

Document of
The World Bank

Report No: 21751

PROJECT APPRAISAL DOCUMENT

ON A

PROPOSED IDA CREDIT

IN THE AMOUNT OF SDR 23.3 MILLION
(US\$30.0 MILLION EQUIVALENT)

TO

INDIA

FOR THE

SECOND NATIONAL LEPROSY ELIMINATION PROJECT

February 27, 2001

**Health, Nutrition and Population Unit
South Asia Region**

CURRENCY EQUIVALENTS

(Exchange Rate Effective January 25, 2001)

Currency Unit = Rupee
Rs. 1 = US\$0.0215763
US\$1 = Rs. 46.3

FISCAL YEAR

April 1 - March 31

ABBREVIATIONS AND ACRONYMS

BBC	British Broadcasting Corporation
CAS	Country Assistance Strategy
Danida	Danish International Development Assistance
DGHS (LD)	Directorate General of Health Service (Leprosy Division)
DGS&D	Director General of Supplies and Disposal
DLS	District Leprosy Society
EA	Environmental Assessment
EMP	Environmental Management Plan
GHS	General Health Services
GOI	Government of India
IBRD	International Bank for Reconstruction and Development
IDA	International Development Association
IEC	Information, Education and Communication
LEC	Leprosy Elimination Campaigns
LQAS	Lot Quality Assurance Sampling
MB	Multi-bacillary
MDT	Multi-drug Therapy
MLEC	Modified Leprosy Elimination Campaign
MOHFW	Ministry of Health and Family Welfare
NGO	Non-Governmental Organization
NLEP	National Leprosy Eradication Project
PAD	Project Appraisal Document
PIP	Project Implementation Plan
PB	Pauci-bacillary
PFMS	Project Financial Management System
SAPEL	Special Action Projects for Elimination of Leprosy
SLS	State Leprosy Society
SSL	Single lesion Pauci-bacillary Leprosy
WHO	World Health Organization
UT	Union Territories

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INDIA
SECOND NATIONAL LEPROSY ELIMINATION PROJECT

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INDIA
SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Project Appraisal Document

South Asia Regional Office
SASHP

Date: February 27, 2001 Country Director: Edwin R. Lim Project ID: P067543 Lending Instrument: Specific Investment Loan (SIL)	Team Leader: Peter F. Heywood Sector Director: Richard Lee Skolnik Sector(s): HS - Specific Diseases, including Malaria, TB, Others Theme(s): Health/Nutrition/Population Poverty Targeted Intervention: Y
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Project Financing Data	
<input type="checkbox"/> Loan <input checked="" type="checkbox"/> Credit <input type="checkbox"/> Grant <input type="checkbox"/> Guarantee <input type="checkbox"/> Other:	
For Loans/Credits/Others:	
Amount (US\$m): 30.00 (SDR 23.3 million)	
Proposed Terms: Standard Credit	
Grace period (years): 10	Years to maturity: 35
Commitment fee: 0.5%	Service charge: 0.75%

Financing Plan:	Source	Local	Foreign	Total
BORROWER		12.20	0.00	12.20
IDA		30.00	0.00	30.00
Total:		42.20	0.00	42.20

Borrower: GOVERNMENT OF INDIA
Responsible agency: GOVERNMENT OF INDIA
 Ministry of Health and Family Welfare
 Address: Nirman Bhawan, New Delhi 110 001
 Contact Person: Mr. Javid Chowdhury, Secretary
 Tel: 91-11-3018863 Fax: 91-11-3014252 Email:

Estimated disbursements (Bank FY/US\$m):								
FY	2002	2003	2004	2005				
Annual	13.00	11.00	5.00	1.00				
Cumulative	13.00	24.00	29.00	30.00				

Project implementation period: 3 years FY02-FY05
Expected effectiveness date: 07/01/2001 **Expected closing date:** 12/31/2004

A. Project Development Objective

1. Project development objective: (see Annex 1)

- Transform the national leprosy control program to an effective and sustainable program through a decentralized and integrated approach which increases community access to multi-drug therapy. This transformation would assist India to eliminate leprosy as a public health problem at all levels.

2. Key performance indicators: (see Annex 1)

- Decentralize leprosy control activities to the states over the course of the project.
- Integrate leprosy control activities with general health services.
- Reduce estimated 'actual' disease prevalence to less than 3/10,000 at the national level by the end of 2004.
- Assist India in reducing the recorded national prevalence to less than 1/10,000 by the end of 2004.

B. Strategic Context

1. Sector-related Country Assistance Strategy (CAS) goal supported by the project: (see Annex 1)

Document number: 17241-IN

Date of latest CAS discussion: 02/18/99

Board Discussion of the last full CAS (Report No. 17241-IN) was on January 15, 1998 and Board Discussion of the CAS Progress Report (Report No. 20184-IN) on February 18, 1999.

The proposed operation is fully consistent with the over-riding CAS objective of assisting India to reduce poverty. Leprosy disproportionately affects the poor and the most socially vulnerable groups including women, scheduled castes and tribal groups. Not only does leprosy target the neediest, it aggravates the suffering with devastating social ostracization and the economic burden on the victims through loss of employment opportunities. Reducing infection and disability from this disease is consistent with the CAS objective of enhancing equity and accelerating human development of the poor. The decentralization of leprosy control activities to states and the integration of the vertical program with general health services will support the CAS strategic objective of strengthening management and planning at the state level. Moreover, by making available to disadvantaged groups, a highly effective health intervention, the project would address a key health issue, as proposed in the Comprehensive Development Framework. Finally, the proposed operation is a follow-up to the recently closed first National Leprosy Elimination Project, also partially financed by International Development Association (IDA).

2. Main sector issues and Government strategy:

The major sector issues are:

- poverty-related health problems, with health indicators (including for communicable disease) below average for the country's stage of development and income level
- inadequate institutional arrangements and weak program management, including centralized management of disease control programs
- inadequate framework for engaging private sector participation
- low quality of HNP services in both the public and private sector
- ineffective targeting of public subsidies to the poor and a low overall level of public expenditure on health

The government is addressing these issues as follows:

- increased investments in economic growth and human development
- increased efforts since the early 1990s to control the major communicable diseases
- increased efforts to decentralize disease control efforts to the state and district levels
- health sector reform to improve implementation capacity at the state and central levels, define the role of the private sector in the overall health system more clearly, and improve the quality of care in both public and private sectors

3. Sector issues to be addressed by the project and strategic choices:

The international context of leprosy control

When leprosy control efforts began after World War II, the overall outlook was pessimistic due to long treatment times and the consequent low compliance rates. Treatment times were reduced by the discovery and evaluation of new drug combinations, but gains made were dented by increasing drug resistance resulting from monotherapy with dapsone, the drug of choice at the time. The international leprosy community moved to multi-drug therapy (MDT) in an effort to contain the emergence of even higher levels of resistance. Encouraged by the success of MDT in curing leprosy patients, in 1991 the World Health Assembly adopted a declaration to 'eliminate' leprosy as a public health problem by the year 2000. Internationally, efforts were further intensified in 1995 through Leprosy Elimination Campaigns (LEC) and Special Action Projects for the Elimination of Leprosy (SAPEL).

The Indian response

Leprosy control efforts in India have very much been in step with the international pattern. The National Leprosy Control Program was launched by the Government of India (GOI) in 1955 using the treatment strategies of the time. In 1983, based on international recommendations, the treatment strategy was changed to multidrug therapy. However, coverage remained limited due to a range of organizational issues and fear of the disease. As in other countries in which leprosy was highly endemic, India committed itself to the 1991 World Health Assembly strategy and goal; as part of this commitment, GOI and the IDA collaborated on a national leprosy elimination project, which became effective in 1993. The project, which supported the vertical program structure used by GOI for National Leprosy Eradication Program (NLEP) and instituted large scale Modified Leprosy Elimination Campaigns (MLEC), achieved notable results: nationally recorded prevalence has fallen from 24 per 10,000 (in March 1993) to a reported 5 per 10,000; new case detection increased to reach 600,000 (from 300,000) in 1999; and there is indication that cure rates have improved. However, despite this impressive effort, progress in reducing the case load was less than expected – with prevalence settling at significantly above the elimination level of 1/10,000 and higher than the target for the project (as revised at mid-term) of 3-4 per 10,000. Based on the results of an evaluation of the NLEP undertaken by GOI, an expert group charged with estimating 'actual' prevalence of leprosy in the country, arrived at a midpoint estimate of 7 per 10,000 with lower and upper limits, respectively, of 5 and 9 per 10,000 population (see Annex 11 for details of the estimates and the methods used).

The uncertainties surrounding leprosy indicators and trends make it difficult to estimate how long it will take to reach elimination levels. It appears at this time that the goal of elimination, as measured by the estimated 'actual' prevalence, can not be reached in 3 years – a more realistic target is an estimate of the 'actual' prevalence rate of 3 per 10,000 for the country as a whole by the end of 2003. The project will

assist the GOI in achieving its goal of reducing the recorded national prevalence rate to less than 1 per 10,000. From the experience to date, treatment strategies are likely to remain as they are now - early case-finding and treatment with MDT. Due to continued control efforts the workload due to leprosy is expected to decrease (as it already has in many areas) and there will be increased need to contain costs. These pressures, together with the need to ensure sustainability and increased state-specificity and responsibility for disease control activities will require new institutional arrangements - leprosy control activities will need to be integrated with the general health services (GHS) and responsibility for them decentralized to the states.

Institutional and design issues:

(i) time frame of the second project. A critical design issue for the second project is the period over which it will be implemented. On the one hand, it is clear that elimination levels will not be reached quickly, particularly in those states and districts where prevalence is high. Nevertheless, the total workload in these areas will be relatively low and cost pressures mean that it will not be feasible to continue with the current vertical program. The need is to transform the program in a way, which facilitates sustainability rather than achieves a particular level of prevalence. The time frame for the current project, then, is principally determined by the time needed for transformation of the program.

(ii) an increased role for, and decentralization of leprosy control activities to, the states. The NLEP strategy and funding mechanisms provided for a facilitatory role for the state in leprosy elimination. The Program was centrally sponsored and controlled and implemented through district leprosy societies (DLS), which received money directly from the central government. As a result, the states have had insufficient involvement in the program. The direct involvement of the center in program supervision of the districts has limited development of the technical and supervisory capacity of the states. It is important, during the project period, to prepare the states to administer and manage leprosy control.

(iii) improved integration of the staff of the vertical program with the GHS. GOI recognizes that separation of elimination activities from the GHS has hindered implementation - it has led to limited intervention in some geographical pockets with resulting limited access to MDT, low levels of compliance with treatment and subsequent re-registering of these cases as 'new'. Further, effectiveness of the vertical system is challenged by performance criteria which burden workers with annual case detection targets (reinforced by monetary incentives, since discontinued), and possibly reduce the accuracy of diagnosis, and low workloads. The maintenance of a vertical component in areas of high prevalence is justified in the short term only if it ensures integration of leprosy services into the GHS. Although merging activities of the vertical staff of the Program with the GHS was envisaged in 1993 as occurring once elimination as a public health problem occurred, very little has been done to achieve this.

Technical issues:

(i) uncertainty about the epidemiology of leprosy. The disease has not behaved as expected - despite large increases in case detection and a fall in recorded prevalence, new case detection rates have remained high. Because leprosy has a long incubation period a reduction in transmission may not be evident for some years after prevalence is reduced. Further, a significant, but uncertain, proportion of the reduction in prevalence has been due to the shorter treatment schedules and clearing of registers rather than a reduction in incidence. The MLECs and SAPELs, coupled with an unknown amount of over-diagnosis, have tended to increase prevalence but due to long incubation periods, the intended effect of MLECs on transmission may be much less than originally estimated. The relative importance of these conflicting pressures and, thus, their net effect is unknown. Consequently, fresh doubts have emerged about the value of the case detection

rate as a proxy for incidence and about the extent to which MLECs have contributed to decrease in transmission. Overall, most leprosy epidemiologists agree that we have little information on incidence.

(ii) improved and more accurate case finding. Even though the prevalence of leprosy has decreased during the last decade of leprosy control activities the number of new cases detected has remained relatively constant. This raises questions about the accuracy of diagnosis, extent of re-registering of old cases as new, and whether the incentive structure (annual targets and incentives for staff), rather than the incidence and treatment of the disease, have determined the annual case finding rate. In addition, **it is important that the case finding strategies adopted ensure that all locations and social groups are adequately covered.**

(iii) determine the priority to be given to disability care and prevention in a new project. Despite its inclusion as a component, there was little emphasis on this aspect in the first project, the performance of the public sector was below expectations and disability care was subsequently dropped as a development objective. This raises the question as to whether the government is the best group to deliver, as distinct from finance, these services. At the same time, it is important that the balance between elimination and disability care is such that the overall goal of leprosy elimination is not compromised.

(iv) improved and explicit role for non-government organizations (NGOs). Both national and international NGOs have played an important role in leprosy treatment and rehabilitation, information, education and communication (IEC) and training. However, their role in the leprosy control efforts of the government has not been amplified. This has limited their contribution to significantly less than their potential. There is potential for increased contribution by NGOs to leprosy control.

(v) increased emphasis on, and explicit strategy for IEC activities, including interpersonal counseling skills. At the present time, the NLEP does not have a clear, well-articulated IEC strategy. However, it is recognized that the need for effective IEC activities will increase as the prevalence falls and case finding efforts are intensified.

(vi) improved planning and evaluation of training. Although integration of the leprosy program staff with the GHS requires considerable training and was envisaged in the first project, it has been limited in its effect. As with IEC, there was no overall training strategy, little evaluation of efforts, and these activities received a much lower priority than required.

(vii) strengthening and decentralizing monitoring and surveillance. This will become more critical to targeting of control activities as the overall number of cases decreases and, at the same time, may become more concentrated in clusters. In addition, the uncertainty about the epidemiology of leprosy and our lack of a suitable indicator for transmission means that it will be important to supplement routine surveillance with new case detection monitoring studies in sub-populations of, at least some, endemic states using standardized methods and diagnostic criteria. At the same time, validation of elimination will be dependent on an adequate surveillance system.

In order to address these issues through the project the following strategic choices have been made (see Project Appraisal Document (PAD) Section D.1 for a discussion of the reasons underlying the these choices):

(i) time frame - the project will be implemented over a three year period with emphasis on creation of an effective, integrated and sustainable program.

(ii) sustainability and effectiveness will be promoted through:

- decentralization of responsibility for implementation of control activities to the states
- integration of leprosy services with the GHS
- emphasis on early case-finding (including ensuring that all locations and social groups are covered), treatment with MDT and prevention of disabilities
- involvement of NGOs in leprosy control activities and their coordination with the GOI activities
- increased emphasis on IEC as an integral part of control activities
- strengthening human resource development and management
- monitoring and surveillance, including special studies to assess the effect of the program on disease prevalence in selected endemic populations.

C. Project Description Summary

1. Project components (see Annex 2 for a detailed description and Annex 3 for a detailed cost breakdown):

The policy issues addressed under the project would prepare the country to shift from a cost intensive vertical system of delivery of leprosy to a sustainable system integrated into the general health services of states while assisting the country in the control of leprosy.

IDA would finance about 71 percent of the incremental requirement of the project over three years. The Central Leprosy Unit would oversee investments throughout the country in association with state departments of health, with special attention to the five focus states. Additional support would be available from international donor NGOs and technical support agencies. No formal co-financing with other partners is planned, but all external agencies work under a common leprosy control framework. Specifically: International Federation of Anti-Leprosy Associations agencies / Danish International Development Assistance (Danida) / World Health Organization (WHO) would provide management and technical support to the five highly endemic states and the centre. Danida would also support service delivery in the states of Orissa and Madhya Pradesh.

Component 1. Decentralization and institutional development

Decentralization is based upon the preparation of state-specific and central plans which redefine the roles and responsibilities of the center, states and districts; the development of skills and deployment of sufficient and necessary staff required at each level to implement these roles; central, state and district plans for the project activities which are consistent with these revised roles and responsibilities. Successful decentralization will also require complementary, supportive strategies in other areas and particularly in surveillance, procurement support, fund flow mechanisms and financial management.

Component 2. Strengthen and integrate service delivery

The MDT strategy has been widely implemented in the first project and, together with early case detection, will form the centerpiece of the technical approach to be used in the second. The service delivery strategy will emphasize a mix of active and passive case detection, integration of leprosy control activities with the GHS and attention to hitherto 'un-reached' segments of the populations within states and districts through special campaigns and drives. The Novartis Foundation will make drugs available free of charge, which will be procured and supplied by WHO.

Component 3. Disability prevention

This activity achieved only limited success in the first project and the government approach will be revised in the second to give much greater responsibility to those NGOs who have specific skills in this

area. Thus, the state governments will increasingly provide the funds while the NGOs deliver the services.

Component 4: Information, education and communication

IEC activities will be strengthened to complement the service delivery strategy, including both active and passive case detection, reduction in stigma and an emphasis on the availability of safe and effective treatment.

Component 5: Training

Reorienting staff to an integrated approach and providing the new skills needed by the staff of the GHS will require a large and coordinated training effort in the second project. For this, a clear training strategy and timetable, has been developed.

Retroactive financing. As the first project closed on September 30, 2000, there will be retroactive financing from that date. Retroactive financing to the extent of US\$2.9 million equivalent (approximately 6.9 percent of the proposed Credit) would be provided for expenditures which follow the standard features of eligibility. This would include eligible project related expenditures accepted as consistent with appraised standards, procured in accordance with standard Bank guidelines and clearly accounted and subject to audit.

Component	Sector	Indicative Costs (US\$M)	% of Total	Bank-financing (US\$M)	% of Bank-financing
Decentralization and institutional development	HE	2.50	5.9	2.36	7.9
Strengthen and integrate service delivery	HE	27.80	65.9	16.50	55.0
Disability prevention	HE	3.70	8.8	3.00	10.0
Information, education and communication	HE	5.00	11.8	4.94	16.5
Training	HE	3.20	7.6	3.20	10.7
Total Project Costs		42.20	100.0	30.00	100.0
Total Financing Required		42.20	100.0	30.00	100.0

2. Key policy and institutional reforms supported by the project:

The project would support five key policy and institutional reforms:

2.1. **Decentralization of implementation and management responsibility** for leprosy control activities to the states and districts. This is explicit in the design of the project as set out in the project implementation plans furnished by the GOI. In addition, each state will provide a Memorandum of Understanding indicating their commitment to these state-specific plans and to credible mechanisms for guaranteeing flow of funds to the states and districts.

2.2. **Integration of leprosy activities with the general health services** of the states, with particular emphasis on case detection, treatment and surveillance. This will also be included in the Memorandum of Understanding from the states.

2.3. **Phasing out of central funding of vertical staff and institutions** that are agreed between the Bank and GOI to be superfluous and/or detrimental to the effort to integrate services. In addition, commitment by the Center to provide advice to states regarding the continuing need (or otherwise) of all categories of vertical staff employed by the government for the purposes of leprosy control.

2.4. **Elimination of all incentive payments related to case finding.**

2.5. **Institution of independent surveys of program implementation**, including progress in decentralization and integration of leprosy services with the general health services and monitoring and validating levels of leprosy prevalence in the community.

3. Benefits and target population:

IDA credit extended to India in 1993 has helped make considerable inroads into reducing the leprosy burden in the country. It is expected that the proposed IDA project would enable India to transform the national leprosy control effort to an effective and sustainable program through a decentralized and integrated approach. Beyond the life of the project, this transformation would assist India to eliminate leprosy as a public health problem. The prevention of disability would alleviate human suffering and decrease economic loss and the social burden and stigma of the disease. Leprosy control generates high externalities and the project would have a high social return in terms of healthy life years saved.

The impact of leprosy is highest amongst the poor. The project will reach underprivileged communities and it is estimated that 60 percent of those reached will be living below the GOI poverty line. With respect to tribal people, it is expected that the project would reach about 140,000 tribals all over the country with treatment for leprosy.

4. Institutional and implementation arrangements:

The project, which will decentralize responsibility for project implementation from the center to the states, will be implemented over a period of three years. Implementation arrangements will be as follows:

4.1. **Role of Central Government.** The Project would be coordinated by the Central Leprosy Unit of the Ministry of Health and Family Welfare (MOHFW), New Delhi. The Deputy Director General of Health Services for Leprosy will be the Project Director holding sole charge. S/he will be responsible for overall implementation of the project and its financial management, central level procurement, annual work-plans, management and technical support to states and an annual progress review of the program. GOI will be responsible for ensuring compliance by states with central policies and technical guidelines and will monitor Project progress.

4.2. **Role of the States.** The State Departments of Health through the State Leprosy Officer will be responsible for managing implementation of the leprosy control activities in conformity with NLEP guidelines. This officer will hold sole charge of this project. In his/her capacity as Secretary of the State Leprosy Society (SLS) through which funds for leprosy control will be channeled (of which the Health Secretary is the Chairperson), s/he will be responsible for financial management of the project within the state, state level procurement, annual work-plans, management and technical support to districts and annual progress review of the program in the state. On advice of the center, s/he will be responsible for reviewing continuation of vertical staff employed by the state for leprosy control activities. Where leprosy control activities are contracted to NGOs/private sector, this will be done

through the SLS / other designated funding channel in compliance with guidelines agreed with the center.

4.3. District Leprosy Societies. Implementation of leprosy control work-plans at district level will be funded through DLS, under the overall supervision of State Department of Health. The DLS (through which funds for leprosy control will be channeled), through the District Leprosy Officer, will be responsible for district procurement and implementation of district annual work-plans and financial management systems, including review of vertical staff responsibilities as agreed by the State.

4.4. MLECs, SAPELs and LECs. Large scale MLECs and focused rural SAPELs and urban LECs will continue to be used. These were introduced in the last project and form an important strategy for reaching special groups and areas under this project.

4.5. General health services. States with relatively low prevalence of leprosy, will implement leprosy control activities through the general health staff and will undertake review of continuation of vertical staff and institutions established under the leprosy control program in year 1 of the project. High endemicity states will continue current rosters of vertical staff and institutions. Review of IDA funded rosters will be undertaken during the life of the project, with a view to reductions in the overall complement of vertical staff using agreed triggers.

4.6. NGOs. As in the past, NGOs will continue to play an important role, which will vary by district and state depending on capacity and disease burden. Activities that will be carried out by each NGO will be formalized through an appropriate agreed mechanism with each state. The formal undertaking will include the description of services to be provided, mechanisms and indicators of achievements and accountabilities of the NGO and commitments by the state.

D. Project Rationale

1. Project alternatives considered and reasons for rejection:

Whilst the first project achieved considerable gains, a number of important issues remain. These have been referred to in sections B.2 and D.3. The main project alternatives considered related, first, to the overall design; and second, to the length of the project.

With respect to overall design, the first alternative considered was continuation of the same design as in the first project; and second, a modified design which stressed decentralization of leprosy control activities to the states, integration of the control activities with the general health services and strengthening complementary activities such as training, involvement of NGOs, IEC, and monitoring and surveillance.

Experience with other centrally sponsored disease control programs in general, and with the first leprosy project, in particular, revealed a number of institutional and technical issues and the need for a revised design. Thus, the alternative of a revised design has been accepted by GOI and the Bank – its main characteristics (see Annex 2 for a more detailed description) are:

- Revision of the roles of the center, states and districts as part of an explicit decentralization strategy, with the states having primary responsibility for project implementation
- Increased emphasis, including state-specific plans, on integration of leprosy control with the GHS and decreasing emphasis on campaigns: immediately in low prevalence states and over the course of the project in high prevalence states
- Explicit strategies for complementary activities - reaching special groups
- Involvement of NGOs, IEC, training, financial management and monitoring and surveillance

- Continue with MDT and supply of drugs by WHO

With respect to the length of the project, a period of three years has been chosen for the following reasons: first, at this time, it appears that it is not possible to achieve elimination of leprosy as a public health problem in the next three years (as measured by estimated 'actual' prevalence; see Section B.2 and B.3); second, and given the longer time frame needed, the goal of the project is now to transform the leprosy control program to allow these levels to be achieved over a longer period of time than is usual for Bank projects; and third, given the changes that have occurred under the first project, three years is sufficient to complete the institutional changes required.

2. Major related projects financed by the Bank and/or other development agencies (completed, ongoing and planned).

Sector Issue	Project	Latest Supervision (PSR) Ratings (Bank-financed projects only)	
		Implementation Progress (IP)	Development Objective (DO)
Bank-financed	National AIDS Control II	S	S
	National Leprosy Elimination	S	S
	Cataract Blindness Control	S	S
	Malaria Control	S	S
	Tuberculosis Control	U	U
	Andhra Pradesh First Referral Health System	S	S
	Second State Health Systems Development	S	S
	Orissa Health Systems Development	S	S
	Maharashtra Health Systems Development	S	S
	India Population Project IX	S	S
	Integrated Child Development Services II	S	S
	Reproductive and Child Health Project	S	S
	Women and Child Development Immunization Strengthening	U	U
		S	S
Other development agencies			
WHO	Assistance to GOI's National Leprosy Eradication Program		
DANLEP	Danida-assisted National Leprosy Eradication Program		

IP/DO Ratings: HS (Highly Satisfactory), S (Satisfactory), U (Unsatisfactory), HU (Highly Unsatisfactory)

3. Lessons learned and reflected in the project design:

The lessons learned derive from the experience of the first project and the resulting sector issues as outlined in section B.2. The main lessons, which are reflected in the revised project design, are:

- need to include the state level in the project design
- the campaign approach is not enough and there is a need to integrate leprosy control activities with the general health services
- advantages of MDT
- improve diagnostic accuracy and reporting
- promote NGO/Private sector involvement
- patient segregation should be discontinued
- specific attention to ensuring that all locations and social groups are adequately covered.

The project design also reflects the lessons from more than 20 IDA-supported HNP projects over the last 20 years including:

- the primacy of good training
- the need to assure the flow of essential supplies such as drugs
- the importance of good monitoring and evaluation, especially to increase responsiveness of the health system to needs at the community level
- the need for mechanisms to assure timely start-up
- assured timely flow of funds to the project
- most important of all, borrower commitment

4. Indications of borrower commitment and ownership:

There are strong indications of borrower commitment and ownership.

In 1991, India committed itself to the World Health Assembly strategy and goal of elimination of leprosy and collaborated with IDA in 1993 on the first national leprosy elimination project. Considerable progress has been made during the first project and by project close the full rupee allocation has been disbursed. During the life of the World Bank-assisted project, prevalence of leprosy fell from 24 per 10,000 to about an estimated 'actual' 7 per 10,000, short of the national goal of elimination of the disease as a public health problem. GOI continues to be strongly committed to this goal and requested IDA for support for a second project that would enable further progress toward this goal, while instituting important institutional changes that would permit leprosy to be addressed in a sustainable manner in subsequent years.

The government has taken many steps which exemplify its strong commitment to the goal of leprosy control, such as discontinuation of inappropriate staff incentive payments, preliminary plans to reduce numbers of vertical staff, rationalization of leprosy resources available from all donors and commitment to introduction of a revised WHO monitoring and evaluation system.

A MOHFW Project Preparation Team drafted the detailed Project Implementation Plans (PIPs) after extensive consultation with states, donors and technical partners and detailed assessments of activities in the foregoing project. The preparation team has met regularly with the members of the Bank Task Team and is committed to the transformation of the leprosy control activities described in the project documents.

5. Value added of Bank support in this project:

IDA assistance in leprosy control was recommended by a 1992 World Bank health financing study and the first project commenced in 1993.

Continuing IDA support will add value in three ways: first, it will allow acceleration in the process of leprosy elimination; and second, collaboration with IDA in this follow-on project will allow emphasis to be shifted to transformation of the program to an effective and sustainable one through a decentralized and integrated approach. This shift in emphasis is necessary as it is now evident, that while elimination of leprosy (measured by estimated 'actual' prevalence) as a public health problem is in sight, it is unlikely to be achieved in the 3 years of the project period. Therefore, by the end of the project, a structure that allows the control effort to be sustained for at least a decade should be in place. And third, this project will provide an example of the way in which the centrally sponsored disease control projects can be decentralized; with responsibility and authority for implementation moving to the states and, the center taking on the new role of providing overall policy guidance, technical support, national level surveillance, advocacy, and facilitating the transfer of lessons learned between states. Given the resources required and the previous Bank support, the Bank has a critical role to play through this second project.

E. Summary Project Analysis (Detailed assessments are in the project file, see Annex 8)

1. Economic (see Annex 4):

- Cost benefit NPV=US\$ million; ERR = % (see Annex 4)
- Cost effectiveness
- Other (specify)

As a follow-on to an effective project, preparation and appraisal gained from a re-examination of the economic rationale for the public involvement and an analysis of the roles of the public and private sectors in all aspects of the project. Included in the economic analysis were equity analysis of the burden of the disease and the expected benefits, simple market analysis, and analysis of the cost structure.

Economic Rationale. Based on analysis of public finance criteria, there is a clear economic rationale for public involvement in leprosy control in India. Specifically, the strongest arguments for a public role in financing services relate to the poverty orientation and impact of interventions and the existence of public goods that would not be otherwise provided by the market. A critical and sizable element of the project relates to providing information to both potential patients and medical providers through information campaigns and training. These components of the project would not be provided by the private sector due to the strong characteristics of public goods (non-exclusionary, non-rival). Another form of market failure associated with leprosy control relates to the public externality due to spread and incomplete courses of treatment. Unlike other communicable diseases, however, the associated social externality is small.

The most important economic justification for public involvement in leprosy elimination relates to poverty impact. Analysis of equity found the burden of leprosy to be mostly centered around the poor and socially vulnerable. Starting at the state level, the five most endemic states for leprosy, contributing 70 percent of the total patient load, are also five of the poorest states in India (Uttar Pradesh, Bihar, West Bengal, Orissa and Madhya Pradesh). At the individual level, equity analysis in the five endemic states, confirms that the most socially vulnerable groups shoulder the highest burden of the disease. Project resources will then be targeted to the poorest states, within states, to the poorer districts, and to the neediest populations within the districts.

Not only does leprosy target the neediest in India, it also adds a social and economic burden on the victims.

Social and economic studies have documented the devastating social effect of leprosy and quantified the loss of income due to the disease. Detailed analysis of employability and earnings of leprosy patients in Tamil Nadu found the elimination of the deformity due to leprosy would: (i) raise the probability of gainful employment from 42 to 78 percent, and (ii) increase annual earnings per employed patient by 119 percent. The combined effect of increased employment and earnings would triple the annual earnings for all patients.

Public and Private Roles. Basic market and institutional analysis provided the rationale for some re-orientation of services delivery responsibilities between the public and private sectors. Driving the re-orientation were factors relating to the availability of non-governmental providers, location of underserved populations, existence of specialized skills such as IEC, and the viability of for-profit operations. The project introduces a larger role for the private sector in a number of ways. While financing will continue to be primarily public, a number of delivery elements will be contracted out to the private sector (for and not for profit). Included will be contracting specialized NGOs for disability prevention, care and rehabilitation; contracting for the development of training materials; and, contracting professional media and IEC agencies to assist in developing and implementing and integrated IEC and involving NGOs and neighborhood committees of women for community mobilization and sensitization campaigns.

Costs and Effectiveness. Project costs were analyzed with an eye for balance between inputs and for the breakdown by project outcomes. Outreach, information campaigns and training make up a large share of the total costs. Moreover, health services delivery focuses on interventions that have been identified internationally as highly cost effective and have a proven track record in India in the first project.

2. Financial (see Annex 4 and Annex 5):

NPV=US\$ million; FRR = % (see Annex 4)

Financial analysis considered the fiscal impact of the project and reviewed sustainability, incrementally, absorptive capacity, recurrent cost implications, and financial flows.

Fiscal Impact:

Taken in the context of a relatively smaller follow-on to an on-going project, little budgetary impact is expected in the short-run. Moreover, detailed analysis of the cost structure confirms that most investments are in human capital through training and information. With no new large investments, the main elements of recurrent costs relate to addressing the long-term placement of existing staff. This issue is linked to the shifting of the service delivery model from vertical to horizontal as more leprosy services shift to GHS in the states. Assisting project design on this issue is the on-going experiences from states that have successfully eliminated the public health threat of leprosy.

A related issue is financial sustainability. Since the objective of the project is to assist GOI with the elimination of leprosy as a public health threat, there is little need for a sustainable structure. In fact, an important difference between the new and existing project is the institutional changes taking place in the states that are no longer endemic.

Absorptive capacity for new expenditures is also not a critical issue in this project. The existence of an on-going project and the shrinking size and scope of the project minimize the risk of capacity problems. A remaining risk, however, is relatively weak implementation capacity of some of the endemic states. Management attention and technical assistance on issues relating to the procurement of contracted services is critical for mitigating these risks. Another small risk relates to incrementality of IDA financing. Project

supervision will pay special attention to the sources of financing for the project. Financial reporting on the shares of the government, IDA, and other partner funds (WHO and Danida), should ensure that external funding does not substitute for domestic funds.

While the move to the integration of service delivery at the state level and the new fund flow mechanisms strengthen the role of state implementing agencies, the basic funding roles of the center and states are not changed. As long as leprosy represents a public health concern, the center will continue to finance the bulk of the recurrent costs. In other words, the financial burden is not shifted to the states.

Project Financial Management System

Financial management arrangements for the project are detailed in Annex 6. The project will be budgeted under a single identifiable line item in the budget of the MOHFW, GOI. The implementing agency for the Project is the MOHFW Directorate General of Health Service (Leprosy Division) the finance and accounting department of which, headed by a Deputy Secretary who will function *ex-officio* as the Project Financial Coordinator will consolidate the Project accounts. DGHS(LD) will be supported in the execution of the project by the participating states. The flow of funds from DGHS(LD) will be to SLS and from SLS to DLS and financial reporting from DLS to SLS and from SLS to DGHS (LD).

An integrated project computerized financial management system (PFMS) is being developed for the project. Consultants have been appointed to design, develop and institute a computerized financial management system. The key tasks that will be carried out to implement the integrated financial management system are: (a) procurement of hardware expected to be completed by March 31, 2001; (b) design and development of a PFMS software, expected to be completed by June 30, 2001; (c) appointment of accounting staff at SLS expected to be completed by July 31, 2001; and (d) training of the staff in the implementation of the PFMS, expected to be completed by September 30, 2001.

The PFMS is expected to be fully operational by October 1, 2001.

Disbursements: Disbursements from IDA credit would initially be made in the traditional system (reimbursement with full documentation and against statement of expenditure) and would be converted to the Project Management Report based disbursements after the successful implementation of the computerized PFMS. The target date for this conversion is October 1, 2002.

Retroactive Financing: Retroactive financing up to an amount of US\$ 2.9 million (SDR 2.25 million equivalent) would cover eligible expenditure for implementing activities after October 1, 2000 based on a Statement of Expenditure. Retroactive financing would support procurement of equipment, supportive medicines, materials and supplies, training and workshops, IEC, consultant and contractual services, and vehicle operation.

Audit: DGHS(LD) accounts will be audited by the Comptroller and Auditor General of India. The SLS will be audited by firms of Chartered Accountant and the audit would include a statement on the audit status of the DLS in the state based on Chartered Accountant audits of the DLS. An audited annual project financial statement will be submitted by DGHS(LD) and all the participating states within 6 months of the close of GOI's fiscal year. All these audit certificates, i.e. that of DGHS (LD) and the SLS and the special account audit report will be monitored in Audit Reports Compliance System.

Special Account: A Special Account will be maintained in the Reserve Bank of India; and will be operated

by the Department of Economic Affairs of GOI. The authorized allocation of the Special Account would be US \$ 2.5 million that represent about 6 months of initial estimated disbursements from IDA Credit. The Special Account will be operated in accordance with the Bank's operational policies.

3. Technical:

Experience in India is consistent with that in other countries and indicates that MDT is highly efficacious in the treatment and control of leprosy.

The main technical issues are epidemiological. Leprosy has a long incubation period (usually 2-5 years, but up to 20 years), and we know relatively little about leprosy transmission or its interruption. One implication is that leprosy will continue for many years (hopefully at low levels of endemicity), and that we need to sustain leprosy control efforts in India over the long term, most feasibly done through the GHS.

4. Institutional:

The institutional assessment is based on knowledge derived from the long-standing relationship between IDA and the MOHFW, especially in relation to implementation of leprosy control activities. This included missions to supervise the first project; experience with other disease control projects; an identification mission for the second project; detailed discussions at the central, state and district levels with a wide range of stakeholders (including managerial and technical personnel, beneficiaries, community representatives and NGOs); and the findings of a number of reviews and studies by multilateral and bilateral agencies. The institutional assessment forms the basis for the following project response:

- Continue a mix of campaign and routine case detection with emphasis on active case detection activities targeted to the high endemicity areas and states.
- Continue and intensify efforts directed to special groups which have been missed so far – this will involve concentrating on the high endemicity states and the use of SAPELs/LECs.
- Dismantle the vertical structure and integrate with the GHS and proscribe re-institution of the incentive system.
- Change the role of the state – it will be the “unit of account” and funds will flow through the state to the districts; the states will be responsible for program planning at the state level and for provision of supervision and technical support to the districts; districts' ability to respond to local needs strengthened through decentralized procurement of such goods and services which have less predictable patterns of requirement.
- Strengthen state capacity to manage the program. The states currently have limited management and technical capacity – therefore the center must play an important role in strengthening management and technical capacity at the state level and in becoming a source of technical expertise itself.
- Stimulate a reciprocal change in the role of the center which will become primarily responsible for technical assistance to the states, monitor the elimination on a country and state basis, provide policy guidance and set goals for the country in the international context.
- Introduce some separation of funding and provision as the state and district contract NGOs to deliver reconstructive surgery and, in some cases, the full leprosy control package
- Support greater participation of NGOs in the path to full-scale integration of leprosy services with general health care services in India. In turn, NGOs will become more accountable through service contracts with the states and districts.

4.1 Executing agencies:

Not applicable.

4.2 Project management:

Not Applicable.

4.3 Procurement issues:

1. Procurement. The "Guidelines for Procurement under IBRD Loans and IDA Credits (January 1995, Revised in January and August 1996, September 1997, and January 1999)" shall apply to all Goods and Works financed under the project. The "Guidelines for Selection and Employment of Consultants by World Bank Borrowers (January 1997, revised in September 1997 and January 1999)" shall apply to all Consultants' services financed under the project.

Based on the experience of NLEP I and other health projects, decentralization of implementation including procurement is proposed under this project. Hence, the SLS /DLS would be responsible for procurement of most goods, equipment and services. Most of the contracts are of small value; therefore National Shopping method of procurement will be adopted for most goods and equipment. Since International Competitive Bidding / National Competitive Bidding procedures are not involved, the DLS / SLS will be able to procure goods and services without much change in the existing capacities/capabilities. Items to be procured, services to be hired and procurement schedules for all the three years of the project have been prepared and are attached in the PIP of the Borrower. The procurement arrangements are summarized in Annex 6 which summarizes the NLEP II elements and their estimated costs and proposed methods of procurement.

4.4 Financial management issues:

There are two major issues: (i) the timely flow of funds to the project implementing entities (viz. state society and district societies) and a quick turnover in submission of statements of expenditure to the GOI from these entities will be a crucial challenge. This will be specially important as this is a relatively short duration project; and (ii) timely submission of acceptable audit reports for all project implementing entities in time will be critical. Audit reports from all the participating states will need to be submitted to the Bank within 6 months of the close of the GOI fiscal year. Execution of the project through a society should considerably ease the flow of funds to the implementing agencies. It should also help in timely submission of audit reports as the audit reports for Societies will come from Chartered Accountancy firms instead of State Auditor Generals. A financial coordinator at the Central level and an effective financial management system should ensure that the expenditure reporting from the states is regular and timely and audit arrangements for the DGHS(LD) and SLS are properly set up.

5. Environmental:

Environmental Category: C (Not Required)

- 5.1 Summarize the steps undertaken for environmental assessment and EMP preparation (including consultation and disclosure) and the significant issues and their treatment emerging from this analysis.

The overall incremental medical waste generated due to this project is very limited. There are no significant environmental issues.

5.2 What are the main features of the EMP and are they adequate?

Nevertheless, a simple medical waste management plan has been developed by GOI and consists of the following actions:

1. The volume of leprosy related medical waste generated at each facility is expected to be very low. Leprosy related medical waste will be disposed of according to the existing Government of India Bio-medical Waste (Management and Handling) Rules (1998). These rules provide for incineration/autoclaving/microwaving of solid waste and disinfection/autoclaving/microwaving and mutilation/shredding for sharps. The Gazette of India notification provides that the occupier of an

institution generating medical waste shall be responsible for handling of such waste without harmful effect to human health and environment.

2. At home, patients will be counseled on first contact with health workers, to burn cloth that they have used for dressings, and to wash and sun dry cloth that they use for dressing before re-use.

The compliance with this plan by health workers and facilities will form part of the routine project supervision.

5.3 For Category A and B projects, timeline and status of EA:

Date of receipt of final draft: Not Applicable

5.4 How have stakeholders been consulted at the stage of (a) environmental screening and (b) draft EA report on the environmental impacts and proposed environment management plan? Describe mechanisms of consultation that were used and which groups were consulted?

Not Applicable

5.5 What mechanisms have been established to monitor and evaluate the impact of the project on the environment? Do the indicators reflect the objectives and results of the EMP?

Not Applicable

6. Social:

6.1 Summarize key social issues relevant to the project objectives, and specify the project's social development outcomes.

The key social issue to be addressed by the project is the physical and social access of poor and marginalized populations, particularly women, tribal groups, scheduled castes, the urban poor and migrants, to leprosy diagnostic and treatment facilities. The social development objectives of the project are to (i) improve information and encourage health seeking behavior and increased demand for reliable and effective leprosy services; and (ii) overcome social/cultural barriers and gender discrimination in access to diagnostic and treatment facilities. Through decentralizing and integrating leprosy services into the general health service, the project is expected to increase coverage and provide regular access to leprosy detection and treatment. State Implementation Plans have identified hard-to-reach groups and developed strategies to reach them with special interventions such as the Special Action Projects for the Elimination of Leprosy and the Leprosy Elimination Campaigns.

Women: Women are particularly vulnerable to the myths and stigma associated with leprosy and suffer higher social costs of leprosy owing to fewer options open to them. Though women constitute 25 percent of the leprosy patients, it is more difficult for the service providers and public health information campaigns to reach them. The project seeks to address this by (i) case finding and treatment strategies with specific focus on reaching women through 'female searchers' in all areas, (ii) IEC plan for the project would specifically address the gender perspective, including the "what", "to whom" and "when" questions regarding the content, targeting and timing of the IEC campaign to most effectively address the needs of women, (iii) one-on-one counseling will address challenges faced by women in accessing services, and (iv) training programs planned under the project will be adequately "gendered" so as to sensitize field level staff to the special needs of women.

Scheduled Tribes: There is evidence that tribal populations are less likely to access diagnostic and treatment services in a timely manner. Approximately 75,000 tribal persons are to be treated under the project from Uttar Pradesh, Orissa, Andhra Pradesh, Madhya Pradesh and West Bengal (70 percent of total) apart from other states. Focal active detection campaigns with trained tribal youth along with IEC

efforts using locally adapted models and formats and SAPEL, would be adopted. The project's tribal strategy that seeks to reach tribal populations in remote areas will be finalized by negotiations (annex 15). Health workers of primary health centres and sub-centers in tribal sub-plan areas would be trained to act as first point of referral for patients referred by tribal youth.

Scheduled Castes, Urban Poor, and Migratory Groups: Mass active case detection strategies will be applied through out the country and to areas with high endemicity, through mobilization of departmental staff of several government departments and local volunteers. These campaigns will be supported by directed mass media and local publicity.

Social Exclusion: The project's IEC plans have identified the key audiences and specific strategies to increase awareness and demand among the key target groups. IEC activities will be aimed at improved community awareness and at counseling to ensure that the information leads to (i) appropriate health seeking behavior through one-on-one communication, and (ii) greater social acceptability of leprosy patients. It is expected that the project would put in place an effective and sustainable program of detection and treatment that will assist India in eliminating leprosy as a public health problem. Early case detection and treatment, as well as the treatment of disability, would alleviate human suffering and decrease the social burden of the disease. Since an estimated 60 percent of those reached will be below the poverty line, the positive impact of the project in terms of healthy life years saved will be the highest among the poor.

6.2 Participatory Approach: How are key stakeholders participating in the project?

Project preparation paid special attention to fostering a sense of ownership and commitment among stakeholders of the project. These include: (i) central and state governments, who have played a proactive role in project preparation and development. The states have increasingly taken ownership of the program by preparing individual PIPs, particularly the high-endemic states. Since an important initiative under the project is decentralization of implementation, both state- and district-level administrations have been included in the preparation process; (ii) beneficiaries and communities, who have been consulted to assess the outreach of the program and its impact, and to gain insight into the social factors influencing decisions to seek diagnosis and treatment; (iii) NGOs, which will now be more fully included as partners in implementation; and (iv) international donors, such as the WHO and Danida, who have provided technical assistance and will be involved in the implementation of the project.

6.3 How does the project involve consultations or collaboration with NGOs or other civil society organizations?

The evaluation of the first NLEP indicated that NGOs have played an important role and have the potential to increase their involvement in all aspects of the program, particularly in remote and underserved areas. Active case detection through a mix of strategies will be a priority to increase the access of underserved groups to diagnostic and treatment services. The SAPEL and LECs, set up specifically to implement the project in endemic tribal/hard to reach areas, will be continued and intensified. SAPELs implemented during Phase 1 were able to successfully involve community based organizations such as Mahila Swasthya Samitis, Panchayati Raj Institutions, Development of Women and Children in Rural Areas groups, etc. Community Based Organizations and NGOs will be involved in service delivery in various ways: for IEC activities, disability care, detection, rehabilitation and surveillance. The National and State PIPs for the five focus states have been reviewed with key NGOs. They provide information regarding the availability, level of involvement of NGOs and opportunities for involving NGOs in several areas, including case finding and treatment, monitoring, training and IEC. The role played by the NGOs will vary by state and district depending on NGO capacity and disease

burden. There are increasing consultations with NGOs on program design and implementation. NGOs are also a key partner of the Global Alliance for Elimination of Leprosy which is currently chaired by India.

6.4 What institutional arrangements have been provided to ensure the project achieves its social development outcomes?

The project emphasizes two key institutional initiatives which would improve coverage of vulnerable and excluded groups and elimination of leprosy among them.

- (i) decentralization of planning and implementation to the state and district levels. This would increase the involvement of states and then build capacities to manage and administer the leprosy program over the long term. Guided by local needs, states will prepare and implement state-specific annual plans with emphasis on the needs of special groups. This includes carrying out increased number of SAPELs and LECs to reach target groups; and
 - (ii) integration of leprosy diagnosis and treatment facilities into general health services. This would lead to improved geographical coverage and increased access to MDT, particularly for poor areas.
- Both these initiatives will be supported by appropriate capacity building efforts, for government administrations to plan and manage such activities, and for staff to undertake case finding, treatment and rehabilitation programs.

In addition, the project proposes to:

- (i) increase the outreach of health workers through training and other inputs, and also provide training to other field workers, such as Anganwadi workers to increase the availability of diagnosis and treatment channels for leprosy patients;
- (ii) increase involvement of NGOs, particularly to reach poor and marginalized groups and underserved areas;
- (iii) enhance IEC capacity by engaging professional media agencies;
- (iv) enhance capacity at state and district levels to monitor and track the disease burden of target groups, and thus strengthen capacity to respond in a timely and appropriate manner.

Lessons from the first leprosy project and recommendations from the social and institutional assessments called for the project to include capacity building measures and close partnerships with Danida, WHO and NGOs. Danida has developed experience in SAPELs and gender sensitization, while WHO would assist in building capacity for monitoring project impact on the target groups. See C.4 and Annex 2 for details.

6.5 How will the project monitor performance in terms of social development outcomes?

In order to increase the responsiveness of the health system to needs at the community level, the monitoring and evaluation mechanism will include assessments of program coverage of different social groups differentiated by age, sex, rural/urban location, and scheduled caste/tribe. Information collected will include the number of cases under treatment, number of new cases, number of cases cured and coverage. Special studies are planned to assess treatment completion rates, quality of diagnoses, and quality of care.

In addition to information on case finding and treatment, the monitoring and evaluation mechanism will collect data on the progress of activities on the ground, status of logistics and drug supply, and funds flow and expenditures. This will become an integral part of the project monitoring and evaluation mechanism, repeated at reasonable intervals, and will facilitate monitoring of the impact of the project on socially disadvantaged groups.

Baseline information on underserved areas and special groups has been collected for the five high endemic states and similar independent surveys will provide end-line data for impact evaluation.

7. Safeguard Policies:

7.1 Do any of the following safeguard policies apply to the project?

Policy	Applicability
Environmental Assessment (OP 4.01, BP 4.01, GP 4.01)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Natural habitats (OP 4.04, BP 4.04, GP 4.04)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Forestry (OP 4.36, GP 4.36)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Pest Management (OP 4.09)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Cultural Property (OPN 11.03)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Indigenous Peoples (OD 4.20)	<input checked="" type="radio"/> Yes <input type="radio"/> No
Involuntary Resettlement (OD 4.30)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Safety of Dams (OP 4.37, BP 4.37)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Projects in International Waters (OP 7.50, BP 7.50, GP 7.50)	<input type="radio"/> Yes <input checked="" type="radio"/> No
Projects in Disputed Areas (OP 7.60, BP 7.60, GP 7.60)	<input type="radio"/> Yes <input checked="" type="radio"/> No

7.2 Describe provisions made by the project to ensure compliance with applicable safeguard policies.

The project specifically aims to benefit vulnerable groups and indigenous (i.e. tribal) populations. The national and state-level PIPs identify tribal populations as a target group with unique problems of physical and social access, requiring special culturally-sensitive strategies. The project's tribal strategy (detailed in Annex 15) is aimed at increasing the demand for leprosy services and include the following measures: detailed mapping of tribal groups, providing culturally compatible IEC to promote health education and publicize leprosy services, training volunteers in tribal communities, utilizing tribal youth as community mobilizers and communicators, and conducting SAPELs with the help of tribal leaders, community members and trained volunteers. Partnerships are being developed with the Tribal Development Departments for better information on these groups and channels to expand outreach. Population specific information will be used to develop culturally sensitive IEC materials for both the public and providers.

The revised monitoring mechanism will provide data on provision of services to tribal groups. Additional data, qualitative and quantitative, will be obtained from SAPEL reports and special studies.

F. Sustainability and Risks

1. Sustainability:

Leprosy control activities will be sustained beyond the life of the project because

- the GOI and the states are strongly committed to the project
- the GOI and states are moving to a structure that will reduce the load on the exchequer due to rationalization of staff
- the project enjoys support from all key stakeholders

2. Critical Risks (reflecting the failure of critical assumptions found in the fourth column of Annex 1):

Risk	Risk Rating	Risk Mitigation Measure
From Outputs to Objective GOI and the states not willing to undertake changes in roles and responsibilities under proposed decentralization and integration, and/or not have the capacity to do so.	S	Continuing discussion with states and center or roles; Memorandums of Understanding
Leprosy cases will not come for treatment.	M	IEC campaigns, active case detection and follow up
District level staff inadequately diagnose and treatment leprosy.	M	Training and supervision from state level
Inadequate/irregular supply/distribution of drugs.	N	Experience from first project and continuing WHO involvement
GOI/states not willing to support NGO participation in rehabilitation, IEC or training activities.	M	Memorandums of Understanding, project supervision
From Components to Outputs Inadequate financial management and audits at SGHS (LD) level and irregular funds from GOI to state level	S	All states will be required to establish a state society through which funds will flow. This has proved effective in other disease control projects.
Delays in procurement	M	Procurement plans; relevant necessary procurement actions as condition of negotiations
Overall Risk Rating	M	

Risk Rating - H (High Risk), S (Substantial Risk), M (Modest Risk), N(Negligible or Low Risk)

3. Possible Controversial Aspects:

None.

G. Main Loan Conditions

1. Effectiveness Condition

Nil.

2. Other [classify according to covenant types used in the Legal Agreements.]

To fulfill the Conditions of Negotiations, the following actions have been taken:

- a) Project Implementation Plans for the Centre, 5 endemic states and other states and UTs have been completed and provided to the Association.
- b) The project has been cleared by the Expenditure Finance Committee of the Government of India.
- c) Memorandums of Understanding have been received from key participating states confirming their intention to implement the project in accordance with the Project Implementation Plans.
- c) The procurement plans for each year of the project have been satisfactorily prepared. The GOI confirms that it will use agreed quarterly procurement monitoring formats.
- d) The Bank has cleared procurement actions for the first year.
- e) Donor coordination mechanism has been initiated.

At negotiations, Government of India provided assurances that it would:

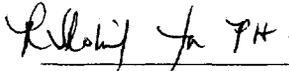
- a) Undertake a mid-term review of the project by September 30, 2002 in accordance with terms of reference agreed with the Bank, using data from agreed surveys.
- b) Ensure adequate budgetary allocations at the centre, and release project funds in a timely manner to the states through agreed channels of funding, only after adequately trained accounting staff are in position, in order to carry out agreed project activities.
- c) Submit biannual project progress reports.
- d) Undertake annual financial and procurement audit under Terms of Reference agreed with the Bank.
- e) Reduce the numbers of regular and contract 'vertical' staff in accordance with the Project Implementation Plans.
- f) Ensure that incentives based on case finding shall not be instituted.
- g) Carry out routine reporting, independent third party surveys, validation of elimination surveys and end-line leprosy prevalence survey in accordance with terms of reference agreed with the Bank.
- h) Organize biannual meetings of the donor coordination committee.

H. Readiness for Implementation

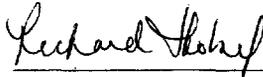
- 1. a) The engineering design documents for the first year's activities are complete and ready for the start of project implementation.
- 1. b) Not applicable.
- 2. The procurement documents for the first year's activities are complete and ready for the start of project implementation.
- 3. The Project Implementation Plan has been appraised and found to be realistic and of satisfactory quality.
- 4. The following items are lacking and are discussed under loan conditions (Section G):

I. Compliance with Bank Policies

- 1. This project complies with all applicable Bank policies.
- 2. The following exceptions to Bank policies are recommended for approval. The project complies with all other applicable Bank policies.



Peter F. Heywood
Team Leader



Richard Lee Skolnik
Sector Director



Edwin R. Lim
Country Director

Annex 1: Project Design Summary

INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Hierarchy of Objectives	Key Performance Indicators	Monitoring & Evaluation	Critical Assumptions
Sector-related CAS Goal: Improve access to and quality of health services	Sector Indicators: Increased coverage and utilization of national leprosy elimination project	Sector/ country reports: <ul style="list-style-type: none"> • CAS discussions • GOI household surveys • Various Bank sector reports 	(from Goal to Bank Mission) <ul style="list-style-type: none"> • Early detection and cure/disability care will improve the quality of life and earning capacity of those affected by leprosy • Prevalence of the disease is mainly among the poor, its elimination as a public health problem will impact poverty as well
Project Development Objective: Transform the national leprosy control program to an effective and sustainable program through a decentralized and integrated approach which increases community access to MDT.	Outcome / Impact Indicators: Decentralization of leprosy control activities from the center to the states Integration of leprosy control activities with the general health services	Project reports: Reports of the NLEP, observations and reports of Bank supervision missions Reports of NLEP, independent surveys, observations and reports of Bank supervision missions State progress reports, surveys	(from Objective to Goal) <ul style="list-style-type: none"> • GOI and state governments support in overcoming administrative and managerial problems during decentralization and integration • Continued inter-agency (specifically GOI and WHO) support for NLEP, including supply of drugs
Output from each Component: Component 1 - Decentralization and institutional development Increased state role in, and responsibility for, leprosy control activities which were previously under central control	Output Indicators: Number of project related activities under state control and in state level reporting on project progress e.g monitoring and supervision, and financial reporting/auditing	Project reports: Quarterly progress reports, reports of Bank supervision missions	(from Outputs to Objective) <ul style="list-style-type: none"> • States have required managerial and technical capacity

Increased support and technical assistance from center to states	Number of technical staff at the center with specific responsibility to ensure continued assistance to states and/or holding workshops to address state-specific technical requirement.	Bank supervision reports	<ul style="list-style-type: none"> GOI willing to adopt new roles
<p>Component 2 - Strengthen and integrate service delivery</p> <p>Integration of leprosy control with GHS at the state and district levels</p> <p>Improved extent and accuracy of detection and successful administration of MDT to all confirmed cases</p>	<p>Number of vertical structure staff ; out-reach of program through GHS and sustained program achievements</p> <p>Improved sensitivity and specificity of diagnoses</p>	<p>Supervision reports, independent surveys</p> <p>Mid-term review and evaluation reports, independent surveys</p> <p>Service statistics, supervision reports, independent surveys</p>	<ul style="list-style-type: none"> Center has capacity to provide support and technical assistance to states States willing to integrate leprosy services with GHS District level staff has adequate diagnostic skills for detection and cure of disease GOI and states willing to eliminate case detection incentives WHO willing to continue supply of drugs to the project GOI and states able to improve distribution of drugs
Adequate procurement and distribution of drugs	Supply and distribution of drugs in all states	Service statistics, supervision reports, independent surveys	<ul style="list-style-type: none"> Willingness of states to promote increased involvement of NGOs in disability prevention
<p>Component 3 - Prevention of Disability.</p> <p>Support for disability, particular those drawing on the substantial experience of NGOs</p> <p>Component 4 - Information, Education and Communication</p> <p>Greater community awareness of leprosy and possibility of prevention; less negative image of the disease</p>	<p>Proportion of new cases with deformity grade II and above receiving adequate care</p> <p>Community awareness and participation in case detection and disability prevention resulting in timely treatment, and fewer disabilities</p>	<p>Service statistics</p> <p>Social assessments, surveys, supervision reports</p>	<ul style="list-style-type: none"> States willing to contract out/increase own capacity for IEC States willing to involve NGOs in promoting community awareness and participation
<p>Component 5 - Training</p> <p>Reorienting staff to an integrated approach and provision of new skills</p>	Proportion of staff appropriately trained		<ul style="list-style-type: none"> Willingness of states to draw on NGO training experience in leprosy control

Hierarchy of Objectives	Key Performance Indicators	Monitoring & Evaluation	Critical Assumptions
Project Components / Sub-components:	Inputs: (budget for each component)	Project reports:	(from Components to Outputs)
Decentralization and institutional development	2.50	Quarterly progress reports	Adequate and timely flow of funds from GOI to state project
Strengthening and integrating service delivery	27.80	Supervision reports	Timely assignment of staff and consultants
Disability care	3.70	On-going social assessments	Timely procurement
IEC	5.00	Mid-term review and evaluation reports	
Training	3.20		

Annex 2: Detailed Project Description
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Leprosy is also called Hansen's Disease (the Norwegian physician G. Armauer Hansen discovered Hansen's bacillus in 1874). Leprosy is a chronic slow developing bacterial disease of humans caused by *Mycobacterium leprae* affecting mainly peripheral nerves and skin. The suffering of leprosy is caused by damage to the peripheral nerves, which leads to sensory loss, paralysis and loss of function of the hands, feet and eyes. It is feared because of its potential for crippling and disfigurement. The resulting deformities are the main cause of social stigma attached to the disease.

- See PAD Section B.2 for discussion of the **main sector issues and government strategy**
- See PAD Section B.3 for identification of the **sector issues to be addressed by the project and strategic choices**

[The preparation of this project has, and the implementation will, involve collaboration between GOI, IDA, WHO, Danida and International Federation of Antileprosy Associations (ILEP)]

As summarized in Sections B.2 and B.3, this project (a follow on from the first IDA-supported project), aims to transform the national leprosy control program into an effective and sustainable program through a decentralized and integrated approach and to reduce the national prevalence of leprosy to less than 3 per 10,000 at the end of the project.

The long term goal is to reach elimination levels in all states within the next 6-8 years - while this is much beyond the project period, reaching elimination levels in all states will be heavily dependent on transformation of the program, the immediate goal of the project described here.

Leprosy control involves

- Finding individuals who have leprosy by actively searching for them (active case detection) or encouraging them to self-report (passive case detection)
- Treating diagnosed individuals with effective drugs
- Provision and distribution of drugs
- Prevention of disability
- Monitoring the amount of leprosy in the community and the implementation of control activities

The Leprosy Control Program in India commenced in 1955. Multiple drug therapy replaced the inadequate single drug regimen in 1983. At the commencement of the first IDA project in 1993, although low levels of leprosy had been reached in a few states, endemicity remained high in many states including the states of Bihar, Uttar Pradesh, Madhya Pradesh, West Bengal and Orissa. The first IDA project implemented as a centrally sponsored and controlled endeavor, reduced overall recorded prevalence of leprosy, greatly expanded the availability of MDT, assisted active (and continued passive) case detection, supported prevention of disability and placed greater emphasis on reducing stigmatization and increasing awareness that the disease could be treated. As the first project closes, technical capacity of the states to implement leprosy control remains low. Endemicity has been remarkably reduced in many states. But prevalence remains high in these 5 states (Bihar, Uttar Pradesh, Madhya Pradesh, West Bengal and Orissa) and elimination levels at the national level have not been reached.

Consequently, the design of this project involves decentralization of project implementation to the states and preparation of state-specific plans. This design is consistent with the move to increased state

responsibility and responds to recognition that central management of programs in a large diverse country has not been able to deal effectively with the local situation.

Decentralization in this project is based on preparation of state-specific plans and plans for central control activities which

- Re-define the role of the center, state and district
- Strengthen management capacity all levels
- Delineate a mix of active and passive case finding strategies (voluntary reporting, campaigns, general health service, and attention to special groups) considered appropriate to the state and district situation
- Support leprosy control activities with high quality social marketing stressing that leprosy can be treated, treatment is available and effective, and disability is avoidable and may be corrected.
- Propose integration of leprosy control with the general health services immediately in low endemic and in a phased manner in high endemicity states and districts.
- Include plans for re-deployment of staff from the vertical program, including to other parts of the health system
- Ensure availability of drugs at the local level (donated by Novartis and procured and supplied by WHO)

Particular emphasis will be placed on the five high-endemicity states of Bihar, Uttar Pradesh, Madhya Pradesh, West Bengal and Orissa.

The project will contain the following components:

By Component:

Project Component 1 - US\$2.50 million

Decentralization and institutional development

The main purpose of this component is to promote revised roles for the center, states and districts in implementing the new project; the new roles are spelled out in the PIPs. In general, the center will be responsible for an annual plan for central activities; technical assistance to the states; review of annual state plans; release of funds to state societies; supervision of progress in training and IEC plans and evaluation; coordination of financial monitoring and expenditure and disbursement reports and claims under the project; overall management of the drug supplies; overall coordination of monitoring and surveillance activities and special cross-state surveys; and dissemination of lessons learned across states.

In turn, the states will prepare and implement state-specific annual plans and strategies with emphasis on the needs of special groups (including SAPEL, LEC projects); channel funds to district societies; provide technical assistance to the districts; monitor implementation; support the DLS in implementing district level activities; manage state level IEC and training; drug supplies; and preparation of physical and financial monitoring of project implementation; and coordination within the state.

The district will prepare and implement annual plans which ensure financial monitoring, management of local level activities including IEC, drug supply, training, monitoring and surveillance and coordination with other sectors.

The project will finance training and workshops, consultants, incremental staff, equipment and furniture.

Project Component 2 - US\$27.80 million

Strengthening and integration of service delivery

The MDT strategy was implemented widely in the first project and will form the centerpiece of the technical approach to be used in the second. The service delivery strategy will emphasize integration with the GHS from the start of the project. For the service delivery strategy, each state will determine the appropriate mix of active and passive case finding through voluntary reporting, campaigns, GHS and emphasis on special groups. While it may be necessary in some areas to continue mass campaigns, this is not a sustainable strategy and will, as soon as possible, give way to an integrated model of service delivery. Patient segregation will be discontinued. NGOs will be contracted to provide services; where feasible this will include provision of all leprosy control activities in a district. The actual mix of activities and their timing are shown for each state in the PIPs.

The project will finance incremental operating costs, drug delivery, campaigns, training, activities to target special groups, service delivery by NGOs.

Project Component 3 - US\$ 3.70 million

Prevention of Disability

Without the disability that is associated with longstanding leprosy infection, leprosy would be a somewhat unusual and infrequent skin disorder. However, the occurrence of disabilities resulting from nerve damage, makes leprosy a dreaded disease with significant social stigma and socio-economic consequence to individuals and families.

Under this component major responsibility for service delivery will rest with general health services and NGO partners. NGOs will be responsible for taking up prevention of disability work in defined populations, training of general health staff in these activities, IEC activities in this respect and in carrying out re-constructive surgery for serious deformities.

The project will finance purchase of services from NGOs, consultant services, training, purchase of equipment and operating expenses.

Project Component 4 - US\$5.00 million

Information, education and communication

The objective of this component is to carry out political advocacy, change society's attitude to leprosy and to increase demand by affected individuals for leprosy control services. An overall IEC strategy has been developed. In general, planning these activities will take account of the declining prevalence as elimination is approached, the need to support the campaign activities at specific times and encourage voluntary reporting as leprosy control is integrated with the general health services. The strategy will differ by state according to level of endemicity. In the moderate/low endemic states the main objective is to encourage early voluntary self-reporting. In the high endemicity states the IEC activities will, initially, also support the campaigns through general awareness of the signs and symptoms of leprosy. The IEC will build on the experience of the BBC World Service Trust whose campaign is coming to an end. The BBC mass media

campaign aimed at improving voluntary self-reporting during the mass case finding and treatment campaign in 1999 carried out in all states of the Indian Union. The BBC campaign used materials produced by local producers of the state owned Doordarshan TV company and supported by BBC. A post campaign evaluation showed high viewership and impact. In addition to the media campaign, the BBC also worked with the Song and Drama division of the Ministry for Information and Broadcasting to carry out local and group forms of communication in these selected states.

A professional agency/agencies will be appointed to manage the media campaign and political advocacy at the center. At the district level the District Leprosy Officer will be responsible for local IEC activities which will be coordinated with state and national efforts.

The project will finance consultant services, workshops, training, technical assistance, IEC materials and media space and operational expenses.

Project Component 5 - US\$3.20 million

Training

Reorienting staff to an integrated approach and providing new skills needed by staff in the general health services and those who will be re-deployed will require a large and coordinated training effort. The training strategy (details given in the PIP) is based around the need for improved management at all levels, and the need for technical re-orientation of various categories of health workers (including those in the general health services as integration progresses). The training will be based on the specific problems faced by each state, needs and competency based, and include explicit evaluation activities. A core team for training will be established in each state and will be charged with detailed planning and implementation of training activities, and production/adaptation of appropriate training materials. Where feasible training activities will be contracted to outside agencies, including qualified NGOs.

The project will finance workshops, review meetings, training activities, contractual services and operational expenses.

In addition, there are a number of issues which cut across all of these components and have influenced project design. They are:

Drugs will be donated by Novartis and procured and supplied by WHO.

NGOs: the GOI plan for involvement of NGOs is spelt out in detail in the PIP. In summary, GOI's NGO strategy allows for increased involvement of NGOs in a range of leprosy control activities while increasing accountability for specified outcomes.

Manpower: in the course of the project the GOI will significantly reduce the number of vertical staff in leprosy control. The details are shown in the PIP.

Special groups: GOI recognizes that reaching the goal of this project will be dependent on reaching groups for whom access is currently limited for social, economic or geographic reasons. The GOI plan for reaching these special groups includes the following: use of local volunteers organized and trained during SAPELs and LECs, training and networking with private and other providers of health related services e.g.: Registered Medical Practitioners and local doctors, use of teachers, village health guides, forest guards etc., provision for accompanied MDT.

Monitoring and surveillance: as discussed above, in Section B.2 of the PAD, while incidence is the preferred method of measuring trends in disease occurrence, it is not feasible to do so for leprosy. To date, programs have used case detection rate but it is becoming increasingly clear that it is flawed as a proxy for incidence rates; despite this and in the absence of an alternative, it will continue to be used as a program indicator. However, it is then important that monitoring and surveillance efforts supplement their use of case detection rate with:

a) Baseline Data and Changes at the End of the Project (Annex 11). The estimated prevalence as of March 2000 with all available data is 7.2 per 10 000 and the most probable situation at the end of 2004 will be around 2 to 3 per ten thousand.

At the end of the project, the same method will be used to estimate the prevalence of the disease. To achieve this, surveys will be conducted to collect information on:

- Proportion of 'recycled cases';
- Proportion of examined cases among suspected and referred cases;
- Proportion of confirmed cases among cases evaluated; and
- Population coverage.

WHO has agreed to assist GOI in undertaking this exercise.

b) Methods for Assessing Progress towards Leprosy Elimination (Annex 12). Rapid assessment based on Lot Quality Assurance Sampling will be used to assist States to determine whether they have reached elimination level or not.

c) Surveys to Monitor Performance of Leprosy Elimination Program (Annex 13) to assess levels of integration, quality care including cure rates, and availability of MDT drugs.

Leprosy Elimination Monitoring has been designed to supplement routinely collected information on disease distribution with more detailed information on program performance and levels of integration. This exercise will be undertaken at the beginning of the project and at least every year thereafter in each of the priority States, and WHO has agreed to assist GOI to carry out these surveys. The last of these surveys will constitute the end-line leprosy prevalence (evaluation) survey.

d) Collection and Analysis of Essential Indicators (Annex 14). Essential indicators will be collected at the local level and aggregated at district, state and national level. They include prevalence, detection by type of leprosy, by age groups, by sex, by scheduled caste and scheduled tribe, disabilities among newly detected cases, and cure. The already existing leprosy information system is to be modified to take into account the distribution of the disease in various population groups such that data is available at a national level on a quarterly basis. Patient cards and reporting forms will be adapted. WHO has agreed to assist GOI in adapting the system and computerizing it at State level.

Annex 3: Estimated Project Costs
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Project Cost By Component	Local US \$million	Foreign US \$million	Total US \$million
1. Decentralization and Institutional Development	2.30	0.00	2.30
2. Strengthening and Integrating Services	25.70	0.00	25.70
3. Disability Prevention and Care	3.30	0.00	3.30
4. IEC	4.50	0.00	4.50
5. Training	3.00	0.00	3.00
Total Baseline Cost	38.80	0.00	38.80
Physical Contingencies	0.90	0.00	0.90
Price Contingencies	2.50	0.00	2.50
Total Project Costs	42.20	0.00	42.20
Total Financing Required	42.20	0.00	42.20

Project Cost By Category	Local US \$million	Foreign US \$million	Total US \$million
Goods*	3.60	0.00	3.60
Works	0.00	0.00	0.00
Services	25.60	0.00	25.60
Operating Costs	13.00	0.00	13.00
Total Project Costs	42.20	0.00	42.20
Total Financing Required	42.20	0.00	42.20

* Drugs for the project of a value US \$10.4 million (approximately) are being donated by Novartis Foundation through WHO.

INDIA NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	1.19	0.57	0.56	2.32
Strengthening & Integrating Services	10.41	9.44	5.83	25.68
Disability Prevention & Care	1.12	1.19	1.03	3.34
IEC	2.63	1.44	0.45	4.51
Training	1.58	1.32	0.06	2.96
Total BASELINE COSTS	16.93	13.96	7.93	38.82
Physical Contingencies	0.41	0.32	0.18	0.91
Price contingencies	0.75	0.96	0.79	2.49
Total PROJECT COSTS	18.09	15.23	8.90	42.22

INDIA NLEP II	2001	2002	2003	Total
<i>Projects Components by year (INRmillion)</i>				
Decentralisation & Institutional Development	55.98	26.83	26.23	109.04
Strengthening & Integrating Services	489.15	443.81	274.05	1207.02
Disability Prevention & Care	52.71	56.05	48.37	157.13
IEC	123.51	67.52	20.98	212.01
Training	74.26	61.89	3.01	139.16
Total BASELINE COSTS	795.61	656.10	372.65	1824.36
Physical Contingencies	19.33	14.81	8.54	42.68
Price contingencies	26.08	64.71	60.22	151.01
Total PROJECT COSTS	841.02	735.63	441.40	2018.05

BIHAR NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.06	0.02	0.02	0.10
Strengthening & Integrating Services	2.02	1.80	1.15	4.97
Disability Prevention & Care	0.18	0.18	0.15	0.51
IEC	0.38	0.15	0.07	0.60
Training	0.24	0.24	0.00	0.48
Total BASELINE COSTS	2.87	2.40	1.39	6.67
Physical Contingencies	0.06	0.05	0.03	0.14
Price contingencies	0.13	0.16	0.14	0.43
Total PROJECT COSTS	3.07	2.61	1.56	7.24

WEST BENGAL NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.05	0.02	0.02	0.08
Strengthening & Integrating Services	1.13	1.03	0.61	2.77
Disability Prevention & Care	0.10	0.10	0.08	0.28
IEC	0.34	0.17	0.05	0.56
Training	0.17	0.17	0.00	0.34
Total BASELINE COSTS	1.78	1.49	0.76	4.04
Physical Contingencies	0.04	0.03	0.01	0.08
Price contingencies	0.08	0.10	0.08	0.26
Total PROJECT COSTS	1.91	1.61	0.85	4.38

MADHYA PRADESH NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.05	0.02	0.02	0.09
Strengthening & Integrating Services	1.26	1.23	0.77	3.25
Disability Prevention & Care	0.14	0.14	0.12	0.40
IEC	0.35	0.13	0.06	0.54
Training	0.16	0.14	0.00	0.30
Total BASELINE COSTS	1.95	1.66	0.96	4.58
Physical Contingencies	0.05	0.05	0.02	0.12
Price contingencies	0.09	0.11	0.10	0.30
Total PROJECT COSTS	2.09	1.81	1.08	4.99

UTTAR PRADESH NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.06	0.02	0.02	0.10
Strengthening & Integrating Services	2.19	1.99	1.28	5.45
Disability Prevention & Care	0.21	0.22	0.18	0.61
IEC	0.45	0.21	0.08	0.74
Training	0.25	0.22	0.00	0.47
Total BASELINE COSTS	3.17	2.66	1.55	7.38
Physical Contingencies	0.08	0.07	0.04	0.18
Price contingencies	0.14	0.18	0.15	0.48
Total PROJECT COSTS	3.39	2.89	1.74	8.02

ORISSA NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.04	0.02	0.02	0.08
Strengthening & Integrating Services	0.59	0.55	0.34	1.48
Disability Prevention & Care	0.06	0.06	0.05	0.16
IEC	0.29	0.12	0.04	0.45
Training	0.13	0.12	0.00	0.26
Total BASELINE COSTS	1.10	0.87	0.45	2.43
Physical Contingencies	0.03	0.02	0.01	0.06
Price contingencies	0.05	0.06	0.05	0.16
Total PROJECT COSTS	0.18	0.95	0.51	2.65

27 STATES NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.78	0.35	0.35	1.48
Strengthening & Integrating Services	3.22	2.85	1.68	7.75
Disability Prevention & Care	0.44	0.48	0.45	1.38
IEC	0.39	0.22	0.11	0.71
Training	0.60	0.37	0.01	0.98
Total BASELINE COSTS	5.43	4.28	2.60	12.31
Physical Contingencies	0.11	0.10	0.06	0.27
Price contingencies	0.24	0.29	0.26	0.80
Total PROJECT COSTS	5.79	4.65	2.92	13.36

GOI/CLU NLEP II	2001	2002	2003	Total
<i>Projects Components by year (US\$million)</i>				
Decentralisation & Institutional Development	0.15	0.13	0.11	0.39
IEC	0.43	0.42	0.04	0.90
Training	0.03	0.05	0.04	0.13
Total BASELINE COSTS	0.62	0.60	0.20	1.42
Physical Contingencies	0.02	0.02	0.00	0.05
Price contingencies	0.03	0.04	0.02	0.09
Total PROJECT COSTS	0.67	0.67	0.22	1.56

¹ Identifiable taxes and duties are 0 (US\$m) and the total project cost, net of taxes, is 42.2 (US\$m). Therefore, the project cost sharing ratio is 71.09% of total project cost net of taxes.

Annex 4

INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Economic and Financial Analysis Summary

I. Introduction

To assist in project preparation and appraisal, a number of basic economic and financial studies and analyses were conducted following World Bank guidelines [see Operational Manual OP/BP 10.04 (1994)]. Specifically, analyses focused on expected benefits, links to poverty reduction, sustainability, risks, and externalities. Since this is a follow-on to a successful project, the analysis focused on ensuring the continued rationale for investments and appropriate adaptation to the shrinking burden of leprosy in India. At issue are long-term sustainability and risk issues of re-organizing interventions from a vertical to a horizontal approach and the shifting of responsibility from the center to the states.

II. Economic Justification

Public finance economics provides a simple framework for analyzing the economic rationale for public involvement. The framework is based on the market's failure to provide a socially optimal quantity of a good or a service. Typical market failures are due to the nature of the good (public goods or externalities) or the nature of the demand for the goods (e.g. low demand due to poverty or asymmetric information).

The rationale for public involvement in leprosy control has both elements of market failure. A substantial element of the project relates to the provision of information to potential patients and providers. This takes the form of information campaigns and training. Such project components, especially IEC campaigns would not be delivered without public involvement because of strong public good characteristics (non-exclusionary and non-rival). Like most communicable diseases, there are some elements of externalities involved in disease control that also result in less than optimal provision of services. Unlike most other communicable diseases, however, the social externality related to leprosy is limited.

The strongest argument for public involvement in leprosy control relates to the nature of demand for services and the burden of the disease on the most vulnerable in the population. Analysis of equity found the burden of leprosy to be mostly centered around the poor and socially vulnerable. Starting at the state level, the five most endemic states for leprosy, contributing 70 percent of the total patient load, are also five of the poorest states in India (Uttar Pradesh, Bihar, West Bengal, Orissa and Madhya Pradesh). Project Resources were then targeted to the poorest states.

Individual level equity analysis in the five endemic states, confirms that the most socially vulnerable groups, scheduled Castes, and women below the poverty line, shoulder the highest burden of the disease. In Bihar for example, prevalence rates for leprosy were 50 percent higher for men and women below the poverty line than the state average. The prevalence rate for scheduled castes were even higher, at twice the state average. In Uttar Pradesh and Orissa, prevalence rates for scheduled castes were 2 to 2.5 times that of the state average. And in West Bengal, prevalence rates for women below the poverty line were 4 times the state average.

Not only does leprosy target the neediest in India, it also a social and economic burden to the victims. Social and economic studies have documented the devastating social effect of leprosy and quantified the loss of income due to the disease. Detailed analysis of employability and earnings of leprosy patients in

Tamil Nadu found the elimination of the deformity due to leprosy would: (i) raise the probability of gainful employment from 42 to 78 percent, and (ii) increase annual earnings per employed patient by 119 percent. The combined effect of increased employment and earnings would triple the annual earnings for all patients.

III. Public and Private Roles

Economic rationale for public involvement need not necessarily mean that the public sector finance and deliver services. Project appraisal reviewed public and private roles as identified in project documentation and reviewed changes in the responsibilities between the center and the states. Due to the nature of the market failures (public goods and low demand) and the concentration of the disease in economically vulnerable population groups in the poorest states, it is important to maintain the financing role of the public sector.

Provision of health services need not necessarily be completely delivered by the public sector. The project introduces a larger role for the private sector. A number of delivery elements will be contracted out to the private sector (for and not for profit). The list of contracted activities includes:

- contracting specialized NGOs for disability prevention, care and rehabilitation;
- contracting for the development of training materials;
- contracting professional media and IEC agencies to assist in developing and implementing and integrated IEC and involving NGOs and neighborhood committees of women for community mobilization and sensitization campaigns; and
- a larger reliance on contracted technical staff in management and service delivery roles.

IV. Budgetary Impact

Typical concerns about the budgetary impact of externally financed projects relate to how budgetary processes are influenced by, and adapt to, injections of external funds. A function of the appraisal process is the review of issues of sustainability, absorptive capacity, incrementality, and flow of funds mechanisms in order to minimize distortions and ensure that project objectives are aligned to, and are supported by, long-term program budgetary directions. Since this project is a follow-on of an existing project, appraisal was assisted by the available evidence on budgetary outcomes.

Sustainability

Analysis of the expenditure estimates by input categories for the new project confirmed that most investments are in disseminating information and human capital. The recurrent cost implications of such investments are minimal, especially as leprosy is eliminated as a public health risk. With no new large physical capital investments, the main elements of recurrent costs relate to addressing the long-term placement of existing staff. This issue is linked to the shifting of the service delivery model from vertical to horizontal as more leprosy services shift to GHS in the states.

The largest component of recurrent costs in the new project is salaries of regular staff, representing 18 percent of estimated total project costs. Detailed analysis of budget plans for the 5 endemic states finds the wage bill distributed between regular and contracted staff with regular staff accounting for 79 percent of positions. Of the regular staff, paramedical workers account for 74 percent of the positions. The critical issue with recurrent staff costs is the ability of the states to absorb staff into general health services. Since the objective of the project is the elimination of leprosy as a public health threat, there is little need for a

sustainable structure beyond elimination. In fact, an important difference between the new and existing project is the significantly increased emphasis on institutional change.

Table 1: NLEP staffing plans for the 5 endemic states

Position	Regular Staff	% of Total	Contract Staff	% of Total	% Contracted
Medical Officers	435	4.5%	117	4.5%	21.2%
NMS	1489	15.3%	120	4.6%	7.5%
Paramed Workers	7245	74.5%	2085	79.9%	22.3%
Lab Tech	417	4.3%	43	1.6%	9.3%
Other non-med.	139	1.4%	244	9.4%	63.7%
Total	9725	100.0%	2609	100.0%	21.2%

Absorptive capacity

Absorptive capacity for new expenditure is also not a critical issue in this project. The existence of an on-going project and the shrinking size and scope of the project minimize the risk of capacity problems. A remaining risk, however, is relatively weak implementation capacity of some of the endemic states. The size and scope of contracting for services highlights the need to strengthen implementation capacity. Management attention and technical assistance on issues relating to the procurement of contracted services is critical for mitigating these risks.

Incrementality of IDA Funds

Another small risk relates to incrementality of IDA financing. Trend analysis over the last 7 years of the NLEP shows the share of domestic spending (GOI funds) currently accounts for about 20 percent of total costs with IDA financing and contributions from WHO and Danida completing the expenditure picture. Project supervision will pay special attention to the sources of financing for the project. Financial reporting on the shares of the government, IDA, and other partner funds (WHO and Danida) should ensure that external funding does not substitute for domestic funds.

Annex 5: Financial Summary
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT
Years Ending

	IMPLEMENTATION PERIOD						
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Total Financing Required							
Project Costs							
Investment Costs	12.9	10.6	5.8	0.0	0.0	0.0	0.0
Recurrent Costs	5.2	4.6	3.1	0.0	0.0	0.0	0.0
Total Project Costs	18.1	15.2	8.9	0.0	0.0	0.0	0.0
Total Financing	18.1	15.2	8.9	0.0	0.0	0.0	0.0
Financing							
IBRD/IDA	13.0	11.0	6.0	0.0	0.0	0.0	0.0
Government	5.1	4.1	3.0	0.0	0.0	0.0	0.0
Central	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Provincial	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Co-financiers	0.0	0.0	0.0	0.0	0.0	0.0	0.0
User Fees/Beneficiaries	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Others	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Project Financing	18.1	15.1	9.0	0.0	0.0	0.0	0.0

Main assumptions:

Annex 6: Procurement and Disbursement Arrangements
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Procurement

The procurement arrangements to be undertaken in the project will be the responsibility of the implementing agency - Directorate General of Health Services (Ministry of Health and Family Welfare, Government of India) and the State and District Societies - in accordance with the Bank Procurement Guidelines and Procedures. The project would be nation wide. The focus of this project is on decentralization of leprosy control activities to States through the transfer of financial and administrative authority to State governments by forming SLS. There will be DLS also. The process of decentralization is being adopted so that the States own the project and take active part in meeting the objectives of the project. Most project activities will be in five major States which are Bihar, Madhya Pradesh, Orissa, Uttar Pradesh, and West Bengal. Activities in the other 27 States/Union Territories (UTs) will comparatively be at a very small level. Total number of districts in these States are: 53 in Bihar, 58 in Madhya Pradesh, 20 in Orissa, 81 in Uttar Pradesh, 18 in West Bengal and 300 in 27 States/Union Territories (Overall 530 districts). Major procurement will be in the above five major states. State/District Leprosy societies would be responsible for procurement of most goods, equipment and services.

A. Civil Works. There are no civil works under this project.

B. Goods. Procurement of goods (equipment, furniture, drugs and supplies) would be phased on an annual basis in accordance with the requirements of the project activities.

Furniture [US\$178,500]: Furniture involves procurement of tables, chairs, steel almirah and other items to equip the State Leprosy Societies, Sample Survey Assessment Units, and Regional Leprosy Training Institutions etc. There will be 216 packages ranging from US\$156 to US\$1445 and one package of US\$6,930 approximately. Contracts for these packages will be awarded under national shopping procedures by the above mentioned organizations and at national level by MOHFW, GOI.

Equipment [US\$121,500]: This involves (i) procurement of minor and major reconstructive surgery instruments to equip District Hospitals and Medical colleges; and (ii) Computer systems for Sample Survey Assessment Units and SLS. There will be 530 packages for minor reconstructive surgery equipment, each costing US\$110 and 111 packages for major reconstructive surgery equipment each costing US\$160 approximately. Similarly there will be 24 packages of computer systems each costing US\$1670 approximately. These items will be procured by DLS following national shopping procedures.

Vehicles [US\$400,000]: The only vehicles to be procured under this project are four wheel drive jeeps (about 42 vehicles) for all SLS and Sample Survey Assessment Units. Procurement would be done by SLS through National Shopping procedures (DGS&D rate contracts are acceptable under National Shopping) with 5 packages of US\$19,050 each and 32 packages of US\$9,525 each.

Supportive Medicines [US\$700,000]: These are required for use of patients at the time of reconstructive surgery. Cost of these supportive medicines per district per year will only be US\$440 approximately and would be procured by DLS and SLS under National Shopping or Direct contracting procedures to meet the demand. Total number of packages are 530 per year.

Multi Drug Therapy drugs in this project will be donated by Novartis Foundation and supplied by WHO free of charge.

Materials & Supplies [US\$2,200,000]: These include Micro-cellular rubber and other footwear, splints and crutches, lab reagents, patient case cards, training manual and patient welfare items (like blankets etc.)

and will be provided to the patients as and when the need arises. However, total number of packages and value of each package is indicated in Attachment I to this Annex 6. Each of these items/packages will be procured through National Shopping procedures and/or by direct contracting by DLS.

C. Services. Procurement of services is planned for a range of project activities which include medical & surgical services, information, education and communication, training and workshops, campaign for case detection, contractual services, research & studies including thesis support and other consultant services.

Medical and Surgical Services [US\$300,000]: These services are required for performing reconstructive surgery and shall be procured by the DLS under contracts awarded to designated healthcare centers selected for their suitability to perform such services on sole source basis. Provision has been made for 50 operations per year in each of the 31 centers in endemic areas during the project period of three years at a flat rate of US\$65 approximately per surgery. Total cost per center per year will be US\$3,250 approximately.

Information, Education and Communication [US\$5,000,000]: Production and implementation of mass media activities in educating the people through Television, Radio, Newspapers etc. will be carried out by hiring the services of an agency following Quality and Cost Based Selection procedures. Total estimated cost of this consultancy service is US\$2.45 million approx.

Outdoor IEC services i.e. hoarding, painting/hoarding on bus shelters, kiosks, etc., will be carried out by each district separately on sole source basis value of each contract being small. Total value of these services per State per year in 5 major states will be in the range of US\$6,770 to US\$19,150. In each of the other 27 States/Union Territories cost per year will still be much lower. Total cost of these services is estimated at US\$354,000 approximately.

Rural activities i.e. wall paintings, leaflets, posters, etc., will also be carried out by each district on the same basis as for Outdoor activities. There will be at least two packages per district per year – one package for wall paintings and the other for leaflets/posters. Total number of districts are 530. Value of these services per state per year in 5 major States will be in the range of US\$34,670 to US\$97,280 equivalent. In the other 27 States/UTs cost per state per year will be much lower. Total cost of these services is estimated at US\$1.651 million approximately.

Production of spots for radio and television will be arranged by MOHFW at the national level. This activity will be for the first two years of the project only and will cost US\$118,000 per year. Since contracts will be awarded for radio and television spots separately, value of each contract will be less than US\$100,000 equivalent and therefore these services will be procured under sole source method of selection.

Political advocacy efforts would comprise activities like publicity services for Asian Leprosy Congress in year 2000 and Gandhi Jayanti on 2 October and Martyr's Day on 30 January every year against stigmatization of those affected by leprosy. In addition meetings will be held with members of the State legislatures to sensitize them about the leprosy program. Total cost of this activity at national level will be US\$47,000 and in all the 32 States/UTs put together at US\$250,000 approximately with cost in any State/UT not exceeding US\$11,800. These services will also be procured on sole source basis, value per contract being very small.

Consultant Services: These services will be hired at national level and will include (i) development, installation and training in computerized financial management system to be procured under sole source costing US\$47,000 approximately; (ii) individual consultant to be appointed for developing strategic plan for IEC including advertisement and publicity at a cost of US\$11,790 approximately per year; (iii) individual training consultant for second and third year of the project costing US\$11,790 approximately each year; (iv) hiring of an agency for independent survey during year one and two of the project costing US\$47,000 each year; and (v) hiring of an agency for independent final evaluation in the third year of the

project at a cost of US\$47,000 approximately following Quality and Cost Based Selection procedures.

Consultancy services for Research and Studies which includes (i) data validation at a cost of US\$25,950 per year for all the three years of the project; (ii) study on organizing model camps for prevention of disability at a cost of US\$9,400 in the second year of the project; and (iii) operations research on general health services staff at a cost of US\$13,900 in the second year of the project shall be procured following sole source method of selection, value of each contract being small.

As part of research and studies, the project also intends to support thesis of scholars (individuals doing MD/Ph.D in the field of leprosy) at a total cost of US\$26,100 approximately @ US\$235 per student over a period of three years under the project.

Terms of Reference, irrespective of value, would be subject to prior review by the Association.

NGO services: NGOs will provide services and technical support in training, monitoring and surveillance, independent assessment, operations research, disability prevention and care and rehabilitation. NGOs shall be provided grant-in-aid by the GOI which will not be financed under this project (Mostly NGOs will be selected on the basis of terms of reference agreed to by the Association).

Training and workshops [US\$3,200,000]: This includes expenditure on (i) training of health staff, Anganwadi Workers and other community workers, Panchayati Raj members etc. for MLEC, IEC, Prevention of Disability, Community Participation and Orientation. Cost pertains to arranging meetings, training materials, expert services and related fees; (ii) co-ordination workshops with State Officers and NGOs; (iii) workshops for review of the performance of program districts every year; (iv) review meetings at regional level with District Leprosy Officers, Chief Medical Officers, etc.; and (v) training of trainers. The training and workshops will be arranged at State and District level on sole source basis, value of each contract being less than US\$100,000.

Contractual Staff [US\$10,500,000]: Large number of individuals such as medical officers, para medical workers, non medical supervisors etc. for deliver of services on a contract basis shall be hired to manage the works of newly formed State / Districts Leprosy Societies and Sample Survey Assessment Units in all the 32 States and Union Territories. At the beginning of the project these will number 3500 which will get reduced to 1800 by the end of the project period. Each contract will be less than US\$10,000. The job description, minimum qualifications, terms of employment, range of remuneration payable and selection procedures shall be agreed with the Association. Letter of agreement for short term assignments for individual consultants to be entered by the project authorities will follow the Bank's model format.

Campaigns for Leprosy Case Detection [US\$ 5,500,000]: These services include MLEC, SAPEL, and LEC in each year of the project for leprosy case detection in tribal endemic pockets and in relatively inaccessible areas, including urban slums of the districts in the States/UTs. For this large numbers of individuals (searchers, helpers, and confirmators for a limited period of 6 days or so and volunteers) will be hired on contract basis with aggregate counseling fee of US\$4,750,000 approximately. The job description, minimum qualifications, terms of employment, range of remuneration payable and selection procedures shall be agreed with the Association. Letter of agreement for short term assignments for individuals to be entered by the project authorities will follow the Bank's model format.

This activity also includes other services like procurement of diagnostic cards, learning materials, patient travel cost, supportive medicines and mobility support at a total cost of US\$750,000 approximately. Value of these items for each of the five major States and 27 States/UTs are indicated in Attachment I to this Annex 6. Diagnostic cards and mobility support required for MLEC and Voluntary Reporting Centers will be procured during first and second year of the project whereas learning materials, patient travel cost, and supportive medicines under SAPEL/LEC will be procured during all the three years of the project. These items will be procured every year as mentioned above under sole source (by direct contracting) by the

SLS/DLS and value of each item per State/District per year will be less than US\$30,000.

D. Miscellaneous. This involves operational expenses for all the components of the project and would include honoraria (awards) for health workers, office operations, vehicle operation (maintenance of vehicles, vehicle hire and mobility support) and consumables. These would be procured on the basis of direct contracting, or three quotations depending upon the situation.

E. Since all the contracts for goods, equipment, medicines, vehicles etc. shall be below US\$30,000 and contracts for consultancy services shall also be of small value except one contract of IEC, prior reviewed by the Association will be for this IEC contract and the terms of reference for all consultancy services.

For National shopping Bank's New Delhi Office model document E-5 and format of letter of agreement for short term assignments of individual consultants given in Bank's New Delhi Office model documents C-10 (Time-Based) or C-8 (Lump Sum) shall be adopted.

For supportive medicines, furniture and other items to be procured under national shopping and/or direct contracting, the norms for such procurement i.e. acceptable range of prices and acceptable/preferable brand names shall be clearly indicated either in the PIP or in the guidelines to the States/UTs so that these are followed by the SLS/DLS while procuring these items.

F. Cost estimate of the items to be procured, estimates of Bid packages for procurement of goods/equipment/consultancy services, details of value of goods/equipment/consultancy services for each year and Procurement Schedule of goods/equipment/consultancy services for all the three years of the project including Retroactive Financing are attached with the PIP of the Borrower.

Procurement Methods (Table A)

IDA financed works and goods will be procured in accordance with Bank Guidelines – Procurement under IBRD Loans and IDA Credits (January 1995, Revised January and August 1996, September 1997 and January 1999). IDA financed services will be procured using Bank Guidelines – Selection and Employment of Consultants by World Bank Borrowers, (January 1997, Revised September 1997 and January 1999). For procurement under the project, the Bank's standard bidding documents shall be used. Attachment II to this Annex 6 summarizes procedures for undertaking procurement on the basis of National Competitive Bidding.

Specific Procurement arrangements summarized in table 'A' are as follows:

- Contracts for the purchase of goods/equipment valued at more than US\$200,000 equivalent each would be procured through International Competitive Bidding.
- Contracts valued more than US\$30,000 but less than US\$200,000 may be awarded on the basis of National Competitive Bidding procedures acceptable to IDA.

Items or groups of items valued US\$30,000 equivalent or less per contract may be procured on the basis of national shopping procedures.

Other items or small groups of items such as supply of furniture, equipment, medicines, materials and other supplies valued at less than US\$10,000 equivalent per contract may be procured through direct contracting.

- Contracts estimated to cost the equivalent of US\$10,000 or less per contract for maintenance of vehicles, hiring of vehicles and consumables may be awarded through:

- Direct Contracting; or
- National Shopping.

Prior Review Thresholds (See Table B)

- All contracts for goods/equipment except vehicles with an estimated value of more than US\$200,000 equivalent.
- All contracts of procurement for vehicles with an estimated value of more than US\$100,000.
- The first National Competitive Bidding contract for goods / pharmaceuticals regardless of the value.
- Consultants' contracts with an estimated value of US\$100,000 or more for firms and US\$50,000 or more for individuals.

Procurement methods (Table A)

<i>Table A: Project Costs by Procurement Arrangements</i>						
(US \$ million equivalent)						
		ICB	NCB	Other	N.B.F	Total Cost
1	Goods					
	Furniture and Equipment	-	-	0.30	-	0.30
				(0.24)		(0.24)
	Vehicles	-	-	0.40	-	0.40
				(0.32)		(0.32)
	Supportive Medicines	-	-	0.70	-	0.70
				(0.56)		(0.56)
	Materials & Supplies	-	-	2.20	-	2.20
				(1.77)		(1.77)
2	Services					
	IEC & Campaign for case detection	-	-	10.50	-	10.50
				(10.50)		(10.50)
	Training & Workshop, Research & Studies	-	-	3.30	-	3.30
				(3.30)		(3.30)
	Consultant Services & Contractual Services	-	-	10.70	-	10.70
				(10.70)		(10.70)
	Medical/Surgical Services	-	-	0.30	-	0.30
				(0.30)		(0.30)
	NGO services	-	-	-	0.80	0.80
3	Operating Costs					
	Salaries etc	-	-	-	7.30	7.30
	Honoraria	-	-	0.40		0.40
				(0.16)		(0.16)
	Vehicle operation	-	-	4.60		4.60
				(1.84)		(1.84)
	Office operation and consumables	-	-	0.70		0.70
				(0.30)		(0.30)
	Total			34.10	8.10	42.20
				(30.00)		(30.00)

Note: Figures in the Parenthesis are the respective amounts financed by IDA/IBRD.

"Other" method of procurement includes Direct Contracting, Comparison of price quotations(Shopping) and Consulting services.

Table A1: Consultant Selection Arrangements (optional)
(US\$ million Equivalent)

Consultant Services Expenditure Category				Selection	Method			Total Cost ¹
	QCBS	QBS	SFB	LCS	CQ	Other	N.B.F.	
A. Firms	2.57 (2.57)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	6.91 (6.91)	0.00 (0.00)	0.00 (0.00)	9.48 (9.48)
B. Individuals	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	15.32 (15.32)	0.00 (0.00)	15.32 (15.32)
Total	2.57 (2.57)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	6.91 (6.91)	15.32 (15.32)	0.00 (0.00)	24.80 (24.80)

¹Including contingencies

Note: QCBS = Quality- and Cost-Based Selection

QBS = Quality-based Selection

SFB = Selection under a Fixed Budget

LCS = Least-Cost Selection

CQ = Selection Based on Consultants' Qualifications

Other = Selection of individual consultants (per Section V of Consultants Guidelines), Commercial Practices, etc.

N.B.F. = Not Bank-financed

Figures in parenthesis are the amounts to be financed by the Bank Credit.

Prior review thresholds (Table B)

TABLE B: THRESHOLDS FOR PROCUREMENT METHODS AND PRIOR / POST REVIEW

Expenditure Category	Value per Contract (Threshold)	Procurement method	Contracts Subject to Prior / Post Review	Value of Prior Review
1. Civil Works	There are no civil works under this project	----	----	----
2. Goods				
(a) Equipment, Furniture, Supportive Medicines, Materials & Supplies.	(a) US\$30,000 or less per contract, up to an aggregate amount not exceeding US\$2,400,000 equivalent as under:			
	(i) Furniture up to an aggregate not exceeding US\$160,000	National Shopping Procedures (includes DGS& D Rate Contracts)	Post review only.	----
	(ii) Equipment up to an aggregate not exceeding US\$110,000	National Shopping Procedures (includes DGS& D Rate Contracts)	Post review only.	----
	(iii) Supportive medicines up to an aggregate not exceeding US\$150,000.	National Shopping Procedures (includes DGS& D Rate Contracts)	Post review only.	
	(iv) Materials & Supplies up to an aggregate not exceeding US\$1,980,000	National Shopping Procedures (includes DGS& D Rate Contracts)	Post review only.	-----
	(b) Less than US\$10,000 per contract up to an aggregate not exceeding US\$800,000.	Direct Contracting	Post review only.	----
	(c) More than US\$30,000 but less than US\$200,000 per contract.	National Competitive Bidding	First goods NCB contract from any one State estimated to cost more than US\$30,000 but below US\$200,000 equivalent and each contract of goods estimated to cost more than US\$200,000 equivalent each by prior review in accordance with paragraphs 2 and 3 of Appendix-1 to the Guidelines.	None anticipated at this stage.

	(d) Above US\$200,000 equivalent per contract.	International Competitive Bidding	Contracts valued at more than US\$200,000 equivalent each by prior review in accordance with paragraphs 2 and 3 of Appendix-1 to the Guidelines. All others: By post review.	None anticipated at this stage.
(b) Vehicles	US\$100,000 equivalent or less per contract, up to an aggregate not exceeding US\$400,000 equivalent. Above US\$100,000 equivalent per contract	National Shopping Procedures (includes DGS& D Rate Contracts) International Competitive Bidding	Post review only. All ICB contracts of vehicles irrespective of value by prior review in accordance with paragraphs 2 and 3 of Appendix-1 to the Guidelines.	----- None anticipated at this stage.
3. Services (a) IEC Services	Above US\$200,000 equivalent per contract up to an aggregate of US\$2,450,000	Quality and Cost Based Selection	Prior review of all consultant contracts shall be governed by the provisions of paragraphs (i), (ii), and (iii) below:	US\$2.45 million
(b) Professional Services Contract, Mass Media/IEC, Training & Workshops and Medical/Surgical Services.	US\$200,000 or less per contract	Quality and Cost Based Selection with Short List (may be comprised entirely of national consultants)	(i) With respect to each contract for the employment of consulting firms estimated to cost the equivalent of US\$100,000 or more, procedures set forth in paragraphs 1, 2 [other than the third sub-paragraph of paragraph 2 (a)] and 5 of Appendix 1 to the Consultant Guidelines shall apply.	None anticipated at this stage.

<p>(c) Training & Workshops, Mass Media/IEC, Research and Studies, Evaluation, Medical/Surgical Services and Financial Management Services.</p>	<p>US\$100,000 equivalent or less per contract up to an aggregate amount not exceeding US\$7,030,000 equivalent.</p>	<p>(i) Quality and Cost Based Selection with Short List (may be comprised entirely of national consultants); and (ii) Single Source Selection in accordance with paragraphs 3.8 to 3.11 of the Consultant Guidelines.</p>	<p>(ii) With respect to each contract for the employment of individual consultants estimated to cost the equivalent of US\$50,000 or more, the qualifications, experience, and terms of employment of the consultants shall be furnished to the Association for its prior review and approval. (iii) Terms of Reference (TOR) in all cases. All Other Cases: Post Review.</p>	<p>----- -----</p>
<p>(d) Service delivery contractors for campaigns for case detection, contractual and individual consultants</p>	<p>US\$10,000 equivalent or less per contract up to an aggregate amount not exceeding US\$15,320,000</p>	<p>(i) Selection in accordance with paragraph 3.19 of the Consultant Guidelines; and (ii) Selection of Individual Consultants in accordance with paragraphs 5.1 to 5.3 of Consultant Guidelines</p>	<p>Job description and experience, minimum qualifications, terms of employment and selection procedures shall be agreed with the Association. Job description and experience, minimum qualifications, terms of employment and selection procedures shall be agreed with the Association.</p>	<p>----- -----</p>
<p>4. <u>Miscellaneous</u> Incremental Operational Costs, vehicle operation and consumables</p>	<p>Incremental operating costs, vehicle hire, maintenance of vehicles and consumables estimated to cost the equivalent of US\$ 10,000 or less per contract, up to an aggregate not exceeding US\$4,840,000 may be executed by: (i) direct contracting up to an aggregate not exceeding US\$1,000,000; or (ii) on the basis of comparison of price quotations obtained from at least three qualified suppliers eligible under the guidelines.</p>	<p>Direct contracting Solicitation of three bids</p>	<p>Post review only Post review only</p>	<p>----- -----</p>

Disbursement

The proposed allocation of loan proceeds is given in Table C.

The disbursement will initially be made in the traditional system (reimbursement with full documentation and against statement of expenditure) and will be converted to Project Management Report based disbursement after the financial management system has been demonstrated to be operating satisfactorily. The target date for this conversion is September 1, 2002.

Financial Management

Current Financial Management System

The project is a follow-on project to the on-going National Leprosy Elimination Project (Cr. 2528) which closed on September 30, 2000. The implementing agency for both the Projects is Directorate General of Health Service (Leprosy Division) in the Ministry of Health and Family Welfare. DGHS(LD) will be supported in the execution of the project by participating states. DGHS(LD), which has considerable experience of running the NLEP in India has the following strengths: (i) a budgeting and accounting system has been established and is operational (ii) staff are trained to carry out basic accounting functions; and (iii) a system of periodic financial reporting from the districts to DGHS(LD) is operational.

However, it must be emphasized that although DGHS(LD) has experience in the project management, the State Leprosy Societies who are going to be key partner in the project are at an initial stage of inception. In fact, out of the 24 SLS proposed to be created, only 15 have been established so far. Nonetheless, at the district level, the District Leprosy Societies are already in place. Considerable effort will need to be made by DGHS(LD) to build capacity quickly in the State Societies on financial management.

Specific areas to be strengthened:

The following aspects need to be addressed to ensure that a satisfactory financial management system commensurate with the size and scope of the project is established:

- (a) satisfactory staffing and training: Financial functions should be staffed by suitably qualified accounts professionals. DGHS (LD) should be supported by a full-time financial controller who can actively aid in setting up the financial management system in the project. The SLS also need to be suitably staffed with accounts staff. At the district level, there is a need to identify accounts personnel who will be working exclusively on the project. The entire financial staff at Central and state level needs to be trained in the operation of the computerized financial management system. Project managers and financial staff need to be sensitized to the importance of financial management for effective project management.
- (b) there is a need for a good financial monitoring system at the GOI level. Currently the financial monitoring of the districts is poor and the review of district audit reports not focussed. There is not much of a concept of funds management. Funds to the districts are released once in a year and there is no mechanism designed to track the amounts advanced to and expenditure reported by the DLS.
- (c) the need to analyze financial information and use it as a decision making tool: Financial reports which provide timely and quality information on the financial performance of the project should be prepared.
- (d) ensuring satisfactory audit arrangements including timely submission of audit reports.
- (e) ensuring linking of physical progress with the financial progress.

(f) need for enhanced clarity and consistency of activities and expenditures which are being charged as project expenditure

DGHS(LD) will develop and implement a comprehensive computerized financial management system which will address all these issues in detail.

The project financial management system (PFMS) would, inter alia, include: (i) funds flow process; (ii) detailed accounting system (including the Chart of Accounts; formats of financial reports; linkages between the Chart of Accounts and financial reports; inputs of budget and other data; data capture, information flow and processing); (iii) internal control mechanisms; (iv) budgeting and forecasting system; and (v) auditing arrangements. The Financial Management System will be supported by an operations manual which would serve as a reference document for all project staff.

Budgeting and Flow of Funds

The funding to DGHS(LD) would be through the Ministry of Health Budget with project funds as a special allocation.

Flow of funds from DGHS(LD) to SLS will be on a semi-annual basis through banking channels. The initial allocation will be based on the cash flow forecasts of SLS (which in turn would be based on their work programs and budgets). The funds from the SLS to the DLS will also be transferred on a half yearly basis. Subsequent funding will be based on performance of key indicators and the projected funds requirement of the SLS / DLS respectively.

Accounting and Internal Controls

The overall framework of the system is given below:

- The PFMS would cover all project-related transactions, i.e., all sources of funds would be accounted for and reflected in the project financial statements; and similarly all project expenditures would be reflected in the project financial statements.
- A chart of accounts will be developed. The chart of accounts will enable the expenditure data to be captured and classified by project components and expenditure categories. The chart of accounts will have linkages to: (i) government budget heads/categories; (ii) disbursement categories and (iii) project components.
- The financial management system is being computerized. The computerized system will be installed and operated at DGHS(LD) and the participating SLS. The participating DLS in the states will be expected to feed the SLS with the financial information on a manual basis.
- The consolidation of accounts will be done first (i) at the SLS level by consolidating the expenditure of the SLS and all the DLS in the state and then (ii) at DGHS(LD) in MOHFW by consolidating the accounts of DGHS(LD) and all the SLS.
- Standard books/records of accounts (cash and bank-books, journals, ledgers, trial balance, etc.) will be maintained at the DGHS(LD) and SLS using an integrated computerized accounting system. A register of fixed assets, indicating assets created through the project or acquired under the project, will also be maintained using the computerized system.

Transaction Information Flow and Accounting

DGHS(LD), SLS and DLS will generate and maintain the transaction vouchers for their various receipts and expenditures made at DGHS(LD), SLS and DLS levels respectively.

Data transfer would be handled through: (i) an integrated computer network; or (ii) periodic data transfer through Electronic Mail or floppy diskettes.

Internal Controls

Internal control mechanisms would include the following:

1. the establishment of appropriate budgeting systems, and regular monitoring of actual financial performance with budgets and targets;
2. development and adoption of simple, clear and transparent financial and accounting policies which would govern financial management and accounting for the project. These policies and procedures would include identification of expenditures which can be charged to the project, and the categories under which the expenditures would be charged; the policies and procedures for transfer of funds and accounting of expenditures; etc.
3. at the transaction level, the establishment of procedures and systems for ensuring standard internal controls such as checking of expenditures, appropriate documentation, levels of authorization, segregation of incompatible duties, periodic bank reconciliation, physical verification, etc.

Staffing

The finance and accounting department at DGHS(LD) would be headed by the designated Deputy Secretary who will function ex-officio as the Financial Coordinator for the project. His team will include two finance officers and 3/4 accountants/data entry operators.

The Finance and Accounting Department at large SLS (viz. Bihar, MP, Orissa, UP and West Bengal) will comprise of a Budget and Finance officer, 1 data entry operator and 1 accountant. In the other 19 SLS, the financial and accounting staff will comprise of 1 Budget and Finance Officer supported by a data entry operator. **The funds will be transferred to the state only after the accounting staff is in position and has been adequately trained.** At the DLS level, for the 300 societies which are in high endemic region, the accounting will be done by an accounts supervisor supported by an accounts clerk, where as in the 250 low endemic societies, the accounting function will be assigned to an existing staff in the department who will maintain accounts for the DLS.

An intensive training program will be developed to ensure that the staff at all the levels are adequately trained in the computerized PFMS. The initial training will be imparted by the consultants developing the computerized PFMS.

Financial Reporting

Quarterly Financial Management Reports will include:

- comparison of budgeted and actual expenditure and analysis of major variances, including on aspects such as sources of funds (indicating separately funds from beneficiaries) and application of funds (classified by components, sub-components, summarized expenditure categories, etc.);
- comparison of budgeted and actual expenditure and analysis of major variances on key physical parameters;
- forecasts for the next 2 quarters; and
- information on procurement management for major contracts.

Project Financial Statements and Financial Management Reports would be generated from the computerized financial management system. DGHS(LD) would generate quarterly financial management reports from the integrated computerized PFMS for the whole project. The SLS will also have the capability of generating these reports for their own monitoring needs. These reports and the Withdrawal Application (which would be based on the financial forecasts and actual expenditures classified by disbursement category) would also be used by the Bank for quarterly disbursements in accordance with the disbursement procedures under Loan Administration Change Initiative.

The reporting from DLS to the SLS and from SLS to DGHS(LD) will be quarterly.

Auditing Arrangements

DGHS(LD) Accounts will be audited by the Comptroller and Auditor General of India. The SLS will be audited by firms of Chartered Accountant and the audit would include a statement on the audit status of the DLS in the state based on Chartered Accountant audits of the DLS. An audited annual project financial statement will be submitted by DGHS(LD) and all the participating states within 6 months of the close of GOI's fiscal year.

Thus the following audit reports will be monitored in Audit Reports Compliance System:

<u>Implementing Agency</u>	<u>Audit</u>	<u>Auditors</u>
DGHS(LD)	SOE/Project Audit	Comptroller and Auditor General
All SLS	SOE/Project Audit	Chartered Accountant firms
Department of Economic Affairs/GOI	Special Account	Comptroller and Auditor General

In accordance with the World Bank's Operational Policies, the Terms of Reference of the firm of Chartered Accountants auditing the SLS should be reviewed by the World Bank. The firms of Chartered Accountants would be appointed before the start of the project.

Under the previous project there were lapses on the part of DGHS(LD) on timely submission of audit reports to the Bank which was a cause for suspension of Statement of Expenditure disbursements. DGHS(LD) will need to ensure that in the upcoming project, special attention is paid to this aspect of the

project and the audit reports are submitted in time.

Time Table for implementation of Project Financial Management System and next steps

The proposed computerized PFMS will be developed for DGHS(LD) with the help of consultants specifically appointed for the purpose of designing, developing and instituting the computerized project financial management system in the project.

The following key activities will need to be completed to successfully implement the computerized PFMS:

<u>Activity</u>	<u>Target Date</u>
Procurement of computers	March 31, 2001
Development and installation of the Project Financial Management System software	June 30, 2001
Appointment of accounts personnel at SLS	July 31, 2001
Training on financial management system in the PFMS software	September 30, 2001
Implementation of the computerized financial management system	October 1, 2001
Conversion to PMR-based system of disbursement	October 1, 2002

Disbursement

Allocation of credit proceeds (Table C)

Table C: Allocation of Credit Proceeds

Expenditure Category	Amount in US\$million	Financing Percentage
1. Goods: Includes: US\$0.24 million: Furniture&Equipment US\$0.32 million: Vehicles US\$0.56 million: Supportive medicines US\$1.77 million: Materials & Supplies	2.90	80%
2. Services: Includes: US\$5.00 million: IEC US\$5.50 million: Campaigns US\$3.20 million: Training &Workshops US\$0.10 million: Research & Studies US\$0.20 million: Consultant Services US\$10.50 million: Contractual services US\$0.30 million: Medical & surgical services	24.80	100%
3. Incremental Operating Costs Includes: US\$0.16 million: Honoraria US\$1.84 million: Vehicle hire & maintenance. US\$0.30 million: Office operation & consumables.	2.30	60% of local expenditures incurred until July 31, 2002; 40% of expenditures incurred from August 1, 2002 until July, 2003; 20% of expenditure incurred thereafter, i.e. 40% overall.
Total Project Costs	30.00	
Total	30.00	

Note: Amounts are inclusive of contingencies

Use of Statement of Expenditures (SOE)

The Bank may require withdrawals from the credit to be made on the basis of statements of expenditure for:

- (a) goods and works under contracts not exceeding US\$ equivalent;
- (b) services under contracts not exceeding US\$ equivalent for employment of consulting firms and US\$ equivalent for employment of individual consultants respectively;
- (c) training and fellowships
- (d) incremental operating expenses

Special Account: A Special Account would be maintained in the Reserve Bank of India; and would be operated by the Department of Economic Affairs of Government of India. The authorized allocation of the Special Account would be US \$2.5 million which represents about 6 months of initial estimated disbursements from the IDA Credit. The Special Account would be operated in accordance with the Bank's operational policies

Attachment I

A. Materials & Supplies:

Item	No. of Packages	Approximate Cost per package
Footwear	530 per year	US\$285
Splints and Crutches	530 per year	US\$145
Lab Reagents	530 per year	US\$285
Patient Welfare Items	530 per year	US\$285
Training Manual	530 packages	US\$955
Patient Case Cards	230 packages	US\$335
Patient Case Cards	300 packages	US\$110

B. Campaign for Case Detection:

[Cost in US\$]

	Madhya Pradesh	Orissa	Uttar Pradesh	Bihar	West Bengal	27 States/ UTs
Diagnostic Cards* (Year 1 & 2)	5,940	1,660	14,220	13,760	5,990	-
Learning material ** (Year 1, 2 & 3)	15,590	12,240	37,840	34,500	17,810	42,290
Patient Travel ** (Year 1, 2, & 3)	15,590	12,240	37,840	34,500	17,810	42,290
Supportive Medicines** (Year 1, 2 & 3)	31,170	24,480	75,690	69,000	35,620	84,580
Mobility support (POL)* (Year 1 & 2)	8,140	2,940	16,630	11,020	3,610	-

* Under modified Leprosy elimination campaign (MLEC) and voluntary reporting center (VRC).

** Under Special Action Plan for Elimination of Leprosy (SAPEL)

Attachment II

With reference to the procedures for undertaking procurement on the basis of National Competitive Bidding referred to in Part C of Section I, Schedule 3 of the Development Credit Agreement, all National Competitive Bidding contracts shall be awarded in accordance with the provisions of paragraphs 3.3 and 3.4 of the Guidelines for Procurement under IBRD Loans and IDA Credits published by the Bank in January 1995 and revised in January and August 1996, September 1997 and January 1999 (the Guidelines). In this regard, all NCB contracts to be financed from the proceeds of the Credit shall follow the following procedures:

- [1] Only the model bidding documents for National Competitive Bidding agreed with the Government of India Task Force [and as amended from time to time], shall be used for bidding.
- [2] Invitations to bid shall be advertised in at least one widely circulated national daily newspaper, at least 30 days prior to the deadline for the submission of bids.
- [3] No special preference will be accorded to any bidder when competing with foreign bidders, state-owned enterprises, small-scale enterprises or enterprises from any given State.
- [4] Except with the prior concurrence of the Bank/Association, there shall be no negotiation of price with the bidders, even with the lowest evaluated bidder.
- [5] Except in cases of force majeure and/or situations beyond control of Ministry of Health & Family Welfare, Government of India and State / District Leprosy Societies, extension of bid validity shall not be allowed without the prior concurrence of the Association [i] for the first request for extension if it is longer than eight weeks; and [ii] for all subsequent requests for extension irrespective of the period.
- [6] Re-bidding shall not be carried out without the prior concurrence of the Bank/Association. The system of rejecting bids outside a pre-determined margin or "bracket" of prices shall not be used.
- [7] Rate contracts entered into by DGS&D will not be acceptable as a substitute for NCB procedures. Such contracts will be acceptable for any procurement under National Shopping procedures.

Annex 7: Project Processing Schedule
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

Project Schedule	Planned	Actual
Time taken to prepare the project (months)		11
First Bank mission (identification)		11/22/99
Appraisal mission departure	09/30/2000	11/15/2000
Negotiations	02/19/2001	02/20/2001
Planned Date of Effectiveness	07/01/2001	

Prepared by:

Directorate General of Health Services (Leprosy Division), Ministry of Health and Family Welfare,
 Government of India

Preparation assistance:

WHO: Denis Daumerie, Vijay Pannikar, Mika Kawano
 Danida: Bouwedjin Peters

Bank staff who worked on the project included:

Name	Speciality
Peter Heywood	Lead Health Specialist (Team Leader)
Suneeta Singh	Senior Public Health Specialist
David Peters	Senior Public Health Specialist
Mam Chand	Senior Procurement Specialist
Rajat Narula	Senior Financial Management Specialist
Abdo Yazbeck	Senior Economist
Rashmi Sharma	Social Development Specialist
Shreelata Rao-Seshadri	Consultant
Supriya Mukherji	Consultant
Mohammad Nawaz	Consultant, LEGOP
Nina Badgaiyan	Consultant
Nira Singh	Office Administrator

Annex 8: Documents in the Project File*
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

A. Project Implementation Plan

Project Implementation Plan Part-A: National Plan, Part-B: Plans for Five High Endemic States, Part-C: Plans for 27 Low Endemic States: National Leprosy Eradication Program for Phase II of World Bank support, Ministry of Health and Family Welfare, Government of India, Dec 5, 2000

B. Bank Staff Assessments

IDA. Identification Mission: Second National Leprosy Elimination Project. *Aide Memoire, Nov 1999.*

IDA. Second National Leprosy Elimination Project: *Project Information Document.*

IDA. Second National Leprosy Elimination Project: *Environmental Data Sheet, Dec 2000.*

Heywood, P. and Singh, S., *Institutional Assessment, Sept 2000.*

Sharma, R. and Rao-Seshadri, S., *Social Assessment, Oct 2000.*

Yazbeck, A., *Economic Assessment, Sept 2000.*

C. Other

NLEP Phase II: *Review of Contracting Mechanism for NGOs: PriceWaterhouseCoopers, Sept 2000.*

Action Plans for 2nd Phase Project, National Leprosy Elimination Program: Uttar Pradesh, Bihar, MP, Maharashtra, Aug/Sept 2000.

Report on Independent Evaluation of National Leprosy Eradication Program, India: National Institute of Epidemiology, Chennai, Aug 2000.

Leprosy Elimination: Track Records and Prospects: Ed. David K. Warndorff, Tropical Medicine and International Health, Vol.5, Jun 2000.

Mycobacterium Leprae - Millennium Resistant Leprosy Control on the Threshold of a New Era: Visschedijk et al, Tropical Medicine and International Health, Vol.5, No.6, Jun 2000.

Leprosy After the Year 2000: Ben Naafs, Tropical Medicine and International Health, Vol.5, No.6, Jun 2000.

NLEP PHC Synergy, Process & Impact of Integration of Leprosy with Primary Health Care - An Evaluation: Community Health Department, Christian Medical College, India, Jun 2000.

Working Together for Better Results - Integration of Leprosy with Primary Health Care Services: DANLEP, Orissa, Mar 2000.

The Source of Infection: An Unsolved Issue: Symposium Paper, Indian J Lepr, Vol. 72(2), 2000.

Impact Evaluation of the Modified Leprosy Elimination Campaign (BBC): ORG Centre for Social Research, Nov 1999.

The Final Push: The Global Alliance for Leprosy Elimination, WHO, Nov 1999.

Minutes of Annual Conference of Voluntary Organizations involved in Leprosy (RLTRI Raipur), Directorate of Health Services, Government of India, Jul 1999.

Report on the Modified Leprosy Elimination Campaign under NLEP: Directorate General of Health Services (LD), Nirman Bhawan, New Delhi, 1999.

Gender and Health, A Handbook for Health Workers: Directorate of Public Health and Preventive Medicine, Chennai, 1997.

*Including electronic files

Annex 9: Statement of Loans and Credits
INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT
20-Sep-2000

Project ID	FY	Purpose	Original Amount in US\$ Millions				Cancel.	Undisb.	Difference between expected and actual disbursements ^a	
			IBRD	IDA	SF	GEF			Orig	Frm Rev'd
P045051	1999	2ND NATL HIV/AIDS CO	0.00	191.00			0.00	166.81	3.17	0.00
P049301	1997	A.P. EMERG. CYCLONE	50.00	100.00			0.00	95.50	93.05	0.00
P010407	1993	ADP - RAJASTHAN	0.00	106.00			0.00	13.57	16.86	0.00
P010503	1995	AGRIC HUMAN RES DEVT	0.00	59.50			0.00	17.38	20.53	0.00
P010489	1995	AP 1ST REF. HEALTH S	0.00	133.00			0.00	43.01	20.14	0.00
P045049	2000	AP DPIP	0.00	111.00			0.00	106.85	0.00	0.00
P049385	1998	AP ECON RESTRUCTURIN	301.30	241.90			0.00	401.16	92.44	0.00
P010449	1994	AP FORESTRY	0.00	77.40			0.00	5.97	6.97	0.00
P035158	1997	AP IRRIGATION III	175.00	150.00			0.00	232.16	83.13	0.00
P049537	1999	AP POWER APL I	210.00	0.00			0.00	147.82	48.16	0.00
P010522	1995	ASSAM RURAL INFRA	0.00	126.00			0.00	80.02	50.79	3.13
P010455	1994	BLINDNESS CONTROL	0.00	117.80			0.00	68.58	51.93	0.00
P010480	1996	BOMBAY SEW DISPOSAL	167.00	25.00			0.00	103.01	96.58	0.00
P043310	1996	COAL ENV & SOCIAL MITIGATION	0.00	63.00			0.00	35.04	25.93	0.00
P009979	1998	COAL SECTOR REHAB	530.00	2.00			268.70	36.67	139.94	139.94
P009870	1994	CONTAINER TRANSPORT	94.00	0.00			15.00	42.81	57.81	53.54
P010464	1995	DISTRICT PRIMARY ED	0.00	260.30			0.00	94.27	63.77	0.00
P035821	1996	DPEP II	0.00	425.20			0.00	204.77	18.65	0.00
P038021	1998	DPEP III (BIHAR)	0.00	152.00			0.00	122.69	61.46	0.00
P036062	1997	ECODEVELOPMENT	0.00	28.00			0.00	19.11	11.20	0.00
P043728	1997	ENV CAPACITY BLDG TA	0.00	50.00			0.00	39.46	24.47	0.00
P010563	1995	FINANCIAL SECTOR DEV PROJ. (FSDP)	700.00	0.00			301.30	88.43	0.00	0.00
P010448	1994	FORESTRY RESEARCH ED	0.00	47.00			0.00	11.66	30.67	0.63
P010566	2001	GUJARAT HWYS	381.00	0.00			0.00	381.00	0.00	0.00
P035160	1998	HARYANA POWER APL-I	60.00	0.00			0.00	28.06	23.40	0.00
P010485	1996	HYDROLOGY PROJECT	0.00	142.00			0.00	71.85	72.47	0.00
P009977	1993	ICDS II (BIHAR & MP)	0.00	194.00			0.00	96.41	100.83	100.18
P039935	1996	ILFS-INFRA FINANCE	200.00	5.00			0.00	178.79	153.86	0.00
P067330	2000	IMMUNIZATION STRENGTHENING PROJECT	0.00	142.80			0.00	139.54	0.00	0.00
P010463	1995	INDUS POLLUTION PREV	143.00	25.00			1.64	141.63	129.85	4.00
P010418	1993	KARNATAKA WS & ENV/S	0.00	92.00			0.00	0.43	1.04	0.00
P049477	1998	KERALA FORESTRY	0.00	39.00			0.00	27.79	1.22	0.00
P010461	1995	MADRAS WAT SUP II	275.80	0.00			189.30	34.27	215.85	5.84
P050651	1999	MAHARASH HEALTH SYS	0.00	134.00			0.00	122.98	130.75	0.00
P010511	1997	MALARIA CONTROL	0.00	164.80			0.00	137.38	68.11	0.00
P009946	1992	NAT. HIGHWAYS II	153.00	153.00			0.00	74.85	60.30	21.56
P009869	1989	NATHPA JHAKRI HYDRO	485.00	0.00			0.00	80.50	80.50	18.29
P009972	2000	NATIONAL HIGHWAYS III PROJECT	516.00	0.00			0.00	516.00	0.00	0.00
P010561	1998	NATL AGR TECHNOLOGY	96.80	100.00			0.00	185.33	63.65	0.00
P010424	1993	NATL LEPROSY ELIMINA	0.00	85.00			8.70	13.32	23.70	14.22
P009982	1990	NOR REG TRANSM	485.00	0.00			35.00	105.16	140.16	0.00
P010496	1998	ORISSA HEALTH SYS	0.00	76.40			0.00	70.37	17.86	0.00
P035170	1996	ORISSA POWER SECTOR	350.00	0.00			0.00	261.10	154.44	0.00
P010529	1996	ORISSA WRCP	0.00	290.90			0.00	121.51	38.58	0.00

Project ID	FY	Purpose	Original Amount in US\$ Millions					Difference between expected and actual disbursements*		
			IBRD	IDA	SF	GEF	Cancel.	Undisb.	Orig	Frm Rev'd
P010416	1993	PGC POWER SYSTEM	350.00	0.00			75.00	37.46	112.46	0.00
P010457	1994	POPULATION IX	0.00	88.60			0.00	39.25	28.81	0.00
P009963	1992	POPULATION VIII	0.00	79.00			0.00	40.82	42.76	0.00
P045050	1999	RAJASTHAN DPEP	0.00	85.70			0.00	78.83	14.04	0.00
P010505	2000	RAJASTHAN DPIP	0.00	100.48			0.00	97.21	0.36	0.00
P049770	2000	REN EGY II	80.00	50.00			0.00	127.93	0.00	0.00
P010410	1993	RENEWABLE RESOURCES	75.00	115.00			0.00	64.67	94.26	0.00
P010531	1997	REPRODUCTIVE HEALTH1	0.00	248.30			0.00	169.10	85.47	45.76
P009959	1993	RUBBER	0.00	92.00			36.61	13.22	50.70	4.22
P044449	1997	RURAL WOMEN'S DEVELOPMENT	0.00	19.50			0.00	16.07	12.02	0.00
P009921	1992	SHRIMP & FISH CULTUR	0.00	85.00			50.02	14.58	62.95	14.34
P035825	1996	STATE HEALTH SYS II	0.00	350.00			0.00	188.14	153.53	0.00
P009995	1997	STATE HIGHWAYS I(AP)	350.00	0.00			0.00	267.98	76.32	0.00
P045600	1997	TA ST'S RD INFRA DEV	51.50	0.00			0.00	18.65	14.49	15.65
P059501	2000	TA for Econ Reform Project	0.00	45.00			0.00	43.55	0.00	0.00
P010476	1995	TAMIL NADU WRCP	0.00	282.90			0.00	142.20	113.47	0.00
P050637	1999	TN URBAN DEV II	105.00	0.00			0.00	87.72	18.24	0.00
P010473	1997	TUBERCULOSIS CONTROL	0.00	142.40			0.00	111.79	76.64	0.00
P055456	2000	Telecommunications Sector Reform TA	62.00	0.00			0.00	62.00	0.00	0.00
P050638	1998	UP BASIC ED II	0.00	59.40			0.00	12.85	11.05	0.00
P009955	1993	UP BASIC EDUCATION	0.00	165.00			0.00	9.48	4.86	0.00
P035824	1998	UP DIV AGRC SUPPORT	79.90	50.00			0.00	116.17	47.74	0.00
P050667	2000	UP DPEP III	0.00	182.40			0.00	164.86	-7.50	0.00
P035169	1998	UP FORESTRY	0.00	52.94			0.00	36.59	11.97	0.00
P050657	2000	UP Health Systems Development Project	0.00	110.00			0.00	105.82	1.18	0.00
P035172	2000	UP POWER SECTOR RESTRUCTURING PROJECT	150.00	0.00			0.00	145.88	0.00	0.00
P010484	1996	UP RURAL WATER	59.60	0.00			7.20	37.60	25.90	0.00
P050646	1999	UP SODIC LANDS II	0.00	194.10			0.00	171.88	28.40	0.00
P009961	1993	UP SODIC LANDS RECLA	0.00	54.70			0.00	2.36	2.35	0.00
P009964	1994	WATER RES CONSOLID H	0.00	258.00			0.00	100.01	82.30	0.00
P035827	1998	WOMEN & CHILD DEVLPM	0.00	300.00			0.00	282.91	15.58	0.00
P041264	1999	WTRSHD MGMT HILLS II	85.00	50.00			0.00	119.34	4.25	0.00
Total:			6820.90	7370.22			988.47	7891.94	3678.82	441.30

INDIA
STATEMENT OF IFC's
Held and Disbursed Portfolio
20-Sep-2000
In Millions US Dollars

FY Approval	Company	Committed				Disbursed			
		IFC				IFC			
		Loan	Equity	Quasi	Partic	Loan	Equity	Quasi	Partic
1997	20TH Century	8.50	0.00	0.00	0.00	8.50	0.00	0.00	0.00
1993	20th Century	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1989	AEC	6.76	0.00	0.00	0.00	6.76	0.00	0.00	0.00
1994	Ambuja Cement	2.67	4.94	0.00	0.00	2.67	4.94	0.00	0.00
1992/93	Arvind Mills	0.00	10.18	0.00	0.00	0.00	10.18	0.00	0.00
1997	Asian Electronic	0.00	5.50	0.00	0.00	0.00	5.50	0.00	0.00
1984/91	Bihar Sponge	0.00	0.05	0.00	0.00	0.00	0.05	0.00	0.00
1997	CEAT	19.80	0.00	0.00	0.00	19.80	0.00	0.00	0.00
1990/92	CESC	21.00	0.00	0.00	46.90	21.00	0.00	0.00	46.90
1995	Centurion Bank	0.00	4.67	0.00	0.00	0.00	4.67	0.00	0.00
2000	Chinai	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1994	Chowgule	12.63	4.58	0.00	19.38	12.63	4.58	0.00	19.38
1997	Duncan Hospital	7.00	0.00	0.00	0.00	7.00	0.00	0.00	0.00
1997	EEPL	0.00	0.03	0.00	0.00	0.00	0.03	0.00	0.00
1986	EXB-City Mills	0.48	0.00	0.00	0.00	0.48	0.00	0.00	0.00
1986	EXB-STG	0.31	0.00	0.00	0.00	0.31	0.00	0.00	0.00
1995	EXIMBANK	11.37	0.00	0.00	0.00	11.37	0.00	0.00	0.00
1995	GE Capital	6.25	5.00	0.00	0.00	6.25	4.39	0.00	0.00
1986/92/93/94	GESCO	0.00	1.86	0.00	0.00	0.00	1.86	0.00	0.00
1988/94	GKN Driveshafts	0.00	0.33	0.00	0.00	0.00	0.33	0.00	0.00
1994/97	GVK	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
0	Gesco Corp. Ltd	0.00	1.18	0.00	0.00	0.00	1.18	0.00	0.00
1994/98/00	Global Trust	0.00	5.00	0.00	0.00	0.00	2.78	0.00	0.00
	Gujarat Ambuja	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1994	HDFC	0.00	0.50	0.00	0.00	0.00	0.50	0.00	0.00
1978/87/91/93	HOEL	0.00	0.28	0.00	0.00	0.00	0.28	0.00	0.00
1990	Hindustan	0.62	0.00	0.00	0.00	0.62	0.00	0.00	0.00
1987	IAAF	0.00	6.50	0.00	0.00	0.00	0.98	0.00	0.00
1998	ICICI-IFGL	0.00	0.14	0.00	0.00	0.00	0.14	0.00	0.00
1990/94	ICICI-SPIC Fine	0.00	2.79	0.00	0.00	0.00	2.79	0.00	0.00
1990/95/00	IDFC	0.00	15.46	0.00	0.00	0.00	15.46	0.00	0.00
1998	IL & FS	0.00	3.12	0.00	0.00	0.00	3.12	0.00	0.00
1990/93/94/98	IL&FS Venture	0.00	0.60	0.00	0.00	0.00	0.60	0.00	0.00
1992/95	ITW Signode	0.00	0.34	0.00	0.00	0.00	0.34	0.00	0.00
1981/86/91/93/96	India Direct Fnd	0.00	7.47	0.00	0.00	0.00	6.29	0.00	0.00
1996	India Equipment	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1986/93/94/95	India Lease	0.00	0.30	0.00	0.00	0.00	0.30	0.00	0.00
1984/90/94	Indo Rama	0.00	2.14	0.00	0.00	0.00	2.14	0.00	0.00
1993/94/96	Indus II	0.00	5.00	0.00	0.00	0.00	4.50	0.00	0.00
1996	Indus Mauritius	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1996	Indus VC Mgt Co	0.00	0.01	0.00	0.00	0.00	0.01	0.00	0.00
1992	Indus VCF	0.00	0.93	0.00	0.00	0.00	0.93	0.00	0.00
1992	Info Tech Fund	0.00	0.64	0.00	0.00	0.00	0.64	0.00	0.00
1992	Ispat Industries	0.00	3.64	0.00	0.00	0.00	3.64	0.00	0.00
1992/94/97									
	Total Portfolio:	188.28	151.33	5.00	75.28	154.77	135.27	5.00	75.28

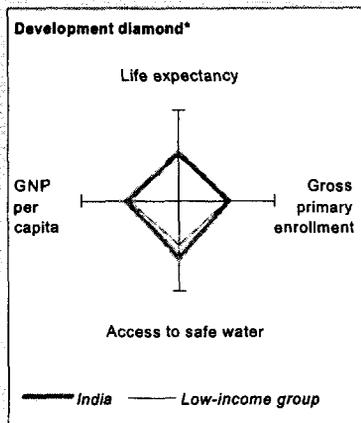
FY Approval	Company	Approvals Pending Commitment			
		Loan	Equity	Quasi	Partic
2000	APCL	7100.00	0.00	1900.00	0.00
1999	Carraro	10000.00	0.00	0.00	0.00
2001	GTB SME Facility	20000.00	0.00	0.00	0.00
2000	IndAsia	0.00	0.00	15000.00	0.00
2001	Internet Express	0.00	0.00	5000.00	0.00
2001	Jetair	0.00	15000.00	0.00	0.00
2000	SREI II	10000.00	0.00	0.00	0.00
1999	Sarshatali Coal	30000.00	0.00	5000.00	0.00
Total Pending Commitment:		77100.00	15000.00	26900.00	0.00

Annex 10: Country at a Glance

INDIA: SECOND NATIONAL LEPROSY ELIMINATION PROJECT

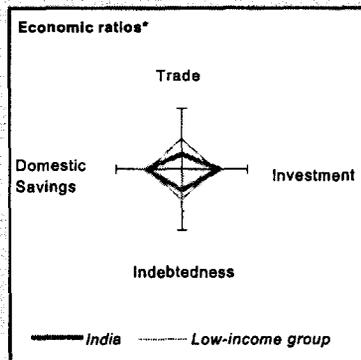
POVERTY and SOCIAL

	India	South Asia	Low-income
1999			
Population, mid-year (millions)	997.5	1,329	2,417
GNP per capita (Atlas method, US\$)	440	440	410
GNP (Atlas method, US\$ billions)	441.8	561	988
Average annual growth, 1993-99			
Population (%)	1.7	1.9	1.9
Labor force (%)	2.1	2.3	2.3
Most recent estimate (latest year available, 1993-99)			
Poverty (% of population below national poverty line)	35
Urban population (% of total population)	28	28	31
Life expectancy at birth (years)	63	62	60
Infant mortality (per 1,000 live births)	70	75	77
Child malnutrition (% of children under 5)	53	51	43
Access to improved water source (% of population)	81	77	64
Illiteracy (% of population age 15+)	44	46	39
Gross primary enrollment (% of school-age population)	100	100	96
Male	109	110	102
Female	90	90	86



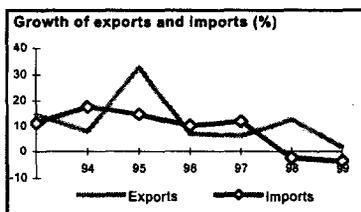
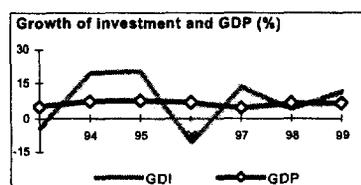
KEY ECONOMIC RATIOS and LONG-TERM TRENDS

	1979	1989	1998	1999
GDP (US\$ billions)	150.1	290.5	419.1	447.3
Gross domestic investment/GDP	22.8	24.1	21.8	22.9
Exports of goods and services/GDP	6.7	7.3	11.3	12.1
Gross domestic savings/GDP	20.7	21.8	19.2	20.0
Gross national savings/GDP	22.2	21.4	20.8	22.1
Current account balance/GDP	-0.5	-1.8	-0.8	-0.8
Interest payments/GDP	0.3	1.1	1.1	1.2
Total debt/GDP	11.9	26.0	23.4	22.9
Total debt service/exports	10.1	28.6	17.0	15.6
Present value of debt/GDP	20.1	..
Present value of debt/exports	143.3	..
	1979-89	1989-99	1998	1999
(average annual growth)				
GDP	5.7	5.8	6.8	6.5
GNP per capita	3.3	3.9	4.9	4.7
Exports of goods and services	4.9	11.8	12.5	1.7



STRUCTURE of the ECONOMY

	1979	1989	1998	1999
(% of GDP)				
Agriculture	36.8	31.6	29.1	27.7
Industry	25.0	27.6	25.7	26.3
Manufacturing	17.4	17.4	15.6	15.9
Services	38.3	40.8	45.2	46.0
Private consumption	69.2	66.1	68.6	68.0
General government consumption	10.0	12.2	12.3	12.0
Imports of goods and services	8.7	9.6	14.0	15.0
	1979-89	1989-99	1998	1999
(average annual growth)				
Agriculture	3.4	3.3	7.2	1.3
Industry	6.6	6.5	4.0	8.8
Manufacturing	7.0	7.0	3.6	8.5
Services	6.7	7.5	8.3	7.9
Private consumption	5.5	5.2	3.2	2.9
General government consumption	7.8	5.9	14.5	10.3
Gross domestic investment	5.7	6.2	4.3	11.5
Imports of goods and services	6.5	8.8	-2.5	-3.6
Gross national product	5.5	5.8	6.7	6.8

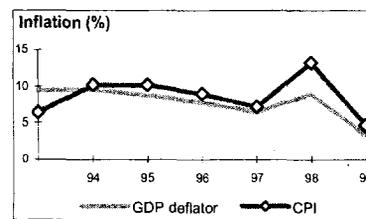


Note: 1999 data are preliminary estimates.

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

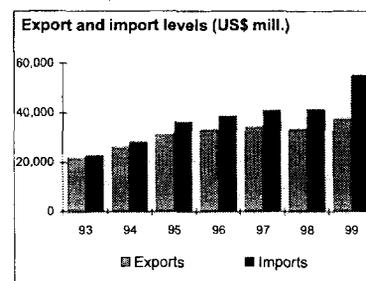
PRICES and GOVERNMENT FINANCE

	1979	1989	1998	1999
Domestic prices				
(% change)				
Consumer prices	..	6.2	13.2	4.6
Implicit GDP deflator	15.8	8.3	8.9	3.3
Government finance				
(% of GDP, includes current grants)				
Current revenue	..	23.5	21.8	23.6
Current budget balance	..	0.4	-1.7	-0.01
Overall surplus/deficit	..	-12.5	-10.6	-11.4



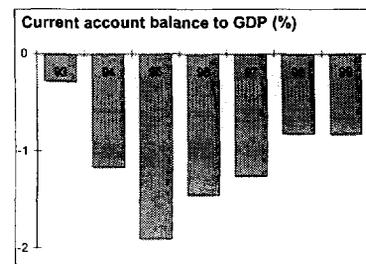
TRADE

	1979	1989	1998	1999
(US\$ millions)				
Total exports (fob)	..	16,613	33,667	38,326
Tea	..	550	547	564
Iron	..	557	380	374
Manufactures	..	12,730	26,870	31,314
Total imports (cif)	..	21,219	41,858	55,385
Food	..	714	2,543	2,459
Fuel and energy	..	3,768	6,435	10,682
Capital goods	..	5,288	9,122	10,192
Export price index (1995=100)	..	113	94	92
Import price index (1995=100)	..	89	92	90
Terms of trade (1995=100)	..	128	102	102



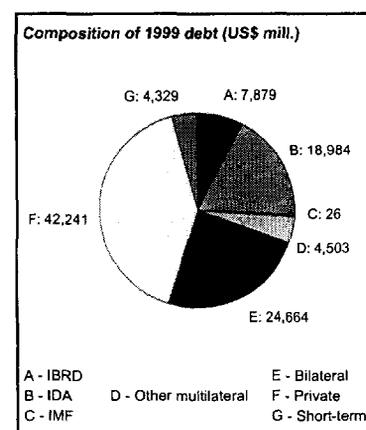
BALANCE of PAYMENTS

	1979	1989	1998	1999
(US\$ millions)				
Exports of goods and services	9,980	21,201	47,484	54,047
Imports of goods and services	13,120	27,934	58,565	67,250
Resource balance	-3,140	-6,733	-11,081	-13,203
Net income	527	-798	-2,955	-3,133
Net current transfers	1,852	2,281	10,587	12,638
Current account balance	-761	-5,249	-3,449	-3,699
Financing items (net)	985	4,400	7,382	9,487
Changes in net reserves	-224	850	-3,933	-5,788
Memo:				
Reserves including gold (US\$ millions)	7,581	4,582	33,584	38,150
Conversion rate (DEC, local/US\$)	8.1	16.7	42.1	43.3



EXTERNAL DEBT and RESOURCE FLOWS

	1979	1989	1998	1999
(US\$ millions)				
Total debt outstanding and disbursed	17,898	75,407	98,232	102,626
IBRD	728	6,615	7,993	7,879
IDA	4,505	12,521	18,562	18,984
Total debt service	1,282	6,955	10,001	10,527
IBRD	127	881	1,627	1,415
IDA	43	188	1,372	458
Composition of net resource flows				
Official grants	717	698	476	300
Official creditors	646	2,489	1,727	1,701
Private creditors	13	2,870	-1,433	414
Foreign direct investment	49	252	2,635	2,155
Portfolio equity	0	168	342	3,026
World Bank program				
Commitments	766	2,987	2,055	909
Disbursements	695	2,011	1,421	1,592
Principal repayments	77	450	2,193	1,211
Net flows	619	1,561	-772	381
Interest payments	93	619	806	663
Net transfers	525	942	-1,578	-282



**Additional
Annex 11**

THE BURDEN OF LEPROSY IN INDIA

METHODS FOR ESTIMATION OF PREVALENCE IN INDIA AS OF MARCH 2000

Principles

The information available from the national programme was analysed to provide the best possible estimate of the leprosy burden in India in a short period of time and in a very cost effective manner.

Data Sources

Most of the data available on the leprosy burden in India are based on information collected from detailed registers kept by the leprosy workers in the field and compiled at the district level. These reports are further compiled at the State level and sent to the National programme.

The available data for the year 1999-2000 are as follows:

- (a) Health Management Information System data available through NLEP:
- (b) Data collected from 5 major endemic states (Bihar, Madhya Pradesh, Orissa, Uttar Pradesh and West Bengal).
- (c) Data collected in areas where MLEC-1 and MLEC-2 were conducted, collected by the GOI
- (d) Independent Evaluation/validation of Indian Leprosy Programme conducted by the World Bank, WHO and GOI for the whole country, with special emphasis on MLEC-2.

Factors considered

1. In light of information available at present, there is no need for sample survey to establish leprosy prevalence for the country.
2. Effort was made to establish the prevalence from available data and accept certain limitations.
3. Basis for the estimates is reported prevalence (State-wise) as of March 2000, provided by the NLEP.
4. MLEC-2 data for five major endemic states was analysed and revealed that MLEC coverage for various sections of the community – caste, gender, age, sex, urban/rural are similar.

Grouping of the States

For the purpose of estimation at the national level, the States/UTs are divided into three groups according to the data available and the magnitude of the burden according to the reported prevalence:

Group 1: Bihar, Madhya Pradesh, Orissa, Uttar Pradesh and West Bengal

Group 2: Andhra Pradesh, Karnataka, Maharashtra and Tamil Nadu

Group 3: All remaining States/UTs (prevalence 10 000 or less)

Group 1 and 2 covers 94 percent of the reported prevalence, while Group 3 contributes about 6 percent to the prevalence pool. Therefore no correction was made for Group 3. For Group 1 and 2, correction factors used are proportion of recycled cases, proportion of examined cases among suspected cases, proportion of wrongly diagnosed cases and coverage. These factors are gained from the evaluation/validation exercise

carried out during MLEC-2. According to data availability for these factors, there are minor differences in calculations between Group 1 and 2. Details are described below.

Steps and correction factors for calculations

Basic concept for calculations

- a. Data reported on prevalence by the NLEP, GoI as of 31 March 2000 was used. (Table 1)

Assumption

§ Data provided by NLEP, GOI is reliable.

Table 1. Prevalence as of 31 March 2000 reported by NLEP, GOI

State	Population (in 100,000s)	Reported Prevalence	Reported Prevalence Rate (per 10,000)
Andhra Pradesh	746.16	36930	4.9
Arunachal Pradesh	11.55	191	1.7
Assam	258.77	3573	1.4
Bihar	981.74	149220	15.2
Goa	15.47	449	2.9
Gujarat	475.57	8556	1.8
Haryana	195.46	673	0.3
Himachal Pradesh	65.45	283	0.4
Jammu Div	87.99	687	0.8
Kashmir	9.9	210	2.1
Karnataka	514.36	13706	2.7
Kerala	319.82	2812	0.9
Madhya Pradesh	783.39	35440	4.5
Maharashtra	901.2	35374	3.9
Manipur	24.41	243	1.0
Meghalaya	23.59	99	0.4
Mizoram	9.22	66	0.7
Nagaland	16.29	64	0.4
Orissa	355.34	40717	11.5
Punjab	232.84	1415	0.6
Rajasthan	526.39	5949	1.1
Sikkim	5.41	44	0.8
Tamil Nadu	612.55	31280	5.1
Tripura	36.65	174	0.5
Uttar Pradesh	1664.04	99754	6.0
W. Bengal	779.72	42429	5.4
A & N Islands	2.8	78	2.8
Chandigarh	8.6	317	3.7
Dadar & Nagar Haveli	1.84	219	11.9
Daman & Diu	1.35	43	3.2
Delhi	134.18	4705	3.5
Lakshadweep	0.69	12	1.7
Pondicherry	10.76	350	3.3
Total	9813.5	516062	5.3

- b. Proportions gained through MLEC-2 for recycled cases, cases examined among cases suspected, specificity and coverage are applied to prevalence data A.

Assumption

§ Proportion of these factors for detection are equally reflected in prevalence and therefore these figures are applicable to prevalence as well.

Steps and Correction factors used for Group 1 (for five states)

a. Point prevalence as reported by NLEP as of 31 March 2000 (Table 1-A)

Assumption

a. Data of prevalence provided by NLEP is the basis of the whole calculations.

Table 1-A. Point Prevalence as reported by NLEP as of 31 March 2000 for Five States

State	Population (in 100 000s)	Reported Prevalence	Prevalence Rate per 10 000
Bihar	981.74	149220	15.2
Madhya Pradesh	783.39	35440	4.5
Orissa	355.34	40717	11.5
Uttar Pradesh	1664.04	99754	6.0
W. Bengal	779.72	42429	5.4
Total	4564.23	367560	8.1

b. **Correcting for proportion of recycled cases:** This data is gained from the Validation / Evaluation exercise. Recycled cases was defined as cases already on treatment or having completed treatment who were re-registered as new cases or cases appear on register for more than once.

Assumption

b. The proportion of recycled cases among cases detected during MELC-2 is applicable to cases detected by routine activities (Table 1-B).

Table 1-B. Correction for proportion of recycled cases for five states

State	Reported Prevalence	Recycle	Recycle Lower Limit	Recycle Upper Limit	Recycle Corrected with Upper Limit	Recycle Corrected with Lower Limit
Bihar	149220	5.3%	3.2%	7.4%	138173	144449
Madhya Pradesh	35440	3.6%	1.5%	5.7%	33420	34909
Orissa	40717	26.1%	22.4%	29.8%	28566	31614
Uttar Pradesh	99754	37.8%	32.7%	42.9%	56913	67181
W. Bengal	42429	82.4%	78.8%	86.0%	5924	9011

c. Correction for proportion of cases examined among cases suspected:

Assumptions

- c. This reflects the cases suspected by teams but were missed for examination and registration.
- d. The proportion of suspects examined is applicable to the cases detected both by routine activities and during MLEC-2.

Table 1-C. Correction for proportion of cases examined among cases suspected

State	Recycle Corrected with Upper Limit	Recycle Corrected with Lower Limit	Proportion Examined/ Suspect	Examined Lower Limit	Examined Upper Limit	Examined Corrected with Upper Limit	Examined Corrected with Lower Limit
Bihar	138173	144449	50.9%	47.7%	54.1%	255415	302771
Madhya Pradesh	33420	34909	94.6%	92.8%	96.4%	34655	37613
Orissa	28566	31614	97.3%	96.3%	98.3%	29070	32837
Uttar Pradesh	56913	67181	72.5%	69.3%	75.7%	75231	96900
W. Bengal	5924	9011	74.1%	71.4%	76.9%	7703	12624

Assumptions

d. Correcting for proportion of cases confirmed as cases among cases evaluated: (Table 1-D)

e. Proportion of cases confirmed as cases among cases evaluated reflects specificity of diagnosis.

f. Proportion of wrongly diagnosed cases is applicable to both patients detected during MELC 2 and routine activities, as this indicates the capacity of health workers.

Table 1-D. Correction for proportion of cases confirmed as cases among cases evaluated

State	Examined corrected with Upper Limit	Examined corrected with Lower Limit	Specificity	Specificity Lower Limit	Specificity Upper Limit	Specificity corrected Lower Limit	Specificity corrected Upper Limit
Bihar	255415	302771	92.2%	89.8%	94.6%	229255	286414
Madhya Pradesh	34655	37613	86.8%	83.2%	90.3%	28841	33980
Orissa	29070	32837	91.4%	89.1%	93.7%	25894	30753
Uttar Pradesh	75231	96900	93.9%	91.5%	96.4%	68825	93406
W. Bengal	7703	12624	87.7%	84.8%	90.6%	6530	11443

e. Correcting for population coverage: (Table 1-E)

Assumption

g. Population coverage is the same for MELC-2 and routine activities.

Table 1-E. Correction for population coverage

State	Specificity corrected Lower Limit	Specificity corrected Upper Limit	House-hold Coverage	House-hold Coverage Lower Limit	House- hold Coverage Upper Limit	Coverage Corrected Lower Limit	Coverage Corrected Upper Limit
Bihar	229255	286414	76.8%	74.3%	79.3%	289252	385265
Madhya Pradesh	28841	33980	62.6%	59.8%	65.4%	44129	56781
Orissa	25894	30753	79.3%	77.0%	81.6%	31740	39929
Uttar Pradesh	68825	93406	51.3%	48.5%	54.1%	127153	192702
W. Bengal	6530	11443	71.9%	69.3%	74.5%	8769	16503

Based on these calculations, the estimated prevalence in these five states are shown in Table 2.

Table 2. Estimated prevalence of five states

State	Reported Prevalence	Proportion of Recycled Cases	Proportion Examined/ Suspect	Specificity	House hold Coverage	Estimated Prevalence Lower Limit	Estimated Prevalence Upper Limit	Estimated Prevalence Mean
Bihar	149220	5.3%	50.9%	92.2%	76.8%	289252	385265	337258
Madhya Pradesh	35440	3.6%	94.6%	86.8%	62.6%	44129	56781	50455
Orissa	40717	26.1%	97.3%	91.4%	79.3%	31740	39929	35835
Uttar Pradesh	99754	37.8%	72.5%	93.9%	51.3%	127153	192702	159927
W. Bengal	42429	82.4%	74.1%	87.7%	71.9%	8769	16503	12636
Total	367560					501043	691180	596112

Steps and Correction factors used for Group 2 (for four states)

- a. Point prevalence as reported by NLEP as of 31 March 2000 (Table 2-A)

Assumption

- h. Data of prevalence provided by NLEP is the basis of the whole calculations.

Table 2-A. Prevalence reported by NLEP as of 31 March 2000 for four states

State	Population (in 100 000s)	Reported Prevalence	Prevalence Rate per 10 000
Andhra Pradesh	746.16	36930	4.9
Karnataka	514.36	13706	2.7
Maharashtra	901.2	35374	3.9
Tamil Nadu	612.55	31280	5.1
Total	2774.27	117290	4.2

- b. Correcting for proportion of recycled cases (Table 2-B): This data is gained from the

Validation/Evaluation exercise. Recycled cases was defined as cases already on treatment or having completed treatment who were re-registered as new cases or cases appear on register for more than once.

Assumptions

- i. Though sample size from which this proportion was gained was small, it reflects the total picture of the four states.
- j. Proportion of recycled cases among cases detected during MLEC-2 is applicable to cases detected by routine activities.

Table 2-B. Correction for proportion of recycled cases

State	Reported Prevalence	Proportion of Recycled Cases	Recycling Lower Limit	Recycling Upper Limit	Recycling Corrected Lower Limit	Recycling Corrected Upper Limit
Andhra Pradesh	36930	40.0%	27.1%	52.9%	17377	26939
Karnataka	13706	6.2%	-1.9%	14.3%	11745	13967
Maharashtra	35374	40.0%	26.3%	53.7%	16372	26077
Tamil Nadu	31280	68.9%	56.8%	81.0%	5936	13521

c. Correction for proportion of cases examined among cases suspected:(Table 2-C)

Assumptions

- k. This reflects the cases suspected by teams but were missed for examination and registration.
- l. Though sample size from which this proportion was gained was small, it reflects the total picture of the four states.
- m. This factor is applicable to cases detected by routine activities and cases detected during MLEC-2.

Table 2-C. Correction for cases examined among cases suspected

State	Recycling Corrected Lower Limit	Recycling Corrected Upper Limit	Proportion Suspect/ Examined	Examined Lower Limit	Examined Upper Limit	Examined Corrected Lower Limit	Examined Corrected Upper Limit
Andhra Pradesh	17377	26939	93.4%	89.3%	97.6%	17808	30173
Karnataka	11745	13967	100.0%	100.0%	100.0%	11745	13967
Maharashtra	16372	26077	92.0%	86.9%	97.0%	16879	29997
Tamil Nadu	5936	13521	98.4%	95.3%	101.5%	5847	14195

Assumption

- a. This is regarded as reflecting the capacity of health workers, i.e. specificity of diagnosis
- b. Though sample size from which this proportion was gained was small, it reflects the total picture of the four states.
- c. The proportion of suspects confirmed applies to the cases detected both by routine activities and MLEC-2.

d. Corrections for proportion of suspects confirmed: (Table 2-D).

Table 2-D. Correction for proportion of suspects confirmed

	Examined Corrected Lower Limit	Examined Corrected Upper Limit	Specificity	Specificity Lower Limit	Specificity Upper Limit	Specificity Corrected Lower Limit	Specificity Corrected Upper Limit
Andhra Pradesh	17808	30173	100.0%	100.0%	100.0%	17808	30173
Karnataka	11745	13967	94.1%	86.2%	100.0%	10125	13967
Maharashtra	16879	29997	81.6%	70.8%	92.5%	11948	27740
Tamil Nadu	5847	14195	80.4%	70.0%	90.8%	4090	12883

e. Correcting for coverage was attempted. As no coverage data for these four states were not available, based on epidemiological pattern, population awareness, infrastructure and expert opinion, a correction factor of 1.2, around 80n percent coverage, was applied (Table 2-E).

Assumptions

q. Coverage in these states are around 80%.

Table 2-E. Correction for coverage

State	Specificity corrected Lower Limit	Specificity corrected Upper Limit	Coverage correction Factor	Coverage corrected Lower Limit	Coverage corrected Upper Limit
Andhra Pradesh	17808	30173	1.2	21369	36208
Karnataka	10125	13967	1.2	12150	16761
Maharashtra	11948	27740	1.2	14338	33288
Tamil Nadu	4090	12883	1.2	4908	15460

Based on these assumptions, estimated prevalence in these four states were calculated and shown in table 3.

Table 3. Estimated prevalence for four states

State	Reported Prevalence	Proportion of Recycled Cases	Proportion Suspect/ Examined	Specificity	Coverage Correction Factor	Estimated Prevalence Lower Limit	Estimated Prevalence Upper Limit	Estimated Prevalence Mean
Andhra Pradesh	36930	40.0%	93.4%	100.0%	1.2	21369	36208	28789
Karnataka	13706	6.2%	100.0%	94.1%	1.2	12150	16761	14456
Maharashtra	35374	40.0%	92.0%	81.6%	1.2	14338	33288	23813
Tamil Nadu	31280	68.9%	98.4%	80.4%	1.2	4908	15460	10184
Total	117290					52766	101717	77241

Steps and Correction factors used for Group 3

For this group, which contributes 6 percent of the total prevalence, no attempt is made to apply any correction factors and the prevalence as reported by NLEP is accepted.

Assumption

r. True prevalence of these states, if calculated, does not have a significant impact on the magnitude of disease burden at the national level.

Conclusion for baseline data

Based on the calculation above, the estimated prevalence is 704 565 (7.2 +/- .2 per 10 000) as shown in Table 4.

Table 4: Estimated prevalence

State	Population (in 100 000s) Population data provided by NLEP/GOI	Reported Prevalence	Reported Prevalence Rate (per 10 000)	Estimated Prevalence Lower limit	Estimated Prevalence	Estimated Prevalence Upper Limit	Estimated Prevalence Rate (per 10 000)
Andhra Pradesh	746.16	36930	4.9	21369	28789	36208	3.9
Arunachal Pradesh	11.55	191	1.7	191	191	191	1.7
Assam	258.77	3573	1.4	3573	3573	3573	1.4
Bihar	981.74	149220	15.2	289252	337258	385265	34.4
Goa	15.47	449	2.9	449	449	449	2.9
Gujarat	475.57	8556	1.8	8556	8556	8556	1.8
Haryana	195.46	673	0.3	673	673	673	0.3
Himachal Pradesh	65.45	283	0.4	283	283	283	0.4
Jammu Div	87.99	687	0.8	687	687	687	0.8
Kashmir	9.9	210	2.1	210	210	210	2.1
Karnataka	514.36	13706	2.7	12150	14456	16761	2.8
Kerala	319.82	2812	0.9	2812	2812	2812	0.9
Madhya Pradesh	783.39	35440	4.5	44129	50455	56781	6.4
Maharashtra	901.2	35374	3.9	14338	23813	33288	2.6
Manipur	24.41	243	1.0	243	243	243	1.0
Meghalaya	23.59	99	0.4	99	99	99	0.4
Mizoram	9.22	66	0.7	66	66	66	0.7
Nagaland	16.29	64	0.4	64	64	64	0.4
Orissa	355.34	40717	11.5	31740	35835	39929	10.1
Punjab	232.84	1415	0.6	1415	1415	1415	0.6
Rajasthan	526.39	5949	1.1	5949	5949	5949	1.1
Sikkim	5.41	44	0.8	44	44	44	0.8
Tamil Nadu*	612.55	31280	5.1	4908	10184	15460	1.7
Tripura	36.65	174	0.5	174	174	174	0.5
Uttar Pradesh	1664.04	99754	6.0	127153	159927	192702	9.6
W. Bengal	779.72	42429	5.4	8769	12636	16503	1.6
A & N Islands	2.8	78	2.8	78	78	78	2.8
Chandigarh	8.6	317	3.7	317	317	317	3.7
D & N Haveli	1.84	219	11.9	219	219	219	11.9
Daman & Diu	1.35	43	3.2	43	43	43	3.2
Delhi	134.18	4705	3.5	4705	4705	4705	3.5
Lakshadweep	0.69	12	1.7	12	12	12	1.7
Pondicherry	10.76	350	3.3	350	350	350	3.3
Total	9813.5	516062	5.3	585020	704565	824109	7.2
Prevalence rate				6.0	7.2	8.4	

*The prevalence in Tamil Nadu may be higher than is estimated. Validation of this calculation may be needed by an independent exercise.

Biases and limitations

Estimates are derived mainly from registered figures and the primary data are subject to many biases: standardization, information systems coverage, sensitivity and specificity of the diagnosis. Special efforts are made to standardize definitions and reporting systems, including validation of the quality of the information from most of the major endemic areas.

The estimates do not give separate information by various community sub-groups (scheduled tribes, scheduled cast, urban, rural etc.) mainly because evaluation/validation data suggests that coverage of special populations is not significantly different from other groups. (Table 5, 6)

Table 5. Households visited by Rural/Urban

State	Total Households		Rural		Urban	
	No.	%visited	No.	%visited	No.	%visited
Bihar	1133	76.8	991	84.3	142	72.5
MP	1184	62.6	984	61.4	200	68.5
Orissa	1211	79.3	1092	77.7	119	94.1
UP	1200	51.3	960	50.4	240	55
W.Bengal	1185	71.9	824	69.4	361	77.6
Total	5913	68.3	4851	68.9	1062	71.9

Table 6. Households visited by Caste

State	Scheduled	Caste	Scheduled	Tribe	Others	
	No.	%visited	No.	%visited	No.	%visited
Bihar	295	70.5	54	85.2	784	78.6
MP	210	66.2	233	46.8	741	66.5
Orissa	238	79.0	341	63.9	632	87.5
UP	299	48.5	20	70.0	881	51.9
W.Bengal	357	70.0	108	74.1	720	72.5
Total	1399	66.5	756	61.8	3758	70.3

Prevalence rate among uncovered population

There are some data that indicate that prevalence rate among uncovered population can be different from that of covered population. The data is now under compilation and analysis, and currently not available in the form which can be used for estimation of prevalence among uncovered population.

**Additional
Annex 12**

Methods for Assessing Progress towards Leprosy Elimination

Introduction

There is a need to identify whether progress towards the goal of elimination of leprosy is satisfactory, particularly at the state level. There are no standard methods to assess low levels of prevalence in a population. WHO and its Technical Advisory Group have proposed several methods that will be validated in different parts of the world. As part of the project, the following protocol will be pilot tested in two states of India, namely Meghalaya and Himachal Pradesh. The protocols and results of the pilots carried out in India and elsewhere in the world will be discussed by the Technical Advisory Group of the WHO. Recommendations on the best possible approach will be made before the end of the first year of the project. The terms of reference of future 'validation of elimination' surveys will be based upon the Technical Advisory Group recommendations.

Estimation of leprosy prevalence of 1 per 10,000 with the precision of ± 10 percent through a conventional sample survey requires a large sample size (of the order of 4 million) and will be expensive and time consuming. The alternative to the conventional survey, as described below, is a Rapid Assessment Procedure at the state/regional level, the details of which vary according to the initial level of endemicity.

After application of MDT, leprosy prevalences decline very rapidly and leprosy distribution continues to follow the same geographical patterns as immediately before the intervention. The key factors in testing these methods are: i) adequate sampling taking into account the uneven distribution of the disease and ii) high specificity of diagnosis of cases identified during the survey. Consequently, the following strategy for assessing leprosy elimination is to be pilot tested. This approach is not a one time activity – to be meaningful it should be undertaken periodically (say, each two years) until it is certain that elimination has been achieved.

Approach

- (a) States with very high levels (prevalence above 50 per 10,000) of endemicity before introduction of MDT, e.g. Tamil Nadu, Andhra Pradesh, Orissa. In these states, as the distribution of leprosy is likely to be relatively even, a Lot Quality Assurance Sampling (LQAS) exercise can be performed without inflating sample size to account for the design effect.
- (b) States with medium level of endemicity before introduction of MDT (prevalence between 10-50 per 10,000) e.g. Maharashtra, Kerala, Karnataka, West Bengal, UP, Bihar, MP. In these states the distribution of leprosy is likely to be relatively uneven and this will have to be taken into account by increasing the sample size (Modified LQAS) – the extent of the increase is the design effect.
- (c) Low endemic states before MDT introduction (prevalence below 10 per 10,000), Snowball sampling is suggested.

Methodology

- (1) Lot Quality Assurance Sampling (see Example 1 below)

LQAS can be used for initially highly endemic areas like Tamil Nadu, Andhra Pradesh, parts of Orissa and

West Bengal. The method is described briefly below:

Suppose the true prevalence of leprosy in the region/state is above 3 per 10,000 and the prevalence of 3 per 10,000 and above (baseline) is considered as non-achievement. A sample of 'n' individuals from the region/state as advocated in LQAS is to be taken and examined for disease status of the individuals. If the number of cases in the sample is more than the acceptable number i.e. "critical value"('d'), then it is considered that leprosy prevalence in the region/state is at or above 3 per 10,000. In this process, some samples may be wrongly classified as below 3 per 10,000. Therefore an extra precaution is taken to see that those samples wrongly classified as below 3 per 10,000, should not be below 0.5 per 10,000 - Alternative prevalence.

Defining the sample size:

From Table 1 below, the sample size and the corresponding critical values are 22,600 and 2, respectively.

Selecting the sample units:

A complete sampling frame of individuals in the community, such as an up-to-date listing of individuals in a district, may not be available. In such a situation, it is pragmatic to suggest households consisting of 4 to 5 individuals as sampling units. Selection of the households by simple random sampling is not operationally convenient. The following method is suggested:

- i. Select the region/state for which you want to examine the prevalence
- ii. For the state prepare a list of 'villages/towns' including approximate households/population
- iii. Select 30 villages/towns using Probability Proportional to Size Linear Systematic Sampling (PPS LSS)
- iv. From each village/town selected, prepare a list of households with the help of village President / village administrative officer / Panchayat Assistant and divide the village into 4 quadrants
- v. In the selected village, select 44 households from each of the 4 quadrants and examine every individual from the selected households.

For each household visited, examine all the individuals for leprosy. If the total number of leprosy cases exceeds the 'critical value' 2 then discontinue the survey, otherwise continue.

Table 1: Lot Quality Assurance Sampling: Sample size and 'd'

Prevalence	Below 3 per 10,000	Below 5 per 10,000	Below 10 per 10,000
Alternative prevalence	Above or at 0.5 per 10,000	Above or at 1 per 10,000	Above or at 3 per 10,000
Sample size without design effect	22,600	15,500	11,500
d	2	3	5
Sample size with design effect of 2	45,200	31,000	23,000
d	7	9	15

(2) Modified Lot Quality Assurance Sampling (Modified LQAS) (see Example 2 below)

For moderately endemic areas like Bihar, UP, Maharashtra, Madhya Pradesh and most of Orissa, the distribution of cases is expected to be uneven. To carry out LQAS for assessing elimination standards, the required sample size needs to be increased by applying correction factor (design effect) and the details are given below.

We assume that the design effect (correction factors) will be 2 in estimating the sample size required for examining the baseline prevalence at or above 3 per 10,000 with the alternative prevalence below 0.5 per 10,000, respectively. The corresponding sample size and critical value (d) are 45,200 and 7, respectively (see Table 1 above).

The design is the same as the one proposed for high endemic regions except for the number of households to be included for examination in each selected village/town. To be specific, the design includes 50 villages/towns from the region/state and 208 households (52 per quadrant) subsequently from each selected village/town for examining the prevalence at or above 3 per 10,000, with an alternative prevalence below 0.5 per 10,000.

(3) Snowball sampling (see Example 3 below)

Distribution of cases is expected to be highly uneven and patchy in very low endemic regions such as Punjab, Rajasthan, Gujarat, Haryana, etc. In low endemic regions we have to cover more households to have a single case, which means more travel, more manpower, and higher cost. Further we cannot increase the cluster size because the size of the village/town is fixed. For operational convenience and logistic reasons LQAS is not proposed for this situation - snowball is an appropriate sampling method.

Denominators are available from census or health survey data and can be used for working out prevalence rates. The approach is to identify a few known leprosy cases and to ask each of them to identify other leprosy cases, to contact those so identified and ask them to identify others, and so on. The common approach is to continue the snowballing process until a 'sufficient' number of leprosy cases have been found for the survey. (We will add careful examination and confirmation of diagnosis to avoid any possibilities for wrong diagnosis and recycling.)

Example 1

Suppose we want to assess Leprosy Elimination Level of 3 per 10,000 say for Tamil Nadu. The sample size required will be 22,600 with critical value as 2. There are 15,840 villages and 260 towns/cities comprising a population of 55,638,318 in Tamil Nadu as per census 1991. A village or a town or a city is considered as the first level sampling unit. Prepare the list of villages/towns/cities as shown in Table 2 below. (Lists for villages and towns/cities will need to be merged with each other.)

Table 2: Sample Format

Serial Number	Village/Town/City	Population	Cumulative Population	Location of Village/Town/City
1	V1	12,000	12,000	
2	V2	2,500	14,500	
3	T1	55,000	69,500	
4	V3	3,500	73,000	1
5	C1	270,000	343,000	
6	V4	1,500	3,44,500	
7	V5	7,000	351,500	
8	C2	325,000	676,500	
9	C3	1,265,000	1,941,500	2
...	
...	20
...	
...	
...	30
16100	V15840	11,000	55,627,318 55,638,318	
		55,638,318		

Sampling interval = (Total population)/(number of villages to be included in the sample)
 = 55,638,318 / 30
 = 1,854,610

Select a seven digit random number between 1 and 1854610 say 0072000.
 Locate the sampling unit (village/town/city) from the list where the cumulative population equals or exceeds the random number. Write 1 besides this sampling unit. We see from the table above that V3 is selected as the first sample unit.

Add 1,854,610 to 72,000 which is equal to 1,926,610. This falls within the cumulative population 1,941,500. Then C3 is selected and so on till we select 30 villages/towns/cities. The total sample of 22,600 individuals will be drawn from these 30 sampling units, by selecting the required number of households. (Household size in Tamil Nadu is expected to be on an average 4.5.)

(a) Determination of households to be visited in each village

1. Visit the village and make approximately equal quadrants.
2. Number the households in the village.
3. Suppose there are 500 households in the village, then there are approximately 125 households in each quadrant.
4. We have to select 44 households in each quadrant.
5. Calculate the sampling interval $125 \div 44 = 2.8$ (rounded to 3)
6. Select a random number between 1 and 3, say 3.
7. Select the household number 3. Then select every 3rd (i.e. a sampling interval of 3) household i.e. 6, 9, 12, etc. till we get 44 households.

(b) Selection of households in Towns/Cities

1. Select the enumeration block by random selection.
2. Divide the block into four approximately equal quadrants.
3. From each selected quadrant, select 44 households.

The rest of the procedures is the same as that explained for villages.

Example 2

Modified Lot Quality Assurance Sampling

Suppose we want to assess leprosy prevalence in Bihar. The sample size required will be 45,200 with critical value as 7. There are 67,550 villages and 211 cities/towns in Bihar comprising a total population of 86,338,853 as per census 1991. We select 50 villages/towns/cities similar to the procedure done for LQAS for highly endemic areas. From each of the sampling unit 904 individuals are to be examined.

The procedure of selecting households from the sampling units is similar to that given for LQAS in Example 1.

Example 3

Suppose we want to assess the Leprosy Elimination Level of 1 per 10,000 for Punjab. There are 12,345 villages and 120 towns in Punjab comprising a population of 16,788,915 as per census 1991. The sample frame of leprosy cases is generally not available. The advisable approach without construction of the frame is as follows:

A sample of villages or enumeration blocks in urban areas covering 1 percent of the population (i.e. 16,800) is required.

Identify a few known leprosy cases from the selected area. Examine them and confirm the diagnosis of leprosy as a case of leprosy. Ask these patients whether they can identify some more cases. Proceed to these newly identified cases. Examine and confirm the diagnosis of leprosy. This procedure is continued till we exhaust/no further identification of cases from the selected village/census block. Let these total confirmed cases be 'm'.

The prevalence of leprosy can be estimated to be approximately

$$\frac{m}{16,800} \times 10,000$$

We thus can assess the prevalence level of leprosy in Punjab.

**Additional
Annex 13**

Surveys to Monitor Performance of Leprosy Elimination Program

The main purpose of these surveys is to assess the performance of MDT services and their level of integration at the national, sub-national and peripheral levels. The term MDT Services refers to comprehensive health activities, including: diagnosis, classification, prescription of treatment, delivery of MDT, case-holding and cure of leprosy patients. As recycling of known and 'already on record' cases has been identified as a major problem it will also be assessed in these surveys. These surveys can also help in identifying areas where special initiatives are needed.

The methods described are intended to measure specific aspects of leprosy elimination programmes. They are meant to complement existing information systems and other methods for reviewing elimination programmes. The techniques for collecting indicators will be implemented in a standard way by independent contractors, in collaboration with NLEP and WHO.

The surveys will collect key information on the following issues:

1. Case-finding and diagnosis – this will be based on the analysis of existing information and review/updating of leprosy registers.
2. Integration of MDT services within GHS: Availability of MDT blister-packs and geographic coverage of MDT services: this will be based on a cross-sectional survey of randomly selected health facilities;
3. Quality of MDT services (case-holding and treatment). This will be based on a review of individuals' records and leprosy registers. The quality of MDT services will be reviewed on the basis of cohort analysis.

Overview

Only a limited number of indicators will be collected. These are well standardized, have been in use for several years. Most of the required data will be collected from existing patient records, leprosy registers, reporting forms and MDT stock bin cards. Information will be collected at a limited number of health facilities to show the situation prevailing in a specific geographical or administrative area at a given point in time. Proper selection of the sample and adequate sample size will be essential for extrapolating the findings. The monitoring will have to be repeated in order to ensure optimum level of MDT services implementation.

In each state the surveys will be carried out annually by a team of independent contractors using the methods outlined below. The findings will be reported to the States and NLEP. The monitoring should be quick and the complete cycle (from design to report) should not exceed four weeks.

Basic information to be collected by MDT Monitors

Key indicators

The list of key indicators is given in the following table. These indicators are the minimum set of measures to be calculated.

<i>Key indicators</i>	<i>Indicators</i>
Group I Case-finding and diagnosis	1. Diagnosis of leprosy 1.1 Proportion of new cases with disabilities 1.2 Average delay in diagnosis 1.3 Proportion of children 1.4 Proportion of multi-bacillary cases (MB) 1.5 Proportion of single lesion paucibacillary cases (SSL) 1.6 Proportion of male / female 1.7 Proportion of scheduled castes / scheduled tribes 1.8 Proportion of scheduled castes& scheduled tribes population 1.9 Proportion of recycled cases in the new cases 2. Prevalence: absolute numbers and rate 2.1 Reported prevalence 2.2 Prevalence after applying standard definitions (case, cure and defaulters)
Group II Integration indicators	1. Proportion of health facilities supposed to provide MDT. 2. Proportion of existing Primary Health Centres / health facilities providing MDT services out of those supposed to provide MDT. 3. Accessibility to MDT 3.1 Average distance 3.2 Estimated costs for the patients
Group III. Quality of services indicators (case holding and treatment)	1. Proportion of patients treated with MDT 2. Case holding 2.1 Cure rate 2.2 Defaulter rate 2.3 Proportion of patients continuing treatment after completing fixed duration 3. Quality of blister-packs

Steps in organising and conducting a monitoring exercise

In order to produce results that are reliable and comparable across the country, the indicators should be measured in a standardized way. The following list outlines the sequence of steps to carry out such an exercise. In collaboration with the State Leprosy Officer / District Leprosy Officer:

- Select a sample of health facilities as described below;
- Implement field work;

- Record data for indicators;
- Prepare summary tables;
- Report to participating state and national authorities and WHO;
- Follow-up by state authorities.

Qualifications and activities of MDT monitors

Monitors should have some background in public health and leprosy control and preferably be fluent in the language of the area or region in which they are working. They should be able to analyze a situation and be familiar with drug supply issues. The monitors will visit health facilities in randomly selected areas and gather and collate information on key indicators.

Survey implementation

It is initially proposed to introduce these exercises in the 5 most endemic states (Bihar, Madhya Pradesh, Uttar Pradesh, West Bengal and Orissa) on a yearly basis. The proposed key indicators (modified) are given below:

Group I: Case-finding and diagnosis

Indicator 1 - Diagnosis of leprosy

Purpose

To assess the effectiveness of case-finding activities.

Definition

Diagnosis will be evaluated through a set of nine indicators, describing the status of a sample of patients diagnosed during the past one year and who have never been treated for leprosy before diagnosis.

1.1 Proportion of newly detected cases with grade 2 disabilities

The number of patients newly diagnosed with disability grade 2 divided by the number of newly detected patients for whom the disability status is recorded.

1.2 Average time between awareness of the onset of disease and diagnosis

Based on the individual records and/or interviews of a sample of patients, this is the average time (in months) between the awareness of the first symptom and the date of diagnosis.

1.3 Proportion of children

The number of newly diagnosed patients below 15 years divided by the number of newly detected patients for whom the age is recorded.

1.4 Proportion of multi-bacillary (MB) cases

Clinical classification: The number of newly diagnosed patients classified as MB patients divided by the number of newly detected patients for whom classification is recorded.

1.5 Proportion of single lesion pauci-bacillary (SSL) cases

The number of newly diagnosed patients showing a single patch at the time of detection divided by the number of newly detected patients for whom the number of lesions is recorded.

1.6 Proportion of male/female among newly detected cases

1.7 Proportion of Scheduled Castes/Tribes

The number of Scheduled Castes/Tribes among newly detected patients for whom Scheduled Castes/Tribes is known.

1.8 Proportion of Scheduled Castes/Tribes population

1.9 Proportion of recycled cases in the new cases

Recycled cases are the old and known cases to the program. This information is to be collected from the patients as well as from the registers wherever possible.

Please note that for indicators from 1.1 to 1.9 complete information will be collected from registers and by interviewing patients when indicated.

Indicator 2 - Prevalence

Purpose

To measure progress towards the elimination of leprosy at the national and sub-national levels.

Definition

Monitors will have to report on information as reported by programs and ‘re-analyze’ prevalence indicators after applying standard definitions. The main issues are: the definition of a case of leprosy, the definition of defaulters and the definition of cure and duration of treatment prescribed. For the purpose of the study, monitors will adhere to the following definitions:

- Calculation of prevalence indicators *at a given point in time*;
- A case of leprosy is a person presenting clinical signs of leprosy (with or without bacteriological examination) who has *yet to complete a full course of treatment*.
- A patient who has completed a full course of MDT (6 doses PB and 12 doses MB) is cured.
- A patient who has not collected treatment for more than 12 consecutive months is a defaulter and *should be removed from the prevalence*.

Monitors will collect information on these 2 prevalence indicators at the state and district levels:

2.1 Reported prevalence: absolute number and rates

2.2 Prevalence after applying standard definitions

The data for the above indicators is to be collected from registers after scrutiny (particularly for 2.2).

Group II: Integration indicators

(Information to be obtained by direct interview with the patients)

- 1. Proportion of Health Facilities supposed to provide MDT.**
- 2. Proportion of existing Primary Health Centres/Health Facilities providing MDT services out of those supposed to provide MDT.**

Purpose

To estimate the geographic coverage of MDT services.

“MDT services” refers to comprehensive health activities, including: diagnosis, classification, prescription of treatment, delivery of MDT, case-holding, cure of leprosy patients and providing information, education and communication(IEC). Quantitative aspect of MDT services is monitored through these indicators (see Group III).

Definition

Proportion of health facilities where MDT is available among all existing health facilities in a given area. The definition of ‘health facilities’ should be given prior to monitoring according to the State integration plan.

Indicator 3 - Accessibility to MDT

Purpose

To evaluate the extent to which patients have easy access (geographical, financial and technical) to MDT services.

Definition

Accessibility will be estimated through a set of 3 indicators collected in a sample of patients diagnosed and treated during the year.

3.1 Average distance

Average distance traveled is obtained based on the interview of patients.

3.2 Estimated costs for patients

MDT is free but for cost factors like transport in terms of loss of wages and time spent to procure tablets will be assessed.

Group III: Quality of services indicators

Indicator 1 - Proportion of patients treated with MDT

Purpose

To measure the extent to which MDT is given to leprosy patients.

Definition

Proportion of leprosy patients treated with MDT among all patients registered for treatment at a given point in time.

Indicator 2 - Case holding

Fixed duration MDT should lead to the cure of leprosy patients in a relatively short period of time. It is essential to collect reliable information on the outcome of the treatment. This might not be easy through routine information systems, therefore the role of monitors will be to evaluate treatment outcome indicators through the analysis of cohorts of sample patients.

Purpose

To measure the outcome of case-holding activities.

Definition

Treatment outcome will be evaluated through a set of three indicators that can be collected by analyzing cohorts of patients having started treatment during a given year.

2.1 Cure rate: proportion of patients cured

The number of patients cured divided by the number of patients supposed to have been cured in the same cohort (PB and MB).

2.2 Defaulter rate:

The number of patients who have not taken treatment for 12 consecutive months divided by the number of patients supposed to have been cured in the same cohort. (PB and MB).

2.3 Proportion of patients continuing treatment after having completed:

Proportion of patients continuing treatment after having completed fixed duration treatment of MDT, 6 doses for PB and 12 doses for MB, among all patients supposed to have been cured in the same cohort.

Indicator 3 - Quality of blister-packs

Purpose

To identify potential problems in drug supply management.

Definition

Proportion of blister packs showing acceptable physical condition out of a total number of blister packs checked by the monitor.

STEPS IN THE MONITORING EXERCISE

Sampling plan

From each commissionerate register randomly select one district. From the selected district randomly select 10 health facilities. From each health facility randomly select 10 patients for interview. If a health facility has less than 10 patients all will be interviewed. In those health facilities with more than 10 patients on treatment registers a random sample of 10 patients will be selected.

Selection of sample units

For selecting the districts in a given state listed above:

1. List out the commissionerate areas in a given state
2. Prepare the list of districts (may be five or six) for each of the commissionerate areas
3. Select one district proportional to the size of the population of the district
4. Using the rural/urban proportion, list the number of health facilities (definition of health facility: Primary Health Centre, Taluk Hospital, District Hospital, where MDT is supposed to be available)
5. Select a total of 10 health facilities in the district using rural/urban proportion using simple random sampling.
6. Check all the patients in the register and interview all or a sample of them. (If the number of patients is less than 10, "interview" all. If the number exceeds 10, select 10 following random procedure).

Example

We want to conduct a Leprosy Elimination Survey in one endemic state.

Suppose there are 10 commissionerate areas.

List them. Suppose there are six districts in a commissionerate area

Selection of one district in a commissionerate area

District	Population (000s)	Cumulative population (000s)
A	2500	2500
B	3200	5700
C	2800	8500
D	2200	10700
E	3100	13800
F	2600	16400

Select a random number between 1 and 16,400,000 say 6,250,000 which means district 'C' is selected. Similar procedure is done for the remaining commissionerate areas.

Study district 'C' gets selected

Selected district 'C' – Rural area

Health facilities	Registered patients	Cumulative number
1	5	5
2	4	9
3	2	11
4	3	14
5	4	18
100	2	250

Suppose the rural/urban proportion in the district is 70:30. Then seven health facilities in rural area and three health facilities in urban area will be selected.

In the rural areas, select seven random numbers between 1 and 250, say 009, 017, 045 etc. Then the selected health facilities are 2nd, 5th, etc.

In the urban areas, a similar procedure will be adopted for selecting three health facilities.

In each selected health facility, the required data will be collected from the existing patient records, leprosy registers, stock bin cards and patient interviews. A descriptive summary form describing the key indicators as calculated in the selected health facility will be prepared and reported.

**Additional
Annex 14**

NLEP INFORMATION SYSTEM

As part of intensified strategy for leprosy elimination, India is introducing a computerised information system. It has a great possibility to become a robust tool that streamlines the decision making process and programme management. However, if it is not simple enough, it also has a possibility of becoming just an additional work load for health workers who collect data that are not useful for the programme.

Attributes Required for the Information System

In view of limited duration of the project, and the magnitude of the problem in India, the following are the required attributes of the information system to be developed:

Programme oriented: it is very important that data collection by the information system for public health purposes is not confused with that for research purposes. The system should assist the programme, and not the programme assists the data collection.

Simple: the number of indicators to be collected through this information system should be minimum, which will reduce the work load of those who will collect and analyse the data. Overloading health workers with data collection and analysis could even paralyse the leprosy elimination activities and delayed feed back of the result of analysis to the programme becomes meaningless. Data available from other information source, such as census statistics for denominators, should be utilised as much as possible.

Speedy: data will be collected, analysed and then reflected in the programme activities based on the feed back, such as taking corrective actions. This cycle should be fast enough to make the feed back, and thus, information system itself, meaningful. At the national level, one-year delay between data collection and its analysis and feedback should be a maximum. At state and district level, this should be quarterly reporting with three months delay of feedback should be a maximum.

There will be useful indicators to evaluate the programme that may have to be dropped in order to make the system meet these requirements. Such indicators will be collected by other evaluation exercise such as LEM.

CASE DEFINITIONS

Case of leprosy: is defined as a person having clinical signs of leprosy and who has yet to complete a full course of MDT.

Multi-bacillary: is a case of leprosy with more than five skin lesions.

Pauci-bacillary: is a case of leprosy with one to five skin lesions.

Single lesion PB case: is a case of leprosy with one skin lesion.

Disability 0 1 2:

Hands and feet:

Grade 0 No anaesthesia, no visible deformity or damage

Grade 1 Anaesthesia but no visible deformity or damage

Grade 2 Visible deformity or damage present

Eyes:

Grade 0 No eye problems due to leprosy; no evidence of visual loss

Grade 1 Eye problem due to leprosy present, but vision not severely affected as a result (vision 6/60 or better; can count fingers at six metres).

Grade 2 Severe visual impairment (vision worse than 6/60; inability to count fingers at six metres), lagophthalmos, iridocyclitis and corneal opacities.

Essential Indicators

Prevalence: is the number of cases registered for treatment at a given point of time. It reflects the turn-over of the leprosy system: dynamic exchange between the input cases (newly detected cases mainly) and the output cases (mainly cured) according to time. The prevalence of cases registered for treatment reflects both the operational and epidemiological situation of leprosy.

Prevalence helps in planning, setting priorities and estimating the resources required to eliminate the disease. From the epidemiological point of view, it helps to evaluate the trend of the disease and when presented as rate, to show geographical or other differences. However the epidemiological value of the prevalence is relatively low on its own, and should be analysed in conjunction with detection and programme coverage.

Prevalence rate: is defined as the number of cases registered for treatment at the end of the year divided by the population in which the cases have occurred. The prevalence is expressed by absolute numbers and rate per 10 000.

This indicator reflects the magnitude of the problem and helps in planning and evaluating control measures. Its limitation is that it is an outcome indicator and needs careful attentions to case detection activities (recycling, specificity of diagnosis, special case detection activities, i.e. LEC) and the duration of the treatment regimen.

Detection: is the number of cases newly detected never treated before during a year who have not taken treatment before. This has sub-components as follows:

A. **Absolute number and proportion of female patients among new cases:** is defined as the number of female cases divided by the total number of new cases for whom gender is recorded. This indicator is supposed to help identify potential gender problems in terms of operational (e.g. number of female health workers) and social barrier in seeking diagnosis and treatment for female patients.

B. **Absolute number of scheduled caste among new cases and specific detection rate**

C. **Absolute number of scheduled tribes among new cases and specific detection rate**

D. **Absolute number and proportion of patients classified as MB among newly detected cases:** is defined as the number of newly detected patients classified MB among the number of newly detected cases during a given year. Classification for this indicator is based on the clinical signs irrespective of bacteriological findings. This indicator is supposed to reflect the effectiveness of the programme in terms of early case-finding and the level of

community awareness of the disease to some extent. The specificity of diagnosis, inappropriate classification and recycling of patients may affect the proportion and could mislead the interpretation.

E. Absolute number and proportion of children under 15 years of age among newly detected cases: is defined as the number of newly detected patients under 15 years of age among the newly detected cases in a given year. This indicator is believed to reflect the transmission in recent years, and could be useful in interpreting the trend of transmission. Intensified case finding activities targeting this age group, such as school survey, will increase the proportion and needs careful attention in interpretation.

F. Proportion of patients with disabilities grade 2 among new cases: is defined as the proportion of newly detected cases with grade 2 disability among the total number of newly detected cases during the year for whom disabilities status are recorded. This indicator is supposed to reflect the effectiveness of the programme in terms of early case-finding and the level of community awareness of the disease.

Detection Rate: is defined as the number of new cases detected during a year divided by the population in which the cases have occurred. It should always be related to the prevalence, and should be expressed using absolute numbers and rate (per 10000).

Specific detection rates by gender, age-group, scheduled caste and scheduled tribe.

Cure Rate: is defined as the proportion of registered cases cured of leprosy among all registered cases. It can be calculated using cohort reporting, the cohort being defined as a group of patients starting their treatment at the same given time (or over the same period of time).

This data can be compiled at district level as the number of health facilities in three categories (facilities with cure rate below 50 percent, 50-75 percent and above 75 percent) to gain a total picture of activities at the field level and for supervision purposes.

Relapse: is defined as the number of individuals who were cured of leprosy and then show new signs of the disease. The relapse rate has to be expressed in person/years of follow-up and the relapse risk as an annual likelihood for each cured patient to relapse. This type of follow-up is not practicable as a routine measure and, for this reason, absolute numbers of relapses are used.

Data Required to Calculate Indicators

Data source: The data on cases registered for chemotherapy are available using individual clinical files, patient identification forms or special registers for leprosy patients. This information has to be collected from all health units dealing with leprosy, including specialised institutions, hospitals, local NGOs and private practitioners. Wherever the control programme is integrated or partially integrated, there is a need to simplify the recording and to use clear definitions. The timing of recording is continuous.

Data flow: The collection of data from peripheral level to upper level is the key point of the surveillance system. This will be done by supervisors and at this stage the use of standardised procedures is essential. Whatever information is collected to manage individual cases, the relevant data will have to be summarised using a simple form. This form should be simple but comprehensive and should meet the needs of the requested information. Calculation of rates should, as much as possible, be avoided at this stage. Quarterly reporting is sufficient at the state level, who will be responsible for the data collection, compilation, analysis and feed-back, and annual reporting is sufficient at national level.

Attachment: Sample reporting form (any level)

SAMPLE REPORT FORM (Any level)¹

District/State/National:	Period²:
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NEW CASES DETECTED DURING THE PERIOD					
TOTAL	Single Lesion	PB³	PB	MB	Unknown
Cases	Cases	Cases	Cases	Cases	Cases

<u>Number of female among new cases</u>	Cases
Number of cases with grade 2 disability among new cases	Cases
Number of children under 15 years of age among new cases	Cases
Number of Scheduled Caste among new cases	Cases
Number of Scheduled Tribe among new cases	Cases

THE NUMBER OF CASES REGISTERED AT THE END OF THE PERIOD (cases)	Number of cases cured during the period	Number of Relapses after MDT during the period (cases)
	SSL PB MB	

1 Denominators for each population group should be known

2 The period can be a quarter or a year

3 Only for states collecting single lesion PB data

Additional Annex 15

Strategy for Tribal Populations

Project Objectives and Components

This annex describes the project's approach to meeting the requirements of the Bank's O.D. 4.20, i.e.; how it would ensure that (a) indigenous people in the project areas receive culturally-compatible benefits and (b) there are no adverse effects on them.

The project's main **objective** is to transform the national leprosy control program into an effective and sustainable program through a decentralized and integrated approach which increases community access to multi-drug therapy. Beyond the life of the project, this transformation would assist India to eliminate leprosy as a public health problem. For tribal populations this means (a) improving the reach of detection and treatment services into the remote areas in which tribal people usually live, (b) ensuring that they have no social and economic impediments to completing treatment, and (c) that leprosy patients remain socially and economically integrated in their communities and are not ostracized in any way.

The project covers the entire country while focusing efforts on five main states viz., Uttar Pradesh, Bihar, West Bengal, Orissa and Madhya Pradesh where more than 70 percent of the leprosy burden of the country is found. The project's **components** are :

1. Decentralization and institutional development through the strengthening of state leprosy units with technical, organizational and epidemiological inputs
2. Strengthening and integration of service delivery through inclusion of mass and focal campaigns and assistance to general health services to treat cases of leprosy.
3. Disability prevention through the government and non-government services.
4. Information, education and communication which encourages voluntary reporting of leprosy, increases case detection during mass and focal campaigns and promotes attitudinal change among general health services staff.
5. Training which equips community volunteers and health staff to takes up their new responsibility.

To provide commensurate and culturally-compatible benefits to tribal people, the project would ensure that:

- Focal active case detection drives are undertaken in tribal areas.
- Local tribal volunteers are trained and employed during mass and focal active case detection campaigns.
- Appropriate training in leprosy control and disability prevention is designed and provided to health service staff working in tribal sub-plan health facilities.
- Advocacy for leprosy control is undertaken with tribal leaders and tribal panchayat members.
- Culturally-compatible IEC material is designed and utilized in the tribal areas, both for campaigns and for routine information on leprosy.
- Data disaggregated by tribal status and gender are collected during routine monitoring as well as independent surveys to allow tracking of leprosy prevalence and trends among this group.

Project Beneficiaries and Benefits

Project **beneficiaries** would consist of :

1. **Persons having leprosy:** The total number of patients expected to be identified and treated under the project is 925,000 spread throughout the country. Of these, it is expected that 70 percent would be in the five focus states.
2. **Persons affected by leprosy who would need (a) education on prevention of disability and (b) re-constructive surgery:** It is expected that the current trend of approximately 30 percent of all cases being identified at the single lesion stage would hold over the next three years. Such patients would receive single dose treatment, and are not expected to be at special risk of disability. Thus, about 650,000 patients would require counseling during their first contact with health workers on the identification of early signs of onset and prevention of disability. In addition, estimates suggest that about 0.8 – 1 percent of these patients may require reconstructive surgery.
3. **Communities:** The project's IEC programs are designed to inform and educate the general community on the occurrence of leprosy and the availability of free, good quality treatment at all health facilities. The issue of stigma, as it applies to the leprosy patient, will be specifically addressed through general and local advocacy campaigns planned under the project.

Thus, the **benefits** of the project for general as well as tribal populations would include :

- the identification and treatment of persons afflicted with leprosy;
- education on prevention of disability;
- re-constructive surgery for all those who require it;
- increased awareness of free, good quality facilities for leprosy treatment; and
- the reduction of stigma associated with leprosy.

Baseline Data

Population, leprosy prevalence and trends

There are 635 tribes in India located in five major tribal belts across the country. Based on 1991 Census data, they constitute approximately 8 percent of the country's population (68 million out of 846 million). 7 Indian states account for more than 75 percent of the tribal population. 2 of these 7 states which have tribals constituting more than 20 percent of the state population and also have high burdens of leprosy (Orissa and Madhya Pradesh). The other three states with high leprosy burden (Uttar Pradesh, Bihar and West Bengal) have relatively lower tribal populations.

State	1991 Pop (million)	% of State Pop Tribal	Tribal Population (million)	% of National Tribal Pop in State
Bihar	86.37	7.66	6.6	9.8
Orissa	31.66	22.21	7.0	10.3
M.P.	66.18	23.27	15.4	22.7

Maharashtra	78.94	9.27	7.3	10.8
Gujarat	41.31	14.92	6.1	9.1
Rajasthan	44.01	12.44	5.5	8.1
AP	66.51	6.31	4.2	6.2
Meghalaya	1.77	85.53	1.5	2.2
Arunachal P.	0.86	63.66	1.2	1.7
Nagaland	1.21	87.7	1.1	1.5
Mizoram	0.69	94.75	0.6	0.9

The rate of leprosy among tribals is comparable to the rate among the general population, and it is expected that the distribution of leprosy afflicted tribals follows a similar pattern. Using data on the tribal populations of these five states, it is expected that approximately 75,000 tribal persons would be identified with leprosy and treated during the project. Of these, over 55,000 are expected to be in Madhya Pradesh and Orissa. In addition, in these five states, over the three years of the project, 55,000 tribal persons with leprosy would be provided education on the prevention of disabilities, and about 400 are likely to require and receive reconstructive surgery.

The project would also address the leprosy problem in other states. Another 65,000 tribal patients are expected to be detected and treated in the other parts of India in same period, and 200 or so tribal persons are expected to require re-constructive surgery.

Gender

The rate of leprosy among women is less than that among men. Women constitute 1 in every 3 or 4 patients on leprosy registers in India. This ratio has persisted despite the deployment of 'female searchers' during the second countrywide active case detection drive (Modified Leprosy Elimination Campaign), which aimed to improve detection among women. This finding supports the reported international experience that leprosy is more common among men than women. To ensure that this is the case and that women are not missed in detection and treatment efforts, the project will continue to use female searchers in every team.

Women are particularly vulnerable to the myths and stigma associated with leprosy. There is widespread belief that women will pass the disease on to the children they bear. This leads to delay in the diagnosis and treatment of girls, since parents dread the discovery that a daughter may be suffering from leprosy. The social costs for women of leprosy are higher as they have far fewer familial and occupational options open to them than men. Due to their absence from the public domain, women may be less exposed to infection, but this also makes it more difficult for service providers and public health information campaigns to reach them. At least two studies confirm that women are likely to face many more restrictions than men if diagnosed with leprosy.

Cultural Aspects

The propensity of sub-groups such as tribals and women to seek the necessary treatment is low for various reasons:

- their knowledge regarding symptoms is inadequate;
- myths, superstitions and stigma associated with the disease are widely prevalent;
- there are widespread misconceptions about the cause and method of spread;
- there is low awareness of availability of MDT, and greater reliance on indigenous medical practices.

Data indicate that tribal populations are less likely to access diagnostic and treatment services in a timely manner. Tribal populations have been assessed to be particularly at risk, and in Madhya Pradesh and Orissa especially, the project will need to implement a specific strategy to reach tribals in remote areas.

Settlements and Migration

Tribal settlements tend to be small and isolated and difficult to reach with facilities and services. Even when rural tribal people live in larger villages, they may be separated in hamlets. However, there are some tribal people who are relatively well integrated into the communities and access and utilize facilities as other sub-groups do. Some tribal groups are nomadic and undertake seasonal migration in response to the need for livelihood or employment. In addition, economic development is forcing out-migration from traditionally tribal areas into cities, and often to the margins of such agglomerations. The ways in which the project would reach these different residential situations are outlined in the sections on **Institutional mechanisms** and **Implementation and Local Participation** below.

Legal Framework

The Fifth and Sixth Schedules of the Indian Constitution provide protection to tribal populations on account of their disadvantages. The Fifth Schedule designates 'Scheduled Areas' in large parts of central India in which the interests of the 'Scheduled Tribes' are to be protected. The "scheduled" or "agency" areas have more than 50 percent tribal population. The Sixth Schedule applies to the administration of the states of Assam, Meghalaya, Tripura and Mizoram in the North-East. This schedule provides for the creation of autonomous districts, and autonomous regions within districts as there are different Scheduled Tribes within the districts. The broad strategy that evolved from the constitutional mandates was the adoption of the Tribal Subplan since the Fifth Five Year Plan of the Government of India and the Integrated Tribal Development Approach, adopted and implemented with some modifications by subsequent government programs.

Articles 46 and 47 of the Constitution of India provide a framework for tribal policy. Article 46, for example, provides the following directive: "The State shall promote with special care the educational and economic interests of the weaker sections of the people, and in particular, of the Scheduled Castes and Scheduled Tribes, and shall protect them from social injustice and all forms of exploitation". Article 47 states that it is the duty of the State to raise the level of nutrition and the standard of living of the people, as well as to improve public health.

The National Health Policy of 1983 states that first priority in provision of organized services should be accorded to those residing in tribal, hilly and backward areas, and to populations affected by endemic disease.

In response to these Constitutional provisions, the health sector has generally treated tribal areas as requiring higher health facility : population or are norms and are provided service accordingly. There are no laws or statutes that would prevent or constrain tribal access to health care. And on the basis of available data, it does not appear that either traditional or modern laws affecting tribal livelihood patterns (e.g.; land tenure, access to forest produce) mobility or other aspects of social or economic status would in any way

cause tribal people to suffer more from leprosy or deny them participation in, or the benefits of, this project.

Institutional Mechanisms

The Government of India's special provisions in tribal sub-plan areas include additional health facilities. In tribal areas, one Primary Health Centre caters to 20,000 persons instead of 30,000 and one sub-centre to 3000 instead of 5000 people. Tribal areas are also provided with more mobile clinics, allopathic, homeopathic, ayurvedic, unani and siddha dispensaries. In the project, the health workers at these facilities will be trained to perform leprosy confirmation, treatment and counseling activities and will form the first point of referral for patients referred by local tribal volunteers.

The National and state-level Project Implementation Plans identify tribal populations as a target group with unique problems of physical and social access requiring culturally sensitive strategies. The project emphasizes two institutional initiatives which would address the needs of the tribal people:

(i) Decentralization of planning and implementation to the state and district levels. This would increase the involvement of states and build capacity to manage and administer the leprosy program over the long term. Guided by local needs, states will prepare and implement state-specific annual plans with emphasis on the needs of special groups. This includes carrying out increased numbers of special area projects and campaigns in urban slums to reach target groups; and

(ii) Integration of leprosy diagnosis and treatment facilities with the general health services. This will lead to improved geographical coverage and increased access to MDT, particularly for disadvantaged areas such as tribal areas.

Both these initiatives will be supported by appropriate capacity building efforts, for the government to plan and manage such activities, and for the implementing agencies to undertake case finding, treatment and rehabilitation programs.

In addition, the project proposes to:

(i) increase the outreach function of health workers through training and other inputs, and provide training for local tribal volunteers other field workers such as female Anganwadi workers to increase the availability of diagnosis and treatment channels for leprosy patients;

(ii) increase the involvement of NGOs, particularly to reach poor and marginalized groups and underserved areas;

(iii) enhance IEC capacity by engaging professional media agencies; and

(iv) enhance capacity at state and district levels to monitor and track the disease burden of target groups, and thus strengthen capacity to respond in a timely and appropriate manner to those affected.

The project will coordinate with other health activities being carried out by the State Health Directorates for tribal areas, such as immunization. Partnership will be developed with the Tribal Development Departments who would assist in providing mapping and group-specific socio-cultural information on tribal groups and channels to expand outreach. They could also play a role in the participation of tribal groups. Population specific information will be used to develop culturally sensitive IEC materials for both public and providers.

The government will also work in close partnership with Danida and WHO. Danida has developed good experience in carrying out SAPELs, particularly in tribal areas, while WHO would assist in building capacity in monitoring project impact on target groups.

Implementation and Local Participation

The project proposes active and passive case detection strategies. Focal active case detection strategies or SAPELs (rural/ tribal) and LECs (urban) propose to carry out detection, treatment and education activities in geographically limited, presumed highly endemic or unreached pockets. In this, these are similar to the MLECs, but are more focused and are limited in scope. The project proposes to reach remote

As leprosy occurs largely among poor and marginalized groups with little access to health care services, tribal people are a key target group of the project. Marginalized groups vary across states and include: tribal populations, scheduled castes, those living in remote and inaccessible areas, urban and peri-urban slums, nomadic groups, migratory labor and refugee populations. The project aims to reach these groups with SAPELs in rural areas while the urban poor will be covered by the LECs.

SAPELs have been successful in identifying “hidden” cases in difficult and hard-to-reach areas. For example, in Madhya Pradesh, a state with a tribal population of 23 percent and groups scattered across a large and difficult terrain, SAPELs contributed to identifying and treating 822 cases during the NLEP I project period. The Government of India is proposing to extend this intervention in this project in the five high-endemic states: Bihar, Madhya Pradesh, Orissa, West Bengal, Uttar Pradesh.

A SAPEL is an intense exercise of short duration which seeks to provide information on leprosy and services to reduce stigma, increase self-reporting, detection and treatment through early confirmation and start of treatment. It is generally conducted over a period of 5-7 days by a multidisciplinary team of 3-4 persons which would include health and leprosy staff, local volunteers and NGO representatives. SAPELs would train and employ local (tribal) youth to act as ‘searchers’ of leprosy cases. Teams include a female worker and/or local female volunteers from the selected areas to overcome barriers in identifying female patients. Field workers of various other government agencies (such as Women and Child Development, municipalities/corporations concerned with development work in urban areas) are also involved. These campaigns will be strengthened by IEC efforts using locally adapted models and formats previously tested by Danida in its ongoing leprosy control project. SAPELs/LECs may be mediated by local NGOs if they exist in that locality. In addition, NGO facilities in such areas will be supported under GOI’s SET scheme and re-constructive surgery schemes.

Typical activities in a SAPEL would include:

- identification of local leaders and volunteers in the selected community;
- door-to-door survey to prepare list of members in each household;
- IEC activities through a variety of folk and other media (wall paintings, street plays, banners, slide and video shows, distribution of health education materials);
- examination of suspect cases for diagnosis;
- registration of new cases and providing MDT treatment;
- counseling to the diagnosed patients on prevention of disability, need for regularity of treatment and sources for obtaining treatment.

To ensure regularity of treatment by migratory populations (e.g. urban workers, tribals), patients would be given the full course of treatment instead of the usual one month supply. For difficult to access groups, other strategies would be explored such as identifying on-site MDT depots and accompanied MDT (counseling the patient together with a companion).

Experience with SAPELs indicates that they are an important mechanism for promoting leprosy awareness

in hard-to-reach groups, to identify “hidden” leprosy patients and reach out to them with diagnostic services and treatment. However, village members who are missed during a SAPEL (for example, agricultural workers who leave their homes very early and return only after SAPEL activities are over and male members of tribal groups who go to cities for work for extended periods) and therefore, SAPEL activities would be supplemented with routine activities to ensure these missed persons are covered.

Mass active case detection strategies or MLECs will be applied throughout the country in the first year of the project, and to likely areas of high endemicity in the subsequent two years. These are intended to enter particularly difficult to reach areas as well as to address the issue of groups which might in the usual course be ‘left out’ (for example; marginal slum and industrial areas, hamlets of scheduled tribes or castes). MLECs utilize the services of staff of several government departments and local volunteers, and are supported by directed mass media and local publicity.

In addition, the project proposes to strengthen passive case detection through (i) IEC campaign designed to encourage early self-reporting and reduce the stigma of leprosy through education and advocacy and (ii) strengthening and creating incentives for the general health system to undertake leprosy confirmation and treatment activities and support prevention of disability. These will be supported by close referral links between the local tribal volunteers and health facilities.

Cost estimate and financing plan

No separate costing or financing plan has been prepared for tribal populations, because the project as a whole addresses the issue of leprosy control among marginalized groups such as tribals, women and slum dwellers.

Monitoring and Evaluation

Disaggregated data showing the prevalence and treatment rates among tribal people, women and scheduled castes would be generated from a revised routine monitoring system. These would be cross-checked using yearly independent third party surveys, ‘validation of elimination’ surveys in states that are candidates for leprosy elimination and in the final year of the project, a survey of leprosy prevalence. These data would demonstrate the extent to which tribal people have participated in and benefited from the project.

In order to increase the responsiveness of the system to the needs of target groups such as tribals, the monitoring and evaluation mechanism has been revised with the help of WHO. The monitoring and evaluation mechanism will include assessments of program coverage of tribal groups and women as well as by different age groups and rural/urban location. Information to be collected includes the number of cases under treatment, number of new cases, number of cases cured, and coverage. Special studies are planned to assess treatment completion rates, quality of diagnosis, and quality of care.

In addition to information on case finding and treatment, the monitoring and evaluation mechanism will collect data on the progress of activities on the ground, status of logistics and drug supply, and funds flow and expenditures. This information will facilitate monitoring of the impact of the project on these socially disadvantaged groups.