program which will cover all districts within the next 10-12 years. The 102 districts which will implement all aspects of the RNTP during the Project period have a total population of 271 million. Covering the whole population, with the same cost structure as in these districts, would imply a recurrent cost in the year following the completed implementation of Rs.1,227 million plus a drug bill of Rs.657 million. For 1995/96 the National Program budget (mainly for drugs) was Rs.460 million ($13 million) for GOI and, by implication, a similar amount was budgeted by the states. The reduction of the total national drugs bill by almost twenty percent (Rs.800 - 657 million) at the end of the Project compared to the beginning reflects the significant reduction in the cost per treatment of the drugs administered under the new regimen. Whether the financing of drugs remains 100 percent covered by GOI or reverts to a 50:50 share with the states, the drugs bill should provide no problem regarding sustainability.

29. The (non drugs) incremental recurrent costs of the RNTP strategy, however, will increase when it is implemented across the country. For example, around 10 supervision teams consisting of a laboratory technician and treatment supervisor will be required in each district. For the 102 districts covering 30 percent of the population the incremental recurrent costs are anticipated to be around Rs.366 million a year. Once the whole country is covered by the Program the incremental recurrent cost would be around Rs.1,227 million. It is envisaged that these costs will then be the responsibility of the states. Part of this may be financed through savings. Currently the states are required to fund half the cost of drugs. In the current year this is planned to total Rs.400 million. Under the new RNTP Programme GOI may continue to fund drugs. The savings to the states would be equivalent to almost one third of the incremental recurrent costs. The remaining costs, around Rs.800 million, would be spread across all states, implying Rs.5.3 million for each of the major states. Current health expenditures average around Rs.5,700 million in the major states. In ten years time, assuming an annual growth rate of 4%, they would be around Rs.8,500 million. Maintaining the TB program, therefore, implies an increase of around 0.6 percent in each state’s health budget. Even if the financing of the drugs bill did revert to a 50:50 share the total increase in states’ expenditures would not exceed one percent of their health budget. This should not provide a problem.

30. The experiences in recent years, however, indicate the need for some caution. Taking Gujarat as an example, drugs for the national TB program form 0.13 percent of current health department expenditures. Even a doubling of the drugs budget (unlikely, due to the steeply falling drug procurement prices which should also lower the cost of non-project drug supplies) would still result in a very small share. In principle, there should be no problem of sustainability. In practice, the decrease in real expenditures on drugs in 1992/93 and 1993/94 suggests a constraint in that state. Similarly, of the seven states described in table 8, only Karnataka and Maharashtra significantly increased their expenditures on TB drugs between 1991/92 and 1993/94. In Kerala, expenditures are very low and the other three states’ real expenditures fell. More optimistically, the new
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procedures for drug procurement will result in much lower prices than the states have paid in the past, thereby resulting in savings on existing expenditures. Again, the incremental recurring costs of the project to the states will be such that they will form a very small part of the total budget and, in principle, should easily be sustained.

Central and State Government Expenditures on Tuberculosis Programs

31. Per capita expenditures on disease control programs are very low. In 1993/94, only in Andhra Pradesh, Haryana and Tamil Nadu were they above Rs.10. In four states they were between Rs.7 and Rs.10 and in the remaining eight states, between Rs.5 and Rs.7. Average per capita expenditure was Rs.8. Expenditures are made by both the central and state governments. State government expenditures are much higher but tend to concentrate on funding personnel. The central government programs concentrate resources on other recurrent inputs, particularly drugs.

Centrally Sponsored Schemes

32. Central government expenditures on disease programs, such as the national TB program, are made through centrally-sponsored schemes, in which grants - 100% or matching 50% - are distributed across the state governments. The national programs for blindness, leprosy, goiter and AIDS are funded 100% by the central government, while TB, malaria and filaria are funded 50:50 by the central and state governments. Expenditures on each of the major disease programs and on the total public health budget, which mainly comprises of the disease programs, between 1987/88 and 1995/96, is presented in Table 1. The public health budget is also described as a share of total central government expenditures on health.

33. The data in Table 1 indicate that, overall, expenditures on disease programs have increased in importance in recent years compared to total health expenditures by the central government. Among the programs, the greatest increase in emphasis has been given to leprosy and blindness, and, most recently, to AIDS. All three have been supported through development assistance. In 1995/96, expenditures on malaria suddenly increased. While expenditures on the TB program have also increased much more rapidly than overall health expenditures, the growth has not matched that of the other disease programs.

34. The TB centrally sponsored scheme is based on the principle of matching expenditures for drugs by the central government and the state governments. The following steps occur:

(a) states make their applications for drugs on the basis of their estimates of total requirements.

(b) the center analyzes the applications and makes an assessment of its (50%) contribution based on the judged requirement.
(c) since the budgetary allocation to the Department of Health for this item program are normally below that “required”, pro rata reductions are made across the states.

(d) states are meant to fund the other 50% of the requirement for drugs (plus the other recurrent costs required to administer the program).

Table 1: Central Government Expenditure on Disease Programs and Public Health - 1987/88-1995/96 (in Rs Lakhs)

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td>86.0</td>
<td>90.0</td>
<td>75.6</td>
<td>78.8</td>
<td>91.8</td>
<td>91.9</td>
<td>130.8</td>
</tr>
<tr>
<td>Leprosy</td>
<td>17.0</td>
<td>19.5</td>
<td>23.9</td>
<td>35.0</td>
<td>60.7</td>
<td>94.0</td>
<td>72.0</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>13.5</td>
<td>12.0</td>
<td>16.0</td>
<td>29.0</td>
<td>37.5</td>
<td>46.0</td>
<td>46.0</td>
</tr>
<tr>
<td>Blindness</td>
<td>6.7</td>
<td>6.1</td>
<td>12.2</td>
<td>20.0</td>
<td>25.0</td>
<td>40.0</td>
<td>63.0</td>
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<tr>
<td>AIDS</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>69.8</td>
<td>72.1</td>
<td>82.5</td>
<td>69.7</td>
</tr>
<tr>
<td>Public Health</td>
<td>142.8</td>
<td>164.2</td>
<td>179.4</td>
<td>291.8</td>
<td>346.9</td>
<td>417.3</td>
<td>450.0</td>
</tr>
</tbody>
</table>

| Total Plan + Non-plan | 339.2 | 431.5 | 526.2 | 739.8 | 849.5 | 42.4 |
| Public Health % Total Health Exp. | 41.9 | 38.0 | 34.1 | 39.4 | 40.8 | 45.3 |

| Growth of real expenditure 1987/88 to 1994/95 | 93.0 |
| TB Total Health | 46.8 |

Source: Union Government budgets (various years)
Note: 1995/96 expenditures are Revised Estimates

35. In addition to an overall underfunding of drug ‘requirements’ by the center, the allocations to states are under or over spent in individual states. In 1990/91 and 1992/93, overall expenditures were 91 and 95 percent of total allocations; in several states, expenditures were significantly above budgeted allocations, and vice-versa. In 1991/92, overall expenditures were only just over 50% of the allocation and was again below in 1993/94. A number of reasons may explain the discrepancy:
(a) the central ministry procurement unit can be slow to instruct suppliers - this would lead to a rollover in the following year.

(b) for a number of reasons, including an increase in the market price above the tender price, suppliers do not deliver the contracted amounts to the depots.

(c) the six depots across the country are unable to distribute supplies in the planned way.

36. The 1995/96 allocation for the central government’s contribution for the procurement of drugs was Rs.40 crores ($11.5 million) compared to Rs.13 and Rs.26 crores in 1990/91 and 1992/93 respectively. The budget estimate for 1996/97 is Rs.63 crores.

State Government Expenditures

37. While the project will provide some inputs widely across the country, the center piece will be the 102 districts in fifteen states in which the new approach is expected to be adopted in its entirety. In order to provide a context for assessing the absolute and relative expenditures on tuberculosis programs, a sample of states was drawn and their budget documents analyzed to assess the levels and sources of these expenditures. Table 2 on page 132 describes total health expenditures and those on disease control per capita and as a share of total government revenue expenditures in which the project will initially operate.

38. Across the project states in 1993/94, health expenditures as a share of total government revenue expenditures averaged 6.1 percent within a range of 5.3 and 8.1 percent. There was little change over the previous three years. These shares converted to an average per capita expenditures of Rs.66 in 1991/2 and Rs.82 (US$2.6) in 1993/4. The range in 1993/4 was from Rs.49 and Rs.50 in Bihar and Uttar Pradesh to over Rs.80 in Karnataka, Maharashtra and Tamil Nadu, to Rs.105 in Kerala and Rs.197 in Himachel Pradesh. On average, around 11 percent of health expenditures are spent on disease programs. This translated to an average per capita expenditures in 1993/4 of under Rs.9 (US$0.29) with over half of the states recording expenditures of between Rs.5 and Rs.7. Only in Andhra Pradesh, Tamil Nadu and Himachel Pradesh were per capita expenditures above Rs.10.

39. In most of the centrally-sponsored schemes in disease control, the core principle is that the central government funds 50% or a 100% of drugs. These amounts are shown in states' budgets as plan expenditures. In the former case the state government is required to fund a similar amount of drugs - again, usually recorded under plan expenditures; plus the other, mainly salary and transport, costs of operating the programs under non-plan expenditure. All expenditures are not necessarily under the most obvious budget head. The most detailed attempt to calculate central and state government expenditures on public health programs was made for 1992/93 in 12 districts in Gujarat, Tamil Nadu, Uttar Pradesh and West Bengal (NCAER, 1994). The central government’s share averaged 19, 10, 8 and 16 percent respectively - or an average across the 12 districts of 17%. These figures imply that even though the central government helps fund a variety of disease control programs the state governments, through their funding of the basic health service infrastructure, remain the
major source of overall funds.

Table 2: Measures of Health and Disease Control Expenditures - 11 states - 1991/92 and 1993/94

<table>
<thead>
<tr>
<th>State</th>
<th>Health as % Total Expenditure</th>
<th>Health Per Capita Expenditure (Rs)</th>
<th>Disease Control Expenditure as % Health Expenditure</th>
<th>Disease Control Expenditure Per capita Expenditure (Rs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andhra Pradesh</td>
<td>5.8</td>
<td>5.7</td>
<td>55</td>
<td>65</td>
</tr>
<tr>
<td>Assam</td>
<td>5.2</td>
<td>5.1</td>
<td>50</td>
<td>62</td>
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<tr>
<td>Bihar</td>
<td>5.7</td>
<td>6.2</td>
<td>31</td>
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<td>Gujarat</td>
<td>5.4</td>
<td>5.1</td>
<td>67</td>
<td>76</td>
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<tr>
<td>Himachal Pr</td>
<td>7.2</td>
<td>8.1</td>
<td>134</td>
<td>197</td>
</tr>
<tr>
<td>Karnataka</td>
<td>6.0</td>
<td>6.6</td>
<td>64</td>
<td>85</td>
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<tr>
<td>Kerala</td>
<td>6.9</td>
<td>7.1</td>
<td>75</td>
<td>104</td>
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<tr>
<td>Madhya Pradesh</td>
<td>5.8</td>
<td>5.7</td>
<td>40</td>
<td>58</td>
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<tr>
<td>Maharashtra</td>
<td>5.3</td>
<td>5.3</td>
<td>65</td>
<td>80</td>
</tr>
<tr>
<td>Manipur</td>
<td>5.7</td>
<td>6.0</td>
<td>115</td>
<td>110</td>
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<tr>
<td>Rajasthan</td>
<td>6.8</td>
<td>6.3</td>
<td>62</td>
<td>78</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>6.7</td>
<td>6.6</td>
<td>67</td>
<td>95</td>
</tr>
<tr>
<td>Uttar Pradesh</td>
<td>6.0</td>
<td>5.5</td>
<td>44</td>
<td>50</td>
</tr>
<tr>
<td>West Bengal</td>
<td>7.3</td>
<td>7.2</td>
<td>56</td>
<td>69</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td>6.1</td>
<td>6.2</td>
<td>66</td>
<td>82</td>
</tr>
</tbody>
</table>


40. The results of the NCAER study of 12 districts can only be indicative of the overall situation for public health programs within each of the four states, and across all states. However, more recent data for Gujarat tend to corroborate the conclusion: in spite of the national TB program contributed to by the central government, the large majority of the resources spent on TB treatment is directly provided by the states. Table 3 presents central and state government allocations and expenditures on the TB program between 1989/90 to 1993/94 using information provided by the state government. During that period, central government expenditures ranged between 16% and 3% of the total. However, the change in the composition of expenditures funded by the two levels of government indicates a growing problem. Until 1991/92 the state government was matching the central government’s expenditures on drugs. In the following two years, as the center’s expenditures rose...
substantially, the state only maintained its previous allocations for drugs while increasing (nominal) expenditures on the other mainly salary, items. The implication is that while the state has historically developed services for TB treatment, it is finding the provision of additional resources, for drugs, increasingly difficult.

<table>
<thead>
<tr>
<th>Year</th>
<th>Allocation State</th>
<th>Center</th>
<th>Total State</th>
<th>State drugs</th>
<th>Center Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989/90</td>
<td>373</td>
<td>81</td>
<td>395</td>
<td>(76)</td>
<td>69</td>
</tr>
<tr>
<td>1990/91</td>
<td>380</td>
<td>100</td>
<td>362</td>
<td>(61)</td>
<td>80</td>
</tr>
<tr>
<td>1991/92</td>
<td>425</td>
<td>100</td>
<td>390</td>
<td>(78)</td>
<td>78</td>
</tr>
<tr>
<td>1992/93</td>
<td>447</td>
<td>103</td>
<td>429</td>
<td>(69)</td>
<td>131</td>
</tr>
<tr>
<td>1993/94</td>
<td>512</td>
<td>298</td>
<td>464</td>
<td>(67)</td>
<td>114</td>
</tr>
</tbody>
</table>

Source: data provided by state government

41. As a share of total state non-plan expenditures on public health in Gujarat, state expenditures on the TB program in 1993/94 were 5.4%. As a share of all medical and public health non-plan expenditures, they were 1.2%. As a share of all plan and non-plan health expenditures, they were 0.8%. These are small shares. Expenditures on drugs form only one sixth of all expenditures on TB. During the project, incremental expenditures for both drugs and other inputs will be fully funded by the central government in RNTP districts. Hence, there should be no additional burden on the states. At the end of the project, the expectation is that the activities will be financed on the basis of the 'normal' 50:50 central and state government shares. Drugs for TB currently form 0.13% of health department expenditures. Even a doubling of the drugs budgets (unlikely, due to the steeply falling drug procurement prices which have lowered the cost of drugs for the new regimen below that for conventional drugs) would still result in a very small share. In principle, there should be no problem of sustainability. In practice, however, the decrease in nominal expenditures on drugs in 1992/93 and 1993/94 is a cause for concern and does suggest that overall allocations to the health sector needs to be protected in real terms.

42. The situation in Gujarat and the conclusions arrived at above are similar to those for most other states. Tables 4 and 5 provide expenditure data on national and state expenditures, public health and all activities under the departments of health between 19991/92 and 1993/94 for Andhra Pradesh and Maharashtra, respectively.

43. Again, expenditures on TB in Andhra Pradesh constitute very small shares - around 0.5 percent of total expenditures and 2.8 percent of public health expenditures. The leprosy and malaria programs are much larger. Plan expenditures on TB are for drugs - and are less than one percent of plan health expenditures. Non-plan recurring expenditures are six to seven times the size of the state's TB drug budget. If TB drugs had been provided on the
50:50 formula in 1992/93, central government expenditures would have been equal to just over 11 percent of total expenditures on TB in the state.

Table 4: ANDHRA PRADESH State Government Expenditures on TB - 1990/91 to 1992/93 (Rs.1,000)

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</tr>
</thead>
<tbody>
<tr>
<td>Total health expenditure</td>
<td>234,30,000</td>
<td>259,00,86</td>
<td>297,08,26</td>
<td>31,00,92</td>
<td>28,79,16</td>
<td>36,51,38</td>
</tr>
<tr>
<td>Public health expenditure</td>
<td>45,84,95</td>
<td>50,09,67</td>
<td>58,22,91</td>
<td>16,06,73</td>
<td>18,89,22</td>
<td>25,58,58</td>
</tr>
<tr>
<td>TB expenditure</td>
<td>1,31,95</td>
<td>1,47,19</td>
<td>1,70,88</td>
<td>3,68</td>
<td>20,00</td>
<td>25,00</td>
</tr>
<tr>
<td>TB as % of Total health</td>
<td>0.56</td>
<td>0.57</td>
<td>0.57</td>
<td>0.01</td>
<td>0.69</td>
<td>0.69</td>
</tr>
<tr>
<td>TB as % of Public health</td>
<td>2.86</td>
<td>2.93</td>
<td>2.92</td>
<td>0.25</td>
<td>1.06</td>
<td>0.98</td>
</tr>
</tbody>
</table>

In Maharashtra (Table 5 on page 135) the shares of public health and total health expenditures spent on TB are a little higher - around 5.5 and 2.0 percent respectively.
Table 5: MAHARASHTRA State Government Expenditures on Tuberculosis -
1991/92 to 1993/94 (Rs.1,000)

<table>
<thead>
<tr>
<th>Expenditure Category</th>
<th>NON PLAN</th>
<th>PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total health</td>
<td>3,75,98</td>
<td>4,16,40</td>
</tr>
<tr>
<td>Public health</td>
<td>1,44,15</td>
<td>1,62,06</td>
</tr>
<tr>
<td>TB (hospital)</td>
<td>6,61</td>
<td>7,12</td>
</tr>
<tr>
<td>TB program</td>
<td>1,41</td>
<td>1,34</td>
</tr>
<tr>
<td>TB as % of Total health</td>
<td>2.1</td>
<td>2.0</td>
</tr>
<tr>
<td>TB as % of Public health</td>
<td>6.3</td>
<td>5.3</td>
</tr>
</tbody>
</table>

45. Table 6 and 7 present additional data for Tamil Nadu and Madhya Pradesh respectively. TB expenditures claim 2.0 percent of non-plan and 10.0 percent of plan health expenditures in Tamil Nadu. In Madhya Pradesh, the shares are 3.3 and 1.0 percent respectively.

Table 6: TAMIL NADU State Government Expenditures on Tuberculosis -
1992/93 to 1994/95 (Rs.1,000)

<table>
<thead>
<tr>
<th>Category</th>
<th>NON PLAN</th>
<th>PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total health</td>
<td>2,62,73</td>
<td>2,97,08</td>
</tr>
<tr>
<td>TB hospital</td>
<td>1,02</td>
<td>86</td>
</tr>
<tr>
<td>TB state program</td>
<td>4,29</td>
<td>5,11</td>
</tr>
<tr>
<td>TB national program (medicines)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total TB as % of Total health</td>
<td>2.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>
Table 7: MADHYA PRADESH State Government Expenditures on Tuberculosis -
1991/92 to 1993/94 (Rs. 1,000)

<table>
<thead>
<tr>
<th>Category</th>
<th>NON PLAN</th>
<th>PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total health</td>
<td>1,69,11</td>
<td>1,78,16</td>
</tr>
<tr>
<td>TB</td>
<td>5,68</td>
<td>5,89</td>
</tr>
<tr>
<td>Total TB as %</td>
<td>3.4</td>
<td>3.3</td>
</tr>
<tr>
<td>of Total health</td>
<td>46.11</td>
<td>46.32</td>
</tr>
</tbody>
</table>

46. Finally, focusing specifically on medicines in the TB programs, data provided by the state governments of Gujarat, Karnataka, Kerala, Maharashtra, Rajasthan, Tamil Nadu and West Bengal convey a generally common experience (Table 8). Until 1991/92, the state governments (apart from Kerala) were generally matching central government expenditures. In the following two years, while most state government expenditures continued to increase, they did not match the increases in central government expenditures apart from Karnataka and Maharashtra.

Table 8: State and Central Government Expenditures on TB Drugs -
1990/91 to 1993/94 (Rs. Lakhs)

<table>
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<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Gujarat</td>
<td>71</td>
<td>80</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>Karnataka</td>
<td>73</td>
<td>60</td>
<td>11</td>
<td>23</td>
</tr>
<tr>
<td>Kerala</td>
<td>6</td>
<td>36</td>
<td>10</td>
<td>38</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>148</td>
<td>140</td>
<td>156</td>
<td>135</td>
</tr>
<tr>
<td>Rajasthan</td>
<td>43</td>
<td>39</td>
<td>51</td>
<td>30</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>60</td>
<td>69</td>
<td>77</td>
<td>80</td>
</tr>
<tr>
<td>West Bengal</td>
<td>98</td>
<td>98</td>
<td>83</td>
<td>88</td>
</tr>
<tr>
<td>Total</td>
<td>489</td>
<td>522</td>
<td>466</td>
<td>472</td>
</tr>
</tbody>
</table>

Source: State Governments

47. Summarizing the situation across the five states described in tables 3 to 7, expenditures on the treatment of TB average around 2 percent of total health expenditures. Non-plan expenditures are higher than plan expenditures in all cases - considerably so in some states. This corroborates the earlier observation that state government expenditures on this activity are much higher than those of the central government. The shift since 1992/93
in the balance between states’ and central governments’ expenditures on medicines, however, indicates that while the states have been able to maintain expenditures on salaries, they have not matched the increases provided by the center for medicines. Within the cluster of disease programs, there are considerable variations in the priorities given to specific diseases across states, both in plan and non-plan expenditures.

Summary

48. Disease control expenditures are equivalent to around 10-12 percent of total state health expenditures on average. Average expenditure per capita is Rs.8.

49. While many disease programs are supported by the central government, the state governments contribute the majority of resources to public health activities. A study of 12 districts across three states showed that in 1992/93, the central governments’ average share was 12 percent. Non plan expenditures on TB are much higher than plan expenditures - considerably so in several states - implying that state government activity dominates in the treatment of TB, despite the centrally supported national program.

50. Between 1989/90 and 1993/94, the central government contributed between 16 and 23 percent of expenditures on TB control in Gujarat. However, while total state government expenditures on TB have increased each year, expenditures on drugs have decreased since 1991/92.

51. More generally, across a sample of seven states, while the states were able to almost match the central government’s expenditures on drugs until 1991/92, only in Karnataka and Maharashtra has this situation been maintained.
Implementation Plan

INDIA: Tuberculosis Control Project

Date: 1/1/97

Project: INDIA: Tuberculosis Control Project

Task

Milestones

Summary

Page 1
Project: INDIA: TB Control Project
Date: 1/3/97

<table>
<thead>
<tr>
<th>ID</th>
<th>Task</th>
<th>Milestone</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>Prepare Green SAR &amp; MOP</td>
<td></td>
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<tr>
<td>24</td>
<td>Submit draft Green Cover to RVP</td>
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<tr>
<td>25</td>
<td>RVP Clearance &amp; Invitation to Negotiate</td>
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<td></td>
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<tr>
<td>27</td>
<td>NEGOTIATIONS &amp; BOARD PRESENTATION</td>
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<tr>
<td>28</td>
<td>Forward Notice of Invitation to Negotiate to SEC</td>
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<tr>
<td>29</td>
<td>Send Invitation to Negotiate (rejected by GOI)</td>
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<td>30</td>
<td>Send 2nd Invitation to Negotiate</td>
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<td>32</td>
<td>Seek clearance of Major changes from RVP</td>
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<tr>
<td>33</td>
<td>Prepare &amp; Issue Summary of Negotiations</td>
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<tr>
<td>34</td>
<td>Prepare Status of Negotiations Notice &amp; forward to SEC</td>
<td></td>
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<tr>
<td>35</td>
<td>Revise Loan Package: GC Sar/MOP, Legal Doc, Cov Memo</td>
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<tr>
<td>36</td>
<td>Submit Loan Package to CD</td>
<td></td>
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<tr>
<td>37</td>
<td>Send Memo to EXC &amp; Loan Package to Print Shop</td>
<td></td>
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<tr>
<td>38</td>
<td>Release 1767 to SEC for doc distribution to EDs</td>
<td></td>
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<tr>
<td>39</td>
<td>Issue Memo to SEC on Board attendance</td>
<td></td>
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<tr>
<td>40</td>
<td>Prepare Notice of Pre-Board Meeting &amp; Draft Speech</td>
<td></td>
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<tr>
<td>41</td>
<td>Prepare Note on issues raised by EDs</td>
<td></td>
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<tr>
<td>42</td>
<td>Hold Pre-Board Meeting with RVP</td>
<td></td>
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</tr>
<tr>
<td>43</td>
<td>PRESENT OPERATION TO BOARD</td>
<td></td>
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<tr>
<td>44</td>
<td>Send Notice of Board Approval to Govt. Borrower</td>
<td></td>
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</tr>
</tbody>
</table>

Implementation Plan
---|---|---|---|---|---|---|
45 | | | | | | |
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**CENTRE's PREPARATORY ACTIVITIES**
- Consolidation of State/City proposals (Center)

**Project: INDIA: TB Control Project**
Date: 1/3/97

**Task**
- Prepare Initial Form 590
- Send signing arrangements memo to SEC
- Post signing Notice to Borrower
- Declare effectiveness

**Milestone**
- 7/31: 50% of Staff at Centre/States in place
- 7/31: Full time State TB Officer in place for RNTP States
- 9/30: New RNTP Curriculum in place for training
- 3/31: District Societies in Place for 1st 39 districts
- 1/31: District Societies in Place for 2nd 39 districts
- Audit Due 6 months after close of Fiscal Year
- 1/31: District Societies in Place for 3rd 24 districts
- 3/31: Submit 1st Plan of Action for NGO Involvement
- Audit Due 6 months after close of Fiscal Year
- Joint Mid-term Management Review
- Audit Due 6 months after close of Fiscal Year
- 3/31: Submit 1st Plan of Action for NGO Involvement
<table>
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</table>

**Task**: Establishing criteria for eligibility for new districts (Center)

**Milestone**: Approval of EFC

**Summary**: Finalisation of EFC document

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**Project**: INDIA: TB Control Project

**Date**: 1/3/97

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- MIS requirements
- Finalisation of Technical/Operational guide
- Develop training material
- Appointment of Regional Consultants (16)
- Evaluation of STDC & their estimated requirements
- TORs forms to develop material
- Plan of field training of Central Trainers
- Field Training of Central Trainers
- Plan of training in central institutions
- Identification of State level trainers & their nomination
- Trainers training in central institutions
- Channelling preparatory fund to State/State & District Societies, (STDCs, 39 RNTCP districts & 203 NTP districts)
- Distribution - Guidelines, Sample Registers, T&I Cards & Formats.

1st Year - CIVIL WORKS (39 Districts)
- Selection of Laboratory Sites
- Selection of Drug Storage site
- Prepare Sketches for works
- Request 3 quote/issue Force Account for works
- Receive bids for works
- Evaluate bids for works
- Award 3-Quote contracts

Project: INDIA TB Control Project
Date: 1/3/97
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**Project:** INDIA: TB Control Project  
**Date:** 1/3/97  
**Task:** SUPPLY OF DRUGS & EQUIPMENT  
**Milestone:** Yr 1 - Assessment of District Requirements  
**Summary:** Finalize ICB & Specifications, Seek WB Prior Approval, Place ICB Announcement in Development Business  
**Construction Period:**  
**3rd Year - CIVIL WORKS (3rd Batch Districts):**  
- Selection of Laboratory Sites  
- Selection of Drug Storage Site  
- Survey to Finalize Site requirements  
- Finalize Category of work (ICB/Force Account/3 Quote)  
- Prepare Sketches for works  
- Request 3 quote/issue Force Acct for works  
- Receive bids for works  
- Evaluate bids for works  
- Award 3-Quote contracts  

**Construction Period:**  
**3rd Year - FORCE ACCT/3-QUOTE (1st Year Works):**  
- Prepare Sketches for works  
- Request 3 quote/issue Force Acct for works  
- Receive bids for works  
- Evaluate bids for works  
- Award 3-Quote contracts  

**Construction Period:**
Project: INDIA: TB Control Project
Date: 1/3/97

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**DRUGS & EQUIPMENT - YEAR 4**

- Yr 4 - Assessment of District Requirements
- Finalize ICB & Specs (Blister/Combination Drug mix?)
- Seek WBank Prior Approval
- Place ICB Announcement in Development Business
- Bid Invitation Period
- Award and Placement of Orders
- Procurement & Distribution

**Batch 1 - 39 DISTRICT STARTUP ACTIVITIES**

- Deadline for Establishment of District Societies
- Identify Year 1/Project staff requirements

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**INDIA: Tuberculosis Control Project**

**Implementation Plan**

*Annex 14*

**Project:** INDIA: TB Control Project

**Date:** 1/3/97

**Page 9**
Project: INDIA: TB Control Project

Date: 11/97

Implementation Plan

INDIA: Tuberculosis Control Project

Annex 14
Implementation Plan

INDIA: Tuberculosis Control Project

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- Training of SLT
- Training of Lab Supervisors
- Training of Medical Officers

Logistics Input
Civil Works Input
Receipt of 1st Year Drugs from Centre
Receipt of Lab Equipment from Centre
Distribution of guidelines, Registers, etc.
Receipt of equipment from State
Commence Service Delivery

Project: INDIA: TB Control Project
Date: 1/3/97

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INDIA: Tuberculosis Control Project

OUTLINE OF PLAN OF ACTION FOR DELIVERY OF TB SERVICES IN TRIBAL AREAS

Introduction

1. There is a sizable population of tribals scattered in the various districts throughout the country. Due to the various characteristics of the tribals and the constraints faced by them, the Government of India has adopted a broad strategy in the health sector through the concepts of the Integrated Tribal Development Project (ITDP) and Tribal Sub-Plan (TSP) in the Fifth Five Year Plan. The Modified Area Development Agency (MADA) was included in the Sixth Five-Year Plan where even smaller pockets of tribals were identified and resources allocated. In the Seventh Five-Year Plan, the TSP was extended to all the Tribals including those dispersed due to various factors.

Basic Norms in the Health Sector for Tribal Areas

2. The basic health sector norms have been modified for the tribal areas. A Primary Health Center (PHC) has been recommended at 20,000 population instead of at 30,000 population and a sub-center at 3,000 population instead of the usual 5,000 population. A DOT provider, preferably from the same tribe will be selected and trained to provide services per 1,000 population or two DOT providers for areas where population is between 1,500 and 2,000. Within this overall framework, specific provisions will be made to ensure that tribal populations have access to TB services and receive full and effective treatment.

Characteristics of Tribal Areas

3. Tribal populations have their own distinctive life styles and attitudes towards health and its providers. They are also distinctive geographically and socially.

(a) Topography of Tribal Areas.

(1) Most Tribals live in far flung, remote areas, usually cut off from the outside world during the monsoon and winter seasons. Their villages/hamlets are usually in mountainous, hilly areas or in forests. This makes road connections and communication difficult which further isolates this population from the mainstream.

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1 The term “Tribal” is the terminology used in the Indian Constitution to refer to indigenous groups who are currently living or have emigrated from isolated and remote areas and have distinctive social, cultural and economic characteristics.
(2) Because it is their ancestral land, tribals prefer to remain in these isolated areas and often maintain a strict vigil to prevent intrusion by other tribals and government officials. Many tribal groups live in small hamlets consisting only of their tribe to try to protect their land based on their notion of self-sufficiency on food, livestock and forest product. These unique characteristics create major challenges for health care providers in bringing health services to tribal groups.

(b) **Socio-Economic Status.**

(1) Most tribal groups depend on their agricultural products for their livelihood which are often meager due to traditional methods of cultivation or over exploitation of the land.

(2) There is a disproportionately high rate of illiteracy among tribal populations, their overall educational status is poor, and because of their adherence to traditional healing practices they have little knowledge of biomedical health care which is the only proven method to deal with infectious diseases.

(3) The practice of traditional medicine based on tribal concept of health and disease has led to delay in diagnosis and proper treatment of many preventable, communicable diseases, especially Tuberculosis.

(c) **Health Facilities.**

(1) Despite additional inputs through modified health infrastructure norms in tribal areas, there is poor delivery of health services. This is due to lack of the available government health staff to serve in these posts. Moreover, reduced priority at the local level results in deficiency of even basic health facilities in these areas.

(2) This has resulted in the tribals losing confidence in the government health services and it has further deteriorated the interaction between health staff and tribal populations. The situation is particularly serious because most tribals rely on the government for health care when they seek allopathic treatment.

(3) The social assessments conducted in tribal areas identified specific issues affecting tribal populations in relation to TB. The following strategy is designed to address these issues.
Strategy for Revised NTP (RNTP) in Tribal Areas

4. Additional inputs in tribal areas are critical for implementing the RNTP. For an operationally feasible and comprehensive approach, the following strategy is being developed, which is based on respect for the Tribals’ religious customs and habits, and for their sentiments and ethnic preferences.

5. As part of the eligibility criteria to participate in the RNTP, a district would need to submit detailed plans to implement the strategy in tribal areas within the overall framework described here and the attached plan of action outline. This includes:

   (a) Identifying and classifying tribal groups:
       (1) according to their ecological habitat, especially in remote, mountainous terrain and deep forests and their degree of contact with the outside world; and
       (2) according to their social and economic characteristics and their quality of life.

   (b) Developing a community-based approach for mobilization and motivation to seek TB treatment, as tribal life style is mainly community oriented and selecting appropriate individuals to carry out this task.

   (c) Involving Non-Government Organizations (NGOs) or community groups active in tribal areas on whom tribals have confidence.

   (d) Involving specially trained personnel who are familiar with the tribals and have their trust.

   (e) Developing Information, Education and Communication (IEC) activities that take into account the tribal life style, culture, language, and relevant social practices and are consistent with their attitudes and perceptions.

   (f) Selecting health providers, especially Village Health Guides, from the same tribal communities.

   (g) Increasing NTP services by opening more microscopic centers, supervisory teams, proper logistic method for buffer drug stocks and proper transportation to avoid bottlenecks in communications.

Operational Components of Revised Strategy in Tribal Areas

6. For operationally feasibility the walking time for a patient to the nearest health center should not be more than one hour, this would be achieved by:
(a) decentralizing diagnostic facilities and establishing microscopy centers at around 50,000 population instead of the norm of one lakh (100,000) population;

(b) establishing Tuberculosis Units (sub-district supervisory teams) at one per 2.5 lakh population instead of the usual norm of one per 5.0 lakh population;

(c) adequate transport facilities to ensure a proper inventory system for uninterrupted supply of drugs and materials throughout the year;

(d) increased involvement of peripheral health functionaries, preferably from the youth within the same tribal group, to ensure better understanding of the system and compliance with the RNTP;

(e) increased involvement of the NGOs already working in the tribal area for TB work;

(f) adequate budgetary provision for traveling allowances for staff and for Petrol, Oil, Lubricants (POL) and maintenance of vehicles to ensure proper monitoring and supervision;

(g) development of DOT models to enable patients to have acceptable, convenient drug taking during times of the year when the communities are isolated;

(h) Operational Research activities by multi-disciplinary study groups especially in the areas of relevant tribal perceptions, social structures, practices and economic relationships and finding alternative ways of service delivery keeping these in view; and

(i) a Multi-Disciplinary Advisory Committee at the Central, State and District Levels to review and evaluate periodically the RNTP in tribal areas.

Conclusion

7. Delivery of services under the RNTP in tribal areas call for a coordinated effort by all sections of the health and social welfare providers keeping in mind the basic concept of the tribal’s life style and socio-cultural characteristics. To achieve these objectives, the plan of action shown on page 157 has been proposed.
### Outline of Plan of Action

<table>
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| Improve Service Delivery and Quality of Care | - Train government and private doctors in tribal areas in RNTP.  
- Provide IPC and counseling training for government physicians  
- Train government physicians in tribal areas in local culture and medical terms.  
- Integrate NGOs when present in RNTP  
- Increase convenience of OPDs.  
- Create tribal fund, or use District Society funds to reimburse patients’ and accompanying relatives’ transport expenses.  
- Identify TB patients for transport reimbursement.  
- Among pastoralists and in remote areas, train tribal youth or other tribal people to distribute drugs and supervise DOT.  
- Train unlicensed practitioners and non-allopathic health providers in TB and referral. |
| Inform Patients and their Families | - Recruit cured TB patients and tribal youth and train them to educate patients and their families.  
- Use cured TB patients to support and follow-up with current patients.  
- Use NGOs and state mass media officers to develop patient education materials for each tribal group.  
- Government physicians and NGOs provide counseling to patients during visits. |
| Inform Community Members to Decrease Stigma | - Recruit community leaders, anganwadi workers, tribal youth, etc., to hold community meetings about health, including TB.  
- Train and use cured TB patients and tribal youth as information resources about TB. |
| Monitoring | - Conduct periodic meetings with tribal community members to obtain feedback on program effectiveness.  
- Schedule frequent tours and spot checks of facilities and services in tribal and remote areas.  
- Periodically visit to check knowledge of cured TB patients and tribal youth. |
INDIA: Tuberculosis Control Project

SOCIAL ASSESSMENTS

1. Two social assessments of tuberculosis (TB) in India were commissioned by the Government of India (GOI), as part of project preparation, with financial assistance from the Japan Grant Funds and Dutch Trust Funds managed by the World Bank. One study of the socio-cultural factors related to TB among tribal populations was conducted by the Foundation for Research and Development of Underprivileged Groups (New Delhi), in selected tribal-dominated districts of Gujarat, West Bengal, Bihar and Himachal Pradesh. The second assessment was aimed at providing in-depth knowledge and understanding of the issues concerning TB among slum populations in the selected cities of Bangalore, Pune, Jaipur, Lucknow and Hyderabad. This study was conducted by FEMCONSULT, a Dutch organization who employed Indian researchers to carry out the field work. Both quantitative and qualitative approaches were employed in carrying out these studies. The findings were instrumental in the formulation of an effective strategy for the information, education and communication (IEC) component of the project and the plan of action for tribal populations as required by OD 4.20.

2. The Studies. Some of the main differences of the findings of the tribal study from those of the study conducted in slum populations are: (1) except for the state of Himachal Pradesh, TB is not as stigmatized in tribal areas, as it is in slums; (2) the tribal people studied go to public facilities and not to private doctors, whereas the slum dwellers tend to rely on private practitioners; (3) in tribal areas, most of the newly posted physicians do not speak the language nor understand the culture of the tribal patients which poses problems to both patients and physicians; (4) although, in general, there is heavy reliance on traditional healers in the tribal areas, this is not necessarily the case for TB.

3. Compliance. Although the details of the findings differ in both study populations, the main causes of people not completing their treatment are related to poverty. For women, gender inequality is an added major factor affecting their treatment-seeking behavior. The main economic factors that affect the treatment of TB are: (1) lack of funds to pay for transportation; (2) lack of funds for medicines; (3) inability to sustain the costs of treatment in the private sector; (4) inability of the patient to sustain loss of income occasioned by having to collect medicines; in the case of women in tribal areas, inability of the person(s) accompanying the patient to sustain loss of income; (5) women's inability to control their movements and allocation of meager family finances; (6) inability to continue the sick role to obtain medicines after symptoms abate; and (7) labor migration. Those who do not abandon treatment either have enough money to complete the course of treatment or, if they have no money at all, they have access to a competent nearby NGO or a government facility providing free TB treatment. Another
Causes of noncompliance include lack of knowledge on the part of the patients of the importance of continuing treatment even after symptoms disappear primarily because of poor communication from service providers.

4. Private doctors and traditional healers are perceived to play more of the healer role than most government physicians. While in many instances, the perception of the physician as an authority figure and as a healer seems to help patients to continue treatment; in many other cases, patients are reprimanded by health providers for not complying with treatment. However, the major problem in the relationship between providers and patients seems to be the veil of secrecy around the diagnosis of Tuberculosis. In many instances, private physicians, reluctant to tell the patient he or she has TB because of the stigma associated with it in the urban areas, communicate a different diagnosis such as “asthma”. This is not the case with government physicians because TB patients are either diagnosed at TB centers or referred to them when diagnosed in other government facilities. Also related to stigma and the secrecy associated with it, is the patients’ tendency to hide the disease from others.

5. Geography as well as climate prominently affect compliance and access to treatment, particularly in the rural areas where inclement weather makes access to the primary health center (PHC) almost impossible.

6. The quality of medicines, their side effects, and price are also a factor in poor treatment compliance. For example, some patients in cities become nauseated by taking several pills at once on an empty stomach. While some patients report compliance because medicines are free, others may need to be charged a small fee for the medicines in order for them to value the drugs.

7. Treatment Seeking Behavior. Most people with TB symptoms first seek out private health care practitioners because: (1) private doctors are conveniently located; (2) they are not very expensive; (3) they are perceived to treat patients more respectfully and with more understanding than other health providers; (4) government free medicines are perceived to be inferior to private physicians' or chemists' medicines; and lastly (5) the patient wishes the privacy of treatment afforded by a private doctor.

8. Although there are relatively few NGOs caring for TB patients, their services are often highly valued and NGO physicians may be considered to be more caring and dedicated than government health providers. Some NGOs that do not provide clinical services to TB patients have outreach workers who educate the public about TB. It was found that in almost all the slums, the presence of active outreach workers is correlated with increased allopathic knowledge about TB. However, allopathic knowledge is not correlated with decreased stigmatization of TB.
9. Government facilities with a good reputation for curing patients and maintaining a good supply of all TB drugs attract patients from a wide area. Directly-observed therapy (DOT), which is offered at some government facilities, seemed to greatly improve the number of compliant or cured patients. It is not yet clear whether compliance under DOT is related to the rigor of the supervision system associated with DOT or to the fact that patients are receiving more attention from the service providers (the Hawthorn effect). This would be an area for Operational Research under the project.

10. Communication. Mass media play virtually no role in TB education. This is mainly due to the lack of publicity on TB in the mass media. In slums, access to health information through television and radio is spotty and varies by slum and gender. While some slums have no electricity, there are others where most residents have access to televisions, but women are too busy to watch or listen to television. Some slum residents are literate and may read newspapers, while in many other slums people are mostly illiterate.

11. Information about TB and TB treatment facilities and treatment regimens is spread by word of mouth by compliant and cured TB patients. Patients seem most likely to complete the full treatment if they receive information and support from health providers. Irrespective of the type of health care provider, the importance of enthusiastic and committed health care personnel and sufficient funds to manage the TB program seems to be key in program success.

12. Community Perception of TB. TB is a stigmatized illness in all study areas, although the degree of stigma varies greatly. In some areas with the least stigma, only females in certain categories, such as unmarried girls and newly married nulliparous women, experience stigma. It is the private doctor's respect for the stigma associated with TB and its attendant secrecy that attract many TB sufferers to them.

13. Due to stigmatization of the disease and beliefs that TB is contracted through food, clothing, heredity, coughing, etc., TB patients are somewhat isolated in many areas. Folk etiology of TB also varies widely. However, recognition that coughing may spread TB is almost universal. In general, people say they regard TB as curable, although they may not behave in accordance with this stated belief (e.g. by stigmatizing TB patients).

14. Social Indicators. The basic indicator is the percentage of patients cured, although there are other process-based social indicators that include economic, programmatic and social factors that were discussed in the earlier paragraphs.

15. Recommendations. Several recommendations came out of these social assessment studies. They suggest that the current overall health systems be enhanced to accommodate the TB patient and that the training given at all levels of the health delivery system be strengthened with the TB patient in mind.
16. Furthermore, the studies suggest that communication be used as a powerful tool to help health care providers and patients cure TB. Some of the suggestions on this front included:

(a) training in interpersonal communication for all public sector health care;
(b) providers who interact with TB patients and counseling training for public sector;
(c) physicians, nurses and treatment supervisors;
(d) in each local project area, design of pictorial materials for illiterate patients that meet local needs and that contain detailed information on drug regimens;
(e) provision of stylish materials for private sector and NGO physicians for promoting short course chemotherapy;
(f) design of a program to utilize trained, cured and compliant patients in DTCs, slums and villages;
(g) use of the communication paradigm of education and providing information to patients, rather than motivation, which does not seem to be a factor affecting patient compliance; and finally
(h) newly posted physicians going to tribal areas should, when feasible, receive training from Indian anthropologists or people knowledgeable about the local culture and local medical terms.
INDIA: Tuberculosis Control Project

SOCIAL INDICATORS

1. The basic indicator is the percentage of patients cured, however other process-related social indicators include the following:

(a) Economic.
   (1) Minimum cost of transportation to treatment centres (should be affordable to patients and symptomatic people).
   (2) Minimum lost wages in coming to treatment centre (cost should be within comfortable economic limits for patients and their families).

(b) Programmatic.
   (1) Treatment and diagnostic sites readily accessible to patients in catchment area.
   (2) All drugs continuously available at treatment centre.
   (3) Convenience of patient flow protocol to patient (within and between facilities).
   (4) Time spent by patient in diagnostic facility, in treatment facility, in transportation between facilities.
   (5) Patient flow information obvious and comprehensible to illiterate patients (either provided orally or in pictorial form).
   (6) Patient given and understands how to take medicines and duration of treatment.
   (7) Explanation provided and patient understands that bodily experience of well-being is not correlated with TB cure.
   (8) Number of times medicine taking and duration information repeated on different occasions (by different health workers or by same health provider).
   (9) Patients feel doctor has thoroughly examined them.
(10) Patients feel doctor is interested in how they feel and in their recovery.

(11) Patients have faith in doctor's authority.

(12) All health care staff display a modicum of respect for patients, i.e.,

(i) Staff never yell at patients.

(ii) Patients offered seat if in office for more than a few minutes.

(iii) Health workers look at patients when patients or providers are speaking.

(iv) Physicians acknowledge and respond to patients' complaints.

(v) Patients report doctors or drug dispensers have listened to them.

(vi) Percentage of false names given to centre declines.

(vii) Names and addresses of new patients confirmed by household visits.

(c) Social.

(1) TB stigma reduced.

(2) Patients report neighbors and relatives willing to converse and visit with them.

(3) Percentage of female TB patients sent back to parents declines.

(4) Percentage of parents of unmarried daughters with TB willing to disclose daughter's diagnosis increases [difficult to change].

(5) Initial visits to TB treatment centres increase.

(6) Percentage of false names and addresses given to treatment centres declines.

(7) Percentage of TB patients reporting that doctor (especially in private sector) has informed them that they have TB increases.
INDIA: Tuberculosis Control Project

INFORMATION, EDUCATION AND COMMUNICATION (IEC)

Introduction

1. Health communication issues associated with tuberculosis differ from those of other familiar health problems commonly addressed in India through IEC (e.g., family planning, leprosy, blindness). The Revised National Tuberculosis Program is directed toward accurately diagnosing TB among patients with symptoms and curing those with TB. Active case finding is not a goal of the Program. IEC activities support and facilitate the Program’s strategy of passive case finding. Therefore, the strategy postpones and de-emphasizes mass media campaigns and does not contain demand generation activities.

2. The IEC strategy is based on social assessments\(^1\) of stakeholders perceptions of tuberculosis, experiences with TB treatment, and desires for changes in how TB treatment is provided. Continuation of extended drug treatment is problematic, particularly in TB, and discontinuation rates in India have been high. Research indicates that much discontinuation has been due to: (a) the unavailability of drugs; (b) expense of obtaining drugs from the private sector; (c) monetary and logistic difficulties in transport to obtain public sector treatment and drugs; and (d) lack of information (e.g., about treatment duration, patient flow) and unsympathetic treatment by health care providers. Other portions of the Program have been designed to remedy the situation described by the first three research findings (a,b,c). IEC activities would address the last research finding (d).

3. Research reveals also that most symptomatic patients (except in tribal areas) first seek treatment from private licensed or unlicensed doctors. However, repeated consultations and purchasing drugs are expensive. Consequently, patients stop treatment when they feel better. Patients prefer private doctors for their convenient location and because these doctors seem to have an interest in the patient and her/his cure. Public facilities are often expensive to get to and public sector physicians may be perceived to be insensitive and uninterested in the patient.

4. In addition, research indicates that compliant TB patients are usually those who have faith in their physicians, have been told how and how long to take their medicines, have heard this information repeatedly, and have heard the information from their physicians. Regimens for the three categories of TB patients differ. In the absence of medical records, the physician must

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\(^1\) One social assessment was conducted in a total of 13 slums in five Indian cities by FEMCONSULT. The assessment is entitled, "Social Assessment of Target Audiences in 13 Slums." The second social assessment was conducted among tribes in five different states by Dr. Salil Basu and his team of researchers. The title of the tribal assessment is "Social Assessment Study: Perception, Attitude, Experience of Tribal Communities vis-à-vis the Role of Health Providers for the Acceptability and Demand for Tuberculosis Treatment in Tribal Areas."
categorize each TB patient based on medical history interview findings. Mis-categorization of patients will not result in a cure and may further promote drug resistance. However, good interviewing or history taking skills are easily taught.

**Objectives**

5. IEC will help to increase the cure rate through introducing a client-oriented perspective into the health delivery system, especially among health providers. The objective is to improve health care providers' interpersonal communication and counseling skills, including providing TB patients with medically accurate and complete information on what the patient needs to do to collaborate with the physician in achieving a cure. In order to meet this objective, all health workers who interact with TB patients will receive training. Since research indicates that TB patients may discontinue treatment-seeking or drug-taking based on negative experiences with auxiliary personnel in health care facilities, all health workers (including auxiliary personnel) should be trained in a patient-centered approach. For the purpose of this strategy, health workers include:

   (a) Physicians
   (b) Nurses
   (c) Multipurpose health workers
   (d) Pharmacists
   (e) X-ray technicians
   (f) Laboratory technicians
   (g) Clerks

6. Research findings also indicate that TB is stigmatized among many groups in India (e.g., in some slums and in some rural areas). TB patients in some areas report feeling isolated and lonely. Women suffer most from stigmatization: husbands not uncommonly divorce their wives when they are diagnosed with TB or temporarily send wives back to their parents, interrupting drug therapy. Another objective of the strategy, therefore, is to decrease stigmatization through use of cured TB patients for outreach to TB patients and their families, education of school children, and eventually through limited use of mass media to reach all members of the population, once the TB program is running well in most of the country. The objective is to change patients' and community members' perception of the disease from an incurable, shameful illness, to a serious, but curable disease like any other disease. This could result in tubercular wives' unchanged status within the marriage and inclusion of non-infectious TB patients in the community and family.

7. The finding that TB is perceived to be incurable by many community members and patients has been linked to failure to seek treatment or to comply with treatment in some cases. Cured TB patients will be trained and employed as volunteers to support and educate TB patients
and their families, explain patient flow in health care facilities, and to serve as knowledgeable resources within the community (a role which they already occupy informally). Programs for school children will be aimed at education about TB as well as destigmatization of the disease. This supports the previous objective, as well as helping to obviate the need for future active case finding by educating children about TB symptoms, what to do about them, and destigmatizing treatment-seeking for the disease.

**Strategy**

8. **Target audiences.** The primary and secondary target audiences are as indicated below.

   (a) Government health care providers (including all the above categories, including STOs).

   (b) Secondary target audiences include:

      (1) TB patients and their families;

      (2) Private and NGO doctors (from all medical traditions);

      (3) Central Health Education Bureau staff;

      (4) State/district mass media officers;

      (5) Outreach volunteers (cured TB patients or NGO volunteers); and,

      (6) Community members (including school children).

9. A detailed national IEC strategy was developed during the preparation phase of the project. Stakeholders are integrated into the strategy through inclusion of their views and problems, as elicited in the two social assessments, and integration of the NGO community.

10. **Possible Key Messages.** Messages should reflect the concerns and experiences of stakeholders, support skills and supply information needed by physicians to facilitate their use of short-course chemotherapy (SCC).

11. The most important messages for physicians are:

    (a) Treat patients with respect and sympathy.

    (b) Listen to patients.

    (c) Tell the patient at each contact how long to continue treatment and what will happen if the patient stops prematurely.

    (d) Express interest in patient’s welfare and recovery.

12. The most important messages for patients are:

    (a) TB is curable.
(b) Take your medicine until the doctor tells you to stop.
(c) You are not cured until the doctor tells you are cured, even if you feel well.

13. A full summary of messages and channels by target audience appear below.

(a) **Channels of information.** The strategy relies on two main approaches to support passive case finding and cure: training of health care providers and those providing support for patients, and development of counseling and educational materials. Other health care providers (e.g., laboratory technicians and multipurpose health workers) should also receive audience pre-tested materials that facilitate their participation in delivering SCC. Promotional materials should be developed for private and NGO physicians to encourage accurate use of short course chemotherapy.

(b) Pretested, pictorial materials for patients that explain health care facility use and SCC procedures may be developed. In addition, meaningful local rituals or symbolic items could be developed to indicate a patient's commitment to finish treatment and a doctor’s commitment to the patient and his/her cure. A ritual or symbolic gift could also be developed to visually represent that a patient has completed treatment and is cured. Mass media may be employed to aid in decreasing the stigma of TB once services are in place and functioning well throughout most of the country. Health education and games for school children will also be important in destigmatizing and educating about TB for the future.

(c) A secondary approach to support passive case finding is the use of mass media and health educators to encourage a more accepting climate in the community for TB sufferers. The approach would be based on: (a) promoting the concept that TB is curable; and (b) sensitizing community members to the difficulties faced by TB patients.

**Monitoring System**

14. All behavioral changes among health care workers should be observed through a supervisory system of direct observation of patient care by staff members' supervisors, who have received training in supervising for interpersonal communication (IPC) and counseling. Interpersonal communication and counseling (IPC/C) supervisory skills of MOHFW staff and actual patient/staff interaction should be monitored by direct observation during site visits by the National Program team. Interviews with patients selected at random from patient lists and conducted at periodic intervals (e.g., yearly) in patients’ homes by qualitative researchers would also provide a measure of patients’ perceptions of health providers and could detect how provider training affects patients’ compliance. These interviews could also be used to gauge the effect of the Program, including any mass communication activities, on, for example, stigmatization of female TB patients.

15. Outreach volunteers’ role in achieving a higher cure rate could be monitored by direct observation by their supervisors (e.g., multipurpose health workers or a designated IPC
supervisor within a health care facility). Volunteers could also be monitored through patient interviews to assess patients’ knowledge about TB and its treatment, their sources of knowledge, and the volunteer's role in patient satisfaction. Records should be kept by the volunteer on the number of patients contacted, and these should be checked by a supervisor.

16. Materials that have been in use for at least six months should be evaluated by an outside research organization. Materials should be evaluated every two years and new materials developed if necessary (based on research findings). Information on patients, health care providers, and community members' perceptions of TB already exists. However, in some cases it may be necessary to conduct baseline rapid research studies in a few rural areas where data have not previously been collected.

17. The success rate of the IEC component may be inferred through:

(a) Comparison of increased cure rates in concert with increased patient satisfaction;
(b) Proportion of TB patients who come to government facilities for treatment based on recommendations of current or cured patients;
(c) Percentage of TB patients per district and state who report that they do not feel that they are treated differently (e.g., avoided or isolated) due to TB;
(d) Decrease in female TB patients who report that TB has decreased their chances of marrying or remaining married; and,
(e) Gradual increase in patient load in microscopy centers.

Implementation

18. Implementation activities would be divided into five components:

(a) Training (including curriculum development, training management, and conducting training);
(b) Materials development (including planning, designing, Pre-testing to obtain input from stakeholders and those who influence them, disseminating materials, evaluating materials, revising materials as necessary, and (when necessary) training health workers in the use of materials for counseling);
(c) Management of IEC activities (including IEC strategy development and management at national, state, district, health facility and community levels)
(d) Monitoring, evaluation, and research (including supervision of IEC activities, periodic evaluation of IEC activities, and conduct of any additional small research projects to gain baseline data in areas for which no data exist, e.g., some rural areas); and,
(e) Counseling and health education (for patients and their families, health education for school children, and eventually health education to the community).
19. Several issues are key in implementing the strategy. It will be important not to overload MOHFW staff, nor to expect them to complete tasks for which they are not adequately prepared. Among these issues are: (a) Training in IEC management is advisable so that MOHFW staff can tap resources in the private sector and NGO community for specialized IEC tasks (e.g., production of creative materials); (b) NGOs may help to provide a cadre of cured TB patient-volunteers to assist government efforts in outreach; (c) Decision makers with authority to approve IEC materials should be involved in their development from the beginning and should be briefed in materials development procedures; they should also be responsible for insuring that materials reflect extensive audience participation; and (d) whenever possible, Central Health Education Bureau (CHEB) staff should be used to develop materials together with State and/or District staff.

20. Below are matrices of IEC activities.

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>AUDIENCE</th>
<th>IMPLEMENTING AGENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Curriculum</td>
<td>1. National Program staff, CHEB and other identified MOHFW staff</td>
<td>1. CHEB with technical assistance</td>
</tr>
<tr>
<td>development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. IEC management</td>
<td>2. National Program staff, DTOs, STOs, state/district mass media officers, all who</td>
<td>2. CHEB with technical assistance, possibly with private sector or NGO assistance</td>
</tr>
<tr>
<td>&amp; supervision</td>
<td>supervise health workers involved in TB patient interaction</td>
<td></td>
</tr>
<tr>
<td>3. IPC/Counseling</td>
<td>3. National Program staff, CHEB staff, DTOs, STSs, all health workers and</td>
<td>3. CHEB, State TB staff and local arrangements to be approved and supervised by</td>
</tr>
<tr>
<td></td>
<td>volunteers involved in TB patient interaction</td>
<td>CHEB and Central TB Unit</td>
</tr>
<tr>
<td>4. Materials</td>
<td>4. National Program staff, CHEB staff, state/district mass media officers,</td>
<td>4. CHEB and Private sector orgs., appropriate NGO with technical assistance</td>
</tr>
<tr>
<td>development</td>
<td>policy makers</td>
<td></td>
</tr>
<tr>
<td>5. Advanced IEC</td>
<td>5. CHEB staff, state/district mass media officers. State staff of selected</td>
<td>5. Appropriate local organization to be decided; will probably require technical</td>
</tr>
<tr>
<td></td>
<td>appropriate NGOs and private organizations contracted to RNTP in IEC</td>
<td>assistance</td>
</tr>
</tbody>
</table>
### Annex 18

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>AUDIENCE</th>
<th>IMPLEMENTING AGENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. IEC strategy development</td>
<td>6. National Program staff, DTOs, STOs, state/district mass media officers</td>
<td>6. CHEB and another appropriate local organization to be decided; may require technical assistance</td>
</tr>
<tr>
<td>7. Training of Trainers (TOT)</td>
<td>7. Trainers for district, state workshops; trainers for some national workshops (e.g., materials or strategy development, management)</td>
<td>7. National Program, appropriate NGO or government institution; would require technical assistance</td>
</tr>
</tbody>
</table>

### Materials Development:

1. Planning 1. Policy makers and those who must implement policies 1. CHEB, National Unit, with State and District mass media officers, STO, DTO (i.e., local IEC team) -- input from CHEB and local decision makers; National Program approves plans

2. Creative design 2. All audiences for all materials 2. CHEB with local IEC team may choose appropriate NGO or private sector group to develop materials; artist works with materials developers and local IEC team. In materials for private & NGO MDs, Ntl. Program contracts with private ad agency, may also do so for novelty items for public sector staff.

3. Pretesting 3. All audiences for all materials 3. CHEB and trained State and District mass media/IEC officers

4. Publishing/manufacturing 4. All audiences for all materials 4. National or state (depending on material) Program contracts with private sector firm or government institution

5. Dissemination 5. All audiences 5. Depending on material, dissemination through clinics and outreach workers for patients and their families;
<table>
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<tr>
<th>ACTIVITY</th>
<th>AUDIENCE</th>
<th>IMPLEMENTING AGENCY</th>
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<tbody>
<tr>
<td></td>
<td>through workshops for private and NGO physicians; through training workshops for government personnel; through normal government distribution procedures</td>
<td></td>
</tr>
<tr>
<td>7. TB Newsletter</td>
<td>7. National Committee, State TB Officer and IEC Officer</td>
<td>7. National Committee puts together the core part of the TB Newsletter, each state adds its own part and translates and publishes</td>
</tr>
</tbody>
</table>

**Management of IEC Activities:**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Audience</th>
<th>Implementing Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Strategy development</td>
<td>1. Policy makers and those who implement policies</td>
<td>1. National Program &amp; CHEB develop IEC strategy; states, districts, and facilities develop their own plans; National Program review and approves state/district plans</td>
</tr>
<tr>
<td>2. Planning activities</td>
<td>2. N/A</td>
<td>2. National Program team, STO, DTO, state and district mass media officers working together</td>
</tr>
<tr>
<td>3. Managing activities</td>
<td>3. N/A</td>
<td>3. National IEC officer, CHEB and National IEC Committee monitors and approves state IEC activities and responsible for managing national IEC program; STO manages state and supervises district IEC activities; DTO supervises individual facilities' IEC activities and manages district IEC activities; state and district mass media officers may be responsible for portion of IEC management based on local decisions.</td>
</tr>
</tbody>
</table>
**Monitoring, Evaluation, Research:**

1. **Supervision of materials development**
   - 1. N/A
   - 1. National team, including CHEB in leading role, monitors state materials development; STO and state mass media officer supervise materials development by state, with assistance from any district mass media officers.

2. **Supervision of counseling and IPC**
   - 2. Those who counsel patients and their families
   - 2. National Program team monitors supervision by STO; DTO and CMOs supervise and monitor physicians in their district; clinic physicians supervise multipurpose workers; multipurpose workers supervise outreach volunteers.

3. **Evaluation of IPC/C activities**
   - 3. N/A
   - 3. MIS unit of National Program; National Program contracts with research organization to conduct qualitative evaluation research.

4. **Evaluation of materials (including dissemination)**
   - 4. N/A
   - 4. National and state programs contract with independent organization (e.g., appropriate NGO or communication firm) to conduct post testing and evaluation of materials' distribution and use.

5. **Additional rapid baseline research**
   - 5. policy makers, especially National Program
   - 5. National Program contracts with research organization (e.g., the local group that was employed in the pre-assessment phase or a local university department of anthropology, etc.).
## Counseling and Health Education:

1. **Counseling and support for patients and their families**
   - Physicians, multipurpose workers and others who supervise DOT, cured TB patient volunteers, other health staff depending on local situation (e.g., health educators, nurses)

2. **Health education for school children**
   - Primary and secondary school children
   - District health educators, DTOs, etc.

3. **Health education for community***
   - Community leaders, older community members (who are at higher risk for TB), all other members of community
   - Cured TB patient volunteers, multipurpose health workers,* District Mass Media Officers (when trained in TB IEC)

*Should not occur until services are functioning well and prepared to absorb influx of new patients
**Annex 18**

**IEC Strategy at a Glance**

**Theme:** Quality of care and patient-centered care--treatment, support, and information for TB patients

<table>
<thead>
<tr>
<th>TARGET AUDIENCE</th>
<th>INTERVENTION</th>
<th>POSSIBLE MESSAGES</th>
</tr>
</thead>
</table>
| Government physicians | • IPC/counseling training  
|                       | • Counseling card  
|                       | • Audiocassette TB updates  
|                       | • TB Newsletter           | • Treat patient with respect and sympathy  
|                       |                       | • Take history                                         |
|                       |                       | • Show medicines                                           |
|                       |                       | • Listen to patient                                          |
|                       |                       | • Provide diagnosis                                         |
|                       |                       | • Tell patient TB is curable                               |
|                       |                       | • Tell to continue even if feeling better                   |
|                       |                       | • Tell consequences of incomplete treatment                 |
|                       |                       | • Repeat duration of treatment                             |
|                       |                       | • Tell what to do if pills missed                           |
| DTOs, MOs, CMOs       | • Same as other government physicians & supervision and monitoring training  
|                       | • TB Newsletter                                         | • Same as other government physicians, but CMOs require less training  
|                       |                                               | • TB Newsletter - MIS  
|                       |                                               | Information, medical norms, staff member recognition         |
| Laboratory Technicians| • IPC training  
|                       | • Cards with important lab procedures  
|                       | • Microscope covers  
|                       | • TB Newsletter                                     | • Treat patients with respect  
|                       |                       | • Explain in simple language                             |
|                       |                       | • (for cover) Did you clean your microscope?               |
| X-ray technicians     | IPC training  
|                       | • TB Newsletter                                       | • Treat patients with respect  
|                       |                       | • Explain in simple language                             |
| Nurses                | • IPC training  
|                       | • TB Newsletter                                       | • Treat patients with respect and empathy                      |
|                       |                       | • Ensure patient privacy                                 |
|                       |                       | • Explain in simple language                             |
| STSs                  | • IPC supervision, interviewing and training  
<p>|                       | • TB Newsletter                                       | • Ask open, not leading questions                             |</p>
<table>
<thead>
<tr>
<th>TARGET AUDIENCE</th>
<th>INTERVENTION</th>
<th>POSSIBLE MESSAGES</th>
</tr>
</thead>
</table>
| Registrars/clerks                     | • IPC training by MO                                                        | • Treat patients with respect  
• Remember patients are ill  
• Explain clearly what patient needs to do  
• Do not make patients wait unnecessarily |
| DOT Supervisors                       | • IPC training  
• Pictorial and written counseling manuals                                       | • TB is curable  
• Listen to patient, report complaints  
• Help patient to comply, don’t tell patient to comply  
• Report all side effects  
• Repeat duration of treatment  
• Express interest in patient |
| Central Health Education Bureau (CHEB) staff | • Advanced materials development training  
• IPC participatory, competency-based training techniques  
• Advanced IEC update | • Listen, support and counsel for TB; don’t motivate |
| State/District Mass Media Officers    | • Briefing on IEC strategy  
• Materials Development training  
• Advanced IPC update training | • Educate, don’t motivate  
• Postpone mass media and community education |
| State TB Officers                     | • IEC strategy training  
• Awareness of IPC/C issues in TB                                              | N/A |
| Outreach volunteers                   | • Training in tuberculosis, its treatment, access to treatment, and patient flow, as necessary | • TB is curable  
• Help patient to comply, don’t tell patient to comply |
| Outreach volunteers                   | • Patient & family member pictorial booklet                                   | • TB is cured only if the patient takes the medicine  
• please see below (patient and family members) |
<table>
<thead>
<tr>
<th>TARGET AUDIENCE</th>
<th>INTERVENTION</th>
<th>POSSIBLE MESSAGES</th>
</tr>
</thead>
</table>
| Private/NGO doctors  
Licensed Allopathic  
Licensed Ayurvedic  
Licensed Homeopathic  
Yunani  
Traditional healers  
Unlicensed | • IPC training  
• Novelty items  
• Medical Information | • SCC saves lives  
• Diagnose by 3 sputum samples |
| Patients & their families | • Pictorial booklets  
• Posters | • TB is curable  
• Return with sputum sample  
• Take your medicine even when you feel better  
• You can feel better and still have TB |
| Community members*  
*Probably not implementable during next 5 years | • Sound trucks  
• Health education talks  
• Plays  
• TV and radio spots | • TB is curable  
• TB is a disease like any other  
• TB medicines are free at government clinics |
| School children | • Health education talks  
• Games | • TB is curable  
• TB is a disease like any other  
• TB patients must take their medicines until the doctor says they are cured  
• Immunization prevents children from getting TB |

21. **Interpersonal Communication (IPC) Training** needed by:

(a) **National Level TB Unit** (in order to monitor effective implementation);

(b) **DTO** (in order to supervise, train staff of TB units and all medical and paramedical staff of the peripheral health institutions, direct DTC and organize health education);

(c) **Senior Treatment Supervisor** (STS) (in order to supervise, randomly check on patients, interview staff, facilitate patient referral, provide continuous training to staff of health facilities, establish liaison with private practitioners and NGOs who provide TB services);
(d) **Senior TB Laboratory Supervisors** (STLS) (in order to supervise, train Laboratory Technicians);

(e) **Medical Officer for TB Control** (MO TC) (in order to act as a referral point for patients with diagnostic problems, cases reporting with drug reactions, those refusing to take drugs, etc., supervise MOs at peripheral centers, refer problem cases to DTO, supervise, etc.);

(f) **Medical Officer** (MO) (in order to find cases, categorize and treat TB patients, take histories and examine patients, discuss with new patients the most convenient location for DOT and educate them on the importance of completing therapy, see patients with problems, supervision, education of MPWs);

(g) **Microscopists** (in order to instruct patients on proper methodology of sputum production and collection);

(h) **Lady Health Visitor/staff nurse/health assistant/Multipurpose Health Supervisors** (in order to conduct home visits, administer DOT, discuss and counsel new patients on DOT and the importance of treatment completion and DOT, remind patients of importance of regular treatment, sputum exams and follow-up visits);

(i) **Multipurpose Health Worker** (General Model)/**TB Health Visitor** (Special Model) (in order to ensure regularity of DOTs and treatment during continuation phase of treatment, verify address of new patients, counseling patients and family, administer DOT, ensure sputum smears are produced and collected properly, follow-up patients who have missed administration of TB drugs); and

(j) **Registration Clerks** (in order to determine that patients are treated respectfully and understand the patient flow procedure).
INDIA: Tuberculosis Control Project

SUMMARY OF OBJECTIVES AND EXPECTED OUTCOMES

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>INPUTS (Resources provided for project activities)</th>
<th>OUTPUTS (Goods and services produced by the project)</th>
<th>RISKS AND CRITICAL ASSUMPTIONS (The outcome is dependent on...)</th>
<th>OUTCOMES AND IMPACTS (of project activities)</th>
</tr>
</thead>
</table>
| (a) Effectively diagnose and treat about 1.9 million Tuberculosis cases in the RNTP Districts, including an estimated total of more than 800,000 infectious, smear positive, and severe Tuberculosis cases | IDA Credit of US$142.4 million for the Tuberculosis Control Project | Proportion of TB patients in TB registers and with Treatment Cards in public, private and NGO facilities; Proportion of TB patients referred by the private and NGO sectors to government facilities for sputum diagnostic exams and TB treatment evaluation; Proportion of TB patients who underwent DOT and at which part of the treatment process; Proportion of patients who complete their treatment regimen in public, private and NGO sectors; Proportion of staff in public and NGO sectors trained in laboratory equipment maintenance. | • Shift among service providers in their diagnostic and treatment evaluation protocols from X-ray to sputum examination • Uninterrupted supply of quality anti-TB drugs through the creation of buffer stocks of drugs of three months at the peripheral level and six months at the district level • Effective IEC campaigns that promote and foster respiratory symptomatic patients reporting to clinics for diagnosis, treatment evaluation and drug collection, patient adherence to and completion of treatment regimen and correct production and collection of sputum | In the RNTP Districts
- Achieve sputum conversion rates from positive to negative of 85% within first three months for all newly diagnosed smear positive patients who begin treatment
- Improved diagnosis based on increased ratio of smear positive to smear negative (see table 4.4 of the SAR on indicators)
- Steady increase in the proportion of smear positive TB cases
- Reduced proportion of retreatment and relapse cases
- Improved access to diagnosis and treatment by women.

(b) Achieve an 85% cure rate in RNTP districts for newly diagnosed smear positive cases

(c) Provide treatment with Daily Short Course (SCC) to 850,000 smear positive patients in the SCC Districts and prepare them to adopt the RNTP

(d) Treat about 230,000 smear positive patients with conventional drugs in Non-SCC Districts

(e) Improve the quality of diagnosis to achieve at least 50% diagnosed smear positive cases as a proportion of total diagnosed cases in the RNTP and the SCC Districts
<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>INPUTS</th>
<th>OUTPUTS</th>
<th>RISKS AND CRITICAL ASSUMPTIONS</th>
<th>OUTCOMES AND IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>(f) Improve the system of patient registration and follow-up to allow monitoring of treatment completion and cure in the RNTP and the SCC Districts</td>
<td>Training and workshops on Institutional Development and Operations Research involving the public, private, and NGO sectors, consultants, support to NGOs</td>
<td>Number and proportion of Operations Research proposals screened by the TB Division and reviewed by the Steering Committee</td>
<td>Developing an appropriate Management Information System (MIS)</td>
<td>- Efficient and effective Training programs and training institutions at the Center, State and District levels</td>
</tr>
<tr>
<td>(g) Improve the quality, access and outcomes of TB treatment in the public, private and NGO sectors</td>
<td></td>
<td>Number and proportion of approved Operations Research protocols funded by the Ministry of Health</td>
<td>- Faithful and accurate patient registration and treatment card record keeping</td>
<td>- Well trained staff at all levels-fully knowledgeable about the RNTP</td>
</tr>
<tr>
<td>(h) Develop institutional and operational research capacity in the public, private and NGO sectors.</td>
<td></td>
<td></td>
<td>Developing and maintaining a constituency for TB control nationwide through an efficient and effective TB program</td>
<td>- Smear microscopy quality control system in place and good quality of microscopy</td>
</tr>
<tr>
<td>(i) Enhance the technical, managerial and interpersonal patient skills of service providers</td>
<td></td>
<td></td>
<td>Establishment of District TB societies for efficient and effective flow of project funds and quick submission of reimbursement claims to the Center and to IDA</td>
<td>- Improved patient satisfaction</td>
</tr>
</tbody>
</table>

- Operations research topics and findings relevant to project objectives
- At least 80% of the districts will have data available. Efficient and effective management of TB control at all levels through an efficient MIS system
- Credible Tuberculosis Control program, especially among the poor and underserved populations
- Support for TB control is sustained at the Central and State levels
- Timely procurement and disbursement
- Findings of Operations research are incorporated in the program
- High quality training, research and quality control capabilities available in training institutes
<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>INPUTS (Resources provided for project activities)</th>
<th>OUTPUTS (Goods and services produced by the project)</th>
<th>RISKS AND CRITICAL ASSUMPTIONS (The outcome is dependent on...)</th>
<th>OUTCOMES AND IMPACTS (of project activities)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(j) Develop Information, Education, Communication (IEC) and outreach activities and promote</td>
<td>Publicity (IEC) services, support to NGOs particularly those working in urban slum, rural poor, tribal and remote population</td>
<td>Proportion of patients who report to the clinic due to a publicity service intervention and specify which publicity service or services and what message or messages that made them visit the clinic; Proportion of patients who report to the clinic and who come from urban slum, rural poor, tribal and remote areas; Proportion of patients who report to the clinic who are women.</td>
<td>- Willingness of service providers to be trained and change their interaction with TB patients.</td>
<td>- Improved patient satisfaction with TB services and improved treatment adherence</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Effective IEC campaign addressed to the underserved, especially women.</td>
<td>- Increase number of female patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Incentives for public, private, and NGO service providers to bring their resources to those who come from urban slum, rural poor, tribal and remote areas.</td>
<td>- Increase number of tribal patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- diminished stigma among patients' families and community because of appropriate education and counseling to emphasize that TB can be cured by taking complete treatment.</td>
<td>- Improved patient-provider relations</td>
</tr>
</tbody>
</table>
### Performance Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>RNTP</th>
<th>SCC</th>
<th>NON-SCC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Number of smears per chest symptomatic examined</td>
<td>2-3</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>B. Percent of new cases which are smear positive</td>
<td>50%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>C. Proportion of new smear positive patients found in Laboratory Register who are in TB Register as undergoing treatment</td>
<td>≥ 90%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>D. Quality control network for microscopy services in place</td>
<td>≥ 50%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>II. Treatment outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Proportion of new smear positive cases placed on DOTS</td>
<td>≥ 90%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>B. Sputum conversion at 2-3 months of all new smear positive cases begun on treatment</td>
<td>≥ 85%</td>
<td>60%</td>
<td>NA</td>
</tr>
<tr>
<td>C. Cure/completion percentage of new smear positive patients begun on treatment</td>
<td>≥ 85%</td>
<td>60%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>III. Training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Percent of DTOs, STOs trained in RNTP</td>
<td>80%</td>
<td>50%</td>
<td>NA</td>
</tr>
<tr>
<td>B. Percent of STS/STLS trained in RNTP</td>
<td>70%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>C. Percent of MPW/LT trained in RNTP</td>
<td>50%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>IV. Supervision</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Staffing of Central Division consultants</td>
<td>80%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>B. Staffing of regional consultants</td>
<td>80%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>C. Supervisory visits to each subdistrict by DTO:</td>
<td>≥ 4/year</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>D. Supervisory visits to Districts by STO/Central Units:</td>
<td>≥ 2/year</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>E. Quarterly reports received on or before deadline</td>
<td>≥ 95%</td>
<td>&gt; 60%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>V. Disbursement and Logistics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Availability of drugs at the treatment center level (for smear positive &amp; smear negative patients)</td>
<td>&gt; 95%</td>
<td>&gt;90% (smear positive only)</td>
<td>&gt;90% (smear positive only)</td>
</tr>
</tbody>
</table>
INDIA: Tuberculosis Control Project

SUPERVISION AND MONITORING ROLE OF THE CENTRAL DIVISION

1. Supervision would be carried out through field visits and monitoring would be done through reports received from State and District units and from tour reports and from periodic appraisal missions from the Central TB Division.

Supervisory Visits

2. Supervisory visits to State TB Cells, State Training and Demonstration Centers (STDCs) and other Training Facilities will be carried out on a regular basis. The objectives of such supervisory visits would be to:
   (a) assess progress in implementation/preparation;
   (b) identify technical and administrative bottlenecks; and
   (c) assist in problem solving and provide support.

3. These supervisory visits would be planned for all the officers and consultants of the Central TB Division. On a regular basis, the consultants will visit the State Cells, STDCs, other training facilities, and the districts under implementation of the RNTP and the districts in preparation for the RNTP. The Central TB Division officers would give priority to poorly performing districts in scheduling their visit for discussion with State governments.

4. The supervisory strength of the Central TB Division would be augmented by requisitioning the services of officers of the other Central Institutions. The supervisory skills of these officers would be developed through the familiarization with field problems in the districts and the needs of training institutions. This familiarization would be done by linking them to the initial visits of Central TB Division officers.

Monitoring

5. Monitoring would comprise 7 areas, namely:
   (a) Monitoring the Progress of Implementation Plan. This would be done by the concerned officer responsible for the particular activity. The progress report would be made to the director of the TB Control program and would be discussed in the monthly meeting of the Central Division officers.
(b) Monitoring of Logistics and Quality Control. This would be done on the basis of information received from the procuring agency, supplier, MSO (Medical Stores Organization), Monthly Report of GMSDs (Government Medical Store Depots), Quarterly Report from the States/Districts.

(c) Monitoring of Program Indicators. The program indicators would be monitored quarterly on the basis of the quarterly reports on program performance. The information would be shared with other Central Division officers and suitable feedback would be sent to the implementing States/Districts.

(d) Monitoring of Expenditure and Budget Utilization. This would be done monthly on the basis of the monthly expenditure report and information collected from the field by the visiting Central TB Division officers. This would be discussed during the monthly meeting on program implementation.

(e) Monitoring Progress in Training and Strengthening of Training Institutions. This would be done on the basis of Quarterly Reports on Training received at the Central Division and of compiled reports from Central Institutions on progress in development of State Training and Demonstration Centers (STDCs) and other training institutions.

(f) Monitoring Progress in Filling Up of Additional Posts. This would refer to (i) the progress in recruitment of additional staff; (ii) filling up a proportion of such posts by deployment of regular staff from other time bound programs; and (iii) creation of additional posts. The monitoring would be done on the basis of progress reports of state implementation and on the basis of information gathered during supervisory visits by Central TB Division officers.

(g) Monitoring Cost Reimbursement. Progress in reimbursement of costs accrued in the program activities from the World Bank project would be reviewed every quarter for appropriate action.

(h) Monitoring of Patient Satisfaction. This refers to patients satisfaction with the timing and availability of services, treatment by service providers, economic costs involved, and availability of medicines.

Feedback to the Implementing Units

6. Feedback indicating action points as a result of supervisory visits and monitoring would be forwarded to the concerned implementing units.
INDIA: Tuberculosis Control Project

IDA SUPERVISION PLAN

Introduction

1. The supervision strategy for this project would be based on: (a) the technical inputs provided by the WHO TB Advisor posted in India; (b) the progress reports submitted by the MOHFW; and (c) targeted program review missions by IDA or by WHO on behalf of IDA; and (d) a mid-term review. WHO will be the agency which will provide technical assistance and guidance to both the Government of India and IDA with regard to TB Control in India.

Project Review Missions

2. Regular Project Review Missions. IDA's project review mission would be based on progress reports submitted by the Central Division at MOHFW and information provided by the WHO TB technical advisor stationed in India and the Bank staff in NDO. A Bank project review mission would visit the project regularly every six months. The mission would be led by a Bank task manager or a WHO representative and would include multi-disciplinary teams with experience in Tuberculosis control. On each supervision mission there would be a joint meeting of states and central officials involved in implementation, either in Delhi or in one of the state capitals to review generic issues associated with the project. The meeting would serve the purpose of disseminating and sharing experience among states. In addition, the mission would visit project sites in selected districts or cities on a rotating basis.

3. If the project is launched in April, 1997, the first supervision mission would be scheduled between October and November 1997. Then for the following years, it would be scheduled around April-May and around October-November.

4. Composition of Missions. Missions would include, as appropriate, specialists in tuberculosis, epidemiology, general management, drug-logistics, IEC, MIS, operational research, procurement, disbursement, training and social issues. These specialists may visit the states in teams or individually by prior arrangement between the task manager and the project authorities (MOHFW). In addition, specialists in other areas may occasionally be included in missions as needed.

5. Six-month Progress Report. The report would include a summary of project activities in the past 6 months, problems encountered in the field, project budget and expenditures, reviews of project components and progress on the performance indicators. The report will also include a plan of activities to be implemented in the next six months.
6. **Additional Missions.** In addition to routine supervision, the task manager or individual specialist (e.g. from WHO) may visit Delhi or specific states for trouble-shooting or emergencies.

**Mid-term Review.**

7. The objective of the project mid-term review is to determine if the original project design needs re-thinking or if mid-course corrections need to be made. It also may be used for a preliminary evaluation of the project impact, if the project has progressed sufficiently to expect any significant impact. At this time, and based on the progress achieved, a preliminary plan for possible preparation of a follow up project to finance the expansion of RNTP beyond the 102 districts would be discussed. The review would be conducted jointly by MOHFW and Family Welfare and IDA mission and would be based on the findings of the international panel of experts review, which will precede the mid-term review.

8. The review would consist of assessing project progress as measured against the original activities and time schedule set out in the Implementation Plan. To do this, project documents and MIS would be used. Notes on the status of fulfillment of project agreements and covenants would also be included. Special studies may be carried out to assess specific issues such as case relapse or drug resistance as part of the operations research component. The results of the social assessments would be reviewed to evaluate changes in the behavior of the providers and the patients toward tuberculosis.

9. A final mid-term review report will be submitted to IDA and discussed with the government in the following supervision mission. It should highlight any major issues or delays in the project execution, and prospects for resolving them and completing the project on time.

**Role of the Resident Mission**

10. The human resources group of the New Delhi mission has been strengthened to carry out an increasing share of the supervision work for human resources projects in India. This group would play an important role in this project. The supervisory activities delegated to the field office would be carried out by the local PHN official under the advice of the Task Manager or of the Sr. Public Health Advisor. Procurement issues would be handled by the Delhi Office Procurement and Accounting Group as well as issues related to accounting, auditing and disbursement under the overall responsibility of the Task Manager.
<table>
<thead>
<tr>
<th>Approximate Dates</th>
<th>Focus of Supervision</th>
<th>Expected Skill Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>Project Launch Workshop</td>
<td>• Tuberculosis specialist</td>
</tr>
<tr>
<td></td>
<td>Review of project start-up, implementation of organizational arrangements, training, drug logistics, MIS.</td>
<td>• Procurement</td>
</tr>
<tr>
<td></td>
<td>Review of project start-up, implementation of organizational arrangements, training, drug logistics, MIS.</td>
<td>• Disbursement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Drug logistic</td>
</tr>
<tr>
<td>Year 2</td>
<td>Review of first year implementation, preparation of next annual work plan, preparation of operational research frame-work, and IEC</td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td>Review of operational research, MIS, IEC, Training and Drug logistic</td>
<td>• Epidemiologist/OR specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MIS specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• IEC specialist</td>
</tr>
<tr>
<td>Year 3</td>
<td>Review of past year implementation, preparation of next annual work plan, preparation of mid-term Review.</td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td>Mid-term Review</td>
<td>• Epidemiologist/OR specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MIS specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• IEC specialist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Drug logistic</td>
</tr>
<tr>
<td>Year 4</td>
<td>Review of past year implementation, preparation of next annual work plan, review of performance indicators,</td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td>Review of operational research, MIS, IEC, Training and Drug logistic</td>
<td>• Economist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Drug logistic</td>
</tr>
<tr>
<td>Year 5</td>
<td>Review of past year implementation, preparation of next annual work plan, review of performance indicators, year 5</td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td>Preparation of Project Completion Report</td>
<td>• Economist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• General management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MIS specialist</td>
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</tbody>
</table>
INDIA: Tuberculosis Control Project

SUMMARY OF THE PROPOSED PROJECT'S PARTICIPATORY PROCESS

1. The project has been developed with the active involvement of stakeholders who play a critical role in bringing about the paradigm shift required to deal with the TB problem as a public health threat. Unlike other development projects, the proposed project did not require the active participation of beneficiaries in project design, but it did call for the active involvement of the health providers in the public and private sectors, pharmaceutical manufacturers, and NGOs. It also required an understanding of the barriers faced by TB patients in obtaining quality care, their perception of disease and its cure.

2. To achieve these objectives, the preparation process included: First, the participation of pharmaceutical manufacturers in a Symposium organized by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The symposium focused on the benefits, possible problems and international availability of products designed to provide fixed dose combinations of drugs in the dosage recommended for Multi-Drug Therapy of tuberculosis. The purpose of the symposium was to begin raising the awareness of manufacturers regarding the critical needs faced by countries like India for TB control with a public health approach, and to familiarize program officers with the international situation and experiences regarding TB pharmaceuticals. The conclusions of the symposium served as a guide to develop the specifications for drugs including decision on appropriate drug packaging.

3. Second, project preparation involved the implementation of pilot projects in fifteen sites with the purpose of involving service providers in the development of the proposed project by giving them the opportunity to experience first-hand the application of the revised strategy and identifying the obstacles they may face in the process. The pilot phase was launched through a workshop where the action plans for implementation of phase II in the pilot sites were discussed and finalized. The plans also included steps to begin involving the private sector and the NGOs in the implementation of the project.

4. Third, two Social Assessments, one in urban slums and one in tribal areas, were carried out to uncover the issues facing TB patients and the relationship between patients and service providers. A summary of the assessment is given in Annex 16.

5. Fourth, several workshops and meetings were held with representatives from the Indian Medical Association (IMA) and over 25 NGOs involved in TB. The interest and support expressed by both groups were extremely encouraging. During the workshops, initial agreements were reached on the strategy that would be used to involve NGOs and private physicians through the IMA in the fight against TB. In addition, several NGOs participated in the pilot projects; however, despite numerous efforts by the government authorities, the response
of the private physicians in the districts has been slow. Also, despite continuous dialogue with numerous NGOs, there is still one large NGO who has voiced its objection to the Project.

6. Fifth, the outreach and communication strategy of the project calls for a systematic involvement in the community to help reduce the stigma associated with TB, and support the DOT approach to treatment. The social indicators listed in Annex 9 were the result of the involvement of patients, NGOs, and service providers.

7. In sum, the participatory approach used in this project offers an unorthodox but illustrative example of the variety of modalities that can be used in a participatory process, based on the context and objectives of the project and the type of stakeholders involved.
Preamble

1. For proper implementation of the Revised Strategy of the National Tuberculosis Control Program (RNTP), a concerted effort through a process of an inter-sectoral collaboration between Government and Non-Government Organizations (NGOs) would be implemented. A number of NGOs are actively involved in Tuberculosis Control at the national, state and district levels, therefore, involvement of NGOs can greatly enhance the implementation of the RNTP. NGO involvement in the RNTP may not only be limited to treatment of Tuberculosis but to any related activity that an NGO is involved with. This may include diagnosis and microscopy; training; health education or service delivery, including referral systems, in urban slums, rural areas, tribal populations and remote areas; drug supply and distribution (e.g., pharmaceutical stores and dispensaries); Operations Research or any other practical and meaningful NGO work applicable within the RNTP and the TB Control program.

Strategy

2. The strategy to be used would be that of close collaboration with NGOs in implementing the RNTP. Structures in the RNTP at the national (National Tuberculosis Control Board), the state (Tuberculosis Coordinating Committee) and the district levels (District Tuberculosis Control Societies) would provide the vehicle for such collaboration between government and NGO in Tuberculosis Control.

Operational Component

3. The proposed activities to ensure the participation of NGOs as partners in the RNTP would include:

   (a) Inviting representatives of umbrella NGOs to serve as members of the coordination committees at the different levels;

   (b) Providing interested NGOs with information and literature on the RNTP on a regular basis;

   (c) Involving NGOs in the planning, implementation and evaluation of the TB control program through the National Tuberculosis Control Board, the State Tuberculosis Coordinating Committee and the District Tuberculosis Control Societies;
(d) Inviting NGOs to visit pilot sites to get a better understanding of the RNTP and share their knowledge of working with TB patients;

(e) Inviting NGOs working at various levels (national, state, district) to furnish details of their activities and their areas of coverage to the Central government as soon as possible to compile a National Directory. In doing so, NGOs would also specifically define their functions relating to TB Control and clarify the particular area of the RNTP in which they can participate, e.g., DOT, health education (IEC), patient registration, training, diagnosis, treatment, drug supply, etc. NGOs would likewise identify the particular population for the activities they undertake. From such a National Directory would come: (i) a classification and listing of NGOs region wise; (ii) identification of previous experience and role of the NGOs in the community especially in relation to community health services; and (iii) determining the field of expertise and interest of the particular NGO;

(f) Inviting NGOs to participate in RNTP training. Training in the RNTP would be offered free to NGO staff. Adequate resources to undertake the RNTP would be provided to NGOs who have decided to adopt the RNTP strategy;

(g) Inviting the NGOs to develop a methodology for coordinating TB activities among themselves;

(h) Offering NGOs the opportunity to participate in Operations Research;

(i) Assessing the NGOs’ interest to be active implementors of the RNTP;

(j) Agreeing on methods to ensure consistent recording of TB patients by the NGOs as per the RNTP guidelines;

(k) Agreeing, in consultation with the concerned NGOs, on geographic areas to be covered by the NGOs to avoid duplication of efforts and maximize NGO resources for larger and greater impact in the community;

(l) Consulting with NGOs working in underserved areas, such as urban slums, rural areas, tribal populations and remote areas on how best to inform and involve the community in relation to RNTP;

(m) Consulting with NGOs concerning the training of their staff in the RNTP and/or seeking the collaboration of NGOs with successful NGO programs in TB Control in the training of RNTP staff;

(n) Developing health education or IEC materials with qualified NGOs and seeking their involvement in disseminating information and involving the community;
Identifying NGOs interested in taking on program activities such as microscopy and DOT in exchange for selected government inputs.

Developing a system of recognition to members of the NGO community who have contributed to efficient and effective Tuberculosis Control.

Initial Steps

4. To enable the feasibility of NGO active participation and collaboration in the RNTP and Tuberculosis Control, a National Directory of NGOs would be compiled at the center with the information received from the various umbrella NGOs of different areas.

5. This directory would be organized in terms of the type of activities the NGOs undertake in TB Control.

6. These types of activities could include the following headings:

   a. Treatment of Tuberculosis;
   b. Diagnosis and Microscopy;
   c. Training;
   d. IEC or Health Education;
   e. Service delivery (including referral systems, in urban slums, rural areas, tribal populations and remote areas);
   f. Drug Supply and Distribution (e.g., pharmaceutical stores and dispensaries);
   g. MIS;
   h. Operations Research; and
   i. Other practical and meaningful NGO work applicable within the RNTP and the TB Control program.

7. Likewise, it has been agreed that the NGOs would develop a methodology for coordination amongst themselves and demarcating the area of operation and functions e.g. in case finding, DOT training, Health Education, operations research, etc., as suggested during consultation and planning workshops conducted with NGOs.

8. Develop annual plan of action on activities related to NGO involvement in consultation with the NGOs. The coordination of these activities would be managed by an official of the Central TB Division designated for this purpose, under the direction of the project manager and in coordination with the State TB officers, as needed. The State TB Officer would perform a similar task at the State level.
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LOGISTIC SUPPORT - DRUGS, EQUIPMENT AND VEHICLES

Drugs in RNTCP Districts

1. **Drug Requirement.** The drug requirement will be calculated as per estimated number of patients seeking treatment from a Government health facility. Taking an average Annual Risk of Infection (ARI) of 1.7, the smear positive cases are estimated at 85/100,000 population (Styblo Model). Assuming that 60% of TB cases would avail facilities from the Government health system, it is estimated that 50 new smear positive cases per 100,000 population will register with RNTP. On the basis of Pilot Phase I & II, it is observed that the re-treatment cases will be about 50% of the new smear positive i.e. 25/100,000 population. With quality sputum examination for diagnosis, the proportion of new-smear negative cases is expected to be equal to new smear-positives i.e. 50/100,000 population. The extra pulmonary cases are assumed to be 20% of the new smear positive i.e. 10/100,000 population. Based on these assumptions, it is expected that a total of 135 TB cases/100,000 population will be diagnosed and treated under the program and accordingly the drug requirement for the project has been calculated.

2. **Packaging.** The drug will be procured in blister combipacks both for intensive and continuation phase of treatment in different schedule, viz. Schedule I - EHRZ, Schedule II - RH, Schedule III - EHR and Schedule IV - HRZ.

3. **Procurement Method.** Procurement of drugs for the project would be primarily a centrally-managed activity performed by the MOH. Purchases would be through the use of World Bank Standard Bidding Documents and Internationally Competitive Bidding procedures (ICB) to supply multi-drug packs in blister pack containers. Technical and commercial specifications for this type of purchase have already been successfully tested during the Phase II Pilot.

4. **Storage & Distribution.** 50% of the drugs procured would be delivered from the manufacturers directly to different Government Medical Store Depots (GMSD) situated at Karnal, Bombay, Madras, Hyderabad, Calcutta and Guwahati. All the MSDs have facilities for storage of the drugs. Regular flow of supplies from GMSDs to different project areas will be maintained thereby preventing accumulation of huge quantities of drugs in the GMSDs. The remaining 50% of the drugs procured will be delivered directly to the districts by the manufacturers.

5. The GMSDs will dispatch the drugs directly to the project district every six months as per the release order issued by the Central TB Division. The already existing mechanism of Rail/Road transport will be utilized to undertake this delivery. The drug storage facility already available at DTCs is being improved to meet the requirement. Supply of drug beyond the district will be done by the DTO/Project Officer or Senior TB Supervisor on a quarterly basis during their supervisory visit. Drug stock would be replenished every six months at the DTC, quarterly at the TU and monthly at CHC/PHC.
Drugs in NTCP Districts

6. **Drug Requirement.** The requirement has been estimated on the last three years average of the cases reported in the National TB Control Program. One hundred percent supply of drugs for the sputum-positive patients will be made by the Centre whereas conventional drugs required for treating sputum-negative and extra pulmonary cases will be procured by the State Health Authority from the State budget.

7. **Packaging.** SCC drugs will be procured in Blister Combi-pack (EHRZ) for intensive Phase of treatment and in blister strips (Ethambutol & INH) for continuation phase of treatment for six months.

8. **Storage and Distribution.** The MOH directs the manufacturers to supply the drugs directly to a Regional Government Medical Store Depot (GMSD) in different parts of the country as per the distribution schedule communicated by the Central TB Division. These GMSDs have adequate facilities for storage of the drugs. Systems exist by which these GMSDs can dispatch the drugs either by Rail/Road transport to the District TB Centres.

9. The District Tuberculosis Centre (DTCs) will submit their annual indents to the State program Officer with a copy of the indent sent directly to the Central TB Division of the DGHS. These indents will be based on the actual number of patients diagnosed, treated, drug utilization during previous year and current balance in stock.

10. The State Program Officer will scrutinize the indents of all DTCs, compile it and send the compiled report along with the indents in one lot to TB Division DGHS within a month of receiving them.

11. The TB Division DGHS will scrutinize the demand on the basis of number of case expected diagnosed and on consumption of drugs during the last year. Based on these calculations, release order will be issued to GMSDs for each of the DTCs, with intimation to State authorities.

12. GMSD will dispatch the drug within one month from the date of receipt order from TB Division, DGHS. It is being considered that the supply of drugs from the GMSDs to the districts will be done twice a year; the first supply based on the previous years reporting and the second based on consumption of the first supply.

Quality Control for Drug Purchases

13. **Quality Control.** There is an in-built mechanism of quality control in purchase procedures. The Inspector of drug from GMSD will visit the warehouse of manufacturers and collect three random samples of each drug each batch.

14. One set of samples will be sent to the drug laboratory for quality testing, the second sample will be handed over to a manufacturer and the third sample will be retained by GMSD. Once the quality of the drug is checked and recommendation for acceptance is received, the matter is conveyed to the manufacturer, after which the manufacturer will dispatch the stores to different GMSDs as per agreement.
15. Distribution of drugs beyond DTCs is the responsibility of the DTO who ensures that PHIs maintains a drug stock of three months. The DTO has been provided with a vehicle under the program for supervision and supply of logistics.

**Combination Drugs and Bio-availability Testing**

16. In the treatment of pulmonary Tuberculosis with Short-Course Chemotherapy, combination drugs would be very useful in different situations as they prevent selective drug treatment (monotherapy) ensure greater precision of dose, avoid errors in drug ratios, improve drug handling and delivery, and prevent shortage of supplies of individual drug components. Moreover, combination drugs reduce the risk of creating drug resistance in self-administered treatment. Hence, the combination of rifampicin with other drugs has a high priority because of the risk of losing this most effective anti-TB drugs, if used inappropriately.

17. However, the combination of rifampicin with other anti-TB drugs is known to give rise to problems of bio-availability for not only rifampicin but even other drugs in the combination. They may indirectly lead to sub-dosing of drugs in the treatment regimen and can cause failure or drug resistance. Accordingly, steps need to be taken for ensuring the quality and bio-availability of the combined anti-TB drug preparations. These will include:

(a) The data from human bio-availability studies should be an essential pre-requisite for registration of combination drugs in multi-drug treatment regimens. This data should show that the drugs in combination are bio-equivalent to simple component products administered together.

(b) Establishment of testing laboratories which can independently conduct a bio-availability test on behalf of the Government of India.

(c) The testing laboratories should conform to the agreed international standards for bio-availability of the drugs, standard test methodology and to the acceptable international limits.

18. Efforts will be made to establish these mechanisms at the earliest. Only once these have been established, combination drugs will find a place in the National Tuberculosis Control Program.

**Equipment, Supplies and Vehicles**

19. **Laboratory equipment.** Over 90% of the costs for laboratory equipment involves the purchase of binocular microscopes, with the remainder for centrifuge devices, refrigerators, or similar small scale laboratory appliances. Bulk purchases of the microscopes and other laboratory equipment would be procured by the Centre in contracts valued over US$200,000 using ICB procedures. Contracts valued at US$200,000 or less would be procured through NCB procedures acceptable to IDA. For small purchases not exceeding US$10,000, procurement would be through rate contracts or local shopping procedures at the Centre, state or district level, comparing price quotations from at least three suppliers to ensure competitive prices.
20. **Other equipment.** Procurement of other equipment would be phased on an annual basis over the first four years of the project in accordance with the requirements of the project activities as additional districts meet eligibility criteria and initiate new activities. Over 60% of the costs for laboratory equipment involves the purchase of small computers and peripherals, with the remainder for audio visual equipment, photocopiers, FAX machines and other office equipment. Purchases of this equipment would be bulked whenever possible and purchased at the State level. Contracts valued at US$200,000 or less would be procured through NCB procedures acceptable to IDA, and for small purchases not exceeding US$10,000, procurement would be through rate contracts or local shopping procedures at the State or District level, comparing price quotations from at least three suppliers to ensure competitive prices up to an aggregate amount not exceeding US$3.0 million.

21. **Vehicles.** Procurement of vehicles would be phased on an annual basis over the entire five years of the project in accordance with the requirements of the project activities as additional districts are brought into the RNTP. Over 50% of the costs for vehicles would be for the purchase of jeeps to be used at the State and District Headquarters, and the bulk of the remaining costs for some 537 two wheeler vehicles for transportation at the sub-District levels. Because the project involves ten or more states spaced over a five year period, and the total requirement for jeeps is roughly 237 vehicles, no contract is expected to contain more than 10 vehicles. Such a purchasing plan does not lend itself to ICB. Wherever possible, requirements would be bulked at the state level and purchased through NCB procedures. For purchases not exceeding US$200,000, procurement would be through DGS&D rate contracts or local shopping procedures, comparing price quotations from at least three suppliers to ensure competitive prices.

22. **Laboratory supplies.** Procurement of laboratory supplies would be phased on a quarterly or semi-annual basis throughout the life of the project in accordance with the requirements of the project activities. The supplies required include such items as glass microscope slides, slide storage cases, reagents, and sputum cups. Purchases of laboratory supplies would be bulked whenever possible and procured at the State level in contracts valued at US$200,000 or less through NCB procedures acceptable to IDA for an aggregate amount not exceeding US$2.4 million. However, it is recognized that bulking of such items even at the state level may not always be a practical solution for the small quantities that may be involved and the distribution problems that may result. Therefore, for small purchases not exceeding US$10,000, procurement would be through DGS&D rate contracts or local shopping procedures at the state or district level, comparing price quotations from at least three suppliers to ensure competitive prices.
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DOCUMENTS AVAILABLE IN PROJECT FILE

A. Project Proposals and Plans


B. Project Preparation Studies and Reports

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C. Other Reports and Studies

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C-2 International Union Against Tuberculosis and Lung Diseases. Tuberculosis Guide for Low Income Countries. 1994

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C-10 Tuberculosis: A Comprehensive International Approach edited by Lee B. Reichman and Earl S. Hershfield. 1993

C-12 Lesotho: Health and Population Project. Staff Appraisal Report, No. 5437-LSO, April 1985


C-14 China: Infectious and Endemic Disease Control Project. Staff Appraisal Report, No. 9894-CHA, November 15, 1991


C-16 A Report on National Consultation on Tuberculosis. The Voluntary Health Association of India. July 13-14, 1994
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