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## TUBERCULOSIS PROGRAMME REVIEW - INDIA, 1992

**1. EXECUTIVE SUMMARY**

The Government of India, recognizing the magnitude of the problem of tuberculosis, the limited progress achieved by previous control activities and the expected increase in incidence as a consequence of the HIV epidemic has decided to give priority to tuberculosis control. In support of this decision the Government requested WHO to carry out a joint programme review together with other interested parties. A Steering Group was designated to coordinate the evaluation of the programme, as a first step to formulating a project for possible external assistance.

The review of the national tuberculosis programme (NTP) of India was carried out by a team representing the Government of India (GOI), the World Health Organization and the Swedish International Development Agency (SIDA). The purpose of the review was to evaluate present policies and practices, analyze their adequacy to reduce the tuberculosis problem and recommend organizational, technical and administrative measures to improve the programme.

The review team analyzed the available documents including epidemiological data and reports of previous evaluations of the programme, discussed with officers of major institutions involved in disease control and in training, and made field visits in three States (Gujarat, Uttar Pradesh and Tamil Nadu) to assess the programme at the State, District and peripheral levels.

The burden of tuberculosis in India is staggering by any measure. More than half of the adult population is infected. About 1.5 million cases are notified every year and there are probably well over 500 000 tuberculosis deaths annually. Recent trends show that the programme is not having a measurable impact on transmission and appears to function far below its potential.

The Government of India formulated the NTP in 1962. The major objectives were to prevent tuberculosis through BCG vaccination; to diagnose tuberculosis cases among symptomatics and provide efficient treatment, giving priority to sputum positive patients; and to implement these activities as an integral part of general health services. The District was the basic unit for the NTP organization.

At present, organization of the general health system has been extended to reach the community level with primary health services. The tuberculosis programme is integrated into the general health services, and treatment services are provided at the levels where medical staff is available. However, the population growth and the proliferation of public health services has made many Districts unwieldy for supervision by the tuberculosis team which is based in a single District Tuberculosis Center. Further, monitoring and training are mainly under the responsibility of the National Tuberculosis Institute (NTI), the State TB officers playing only a minor role in these important areas.

Human and financial resources are provided by GOI and the States to cover most of the needs of the programme and current policy is to provide free diagnosis and treatment. Currently available data do not allow analysis of the adequacy or efficiency with which these resources are applied, but preliminary indications and overall TB programme performance point to the need for substantial improvements. If the programme is to operate as intended and begin to make a significant impact on the disease, increased funding will be necessary, emphasizing the need for improvements in programme effectiveness and efficiency.



The present management structure at national level requires strengthening to assume leadership in redefining policies, effectively assisting States and supervising programme implementation, retraining staff involved in TB activities, administering funds, and procuring supplies. The States, which provide health services, need also to assume their responsibility in TB programme management, and will require reorganization and training of the public and non government health institutions involved in TB control.

There is little coordination between hospitals and primary health institutions in rural areas, and between the different services providing tuberculosis care in most urban areas, to ensure the management of tuberculosis patients until cure.

Improvements in the methods and management of case finding must take place. In spite of the recognized priority of bacteriological diagnosis and cure of sputum positive cases to reduce the problem of tuberculosis, a large proportion of human and financial resources is currently used to treat cases diagnosed only on clinical and radiological evidence. This practice is common both to the NTP and to private practitioners and is reflected in medical college curricula. Bacteriology is not sufficiently used to confirm medical diagnosis and criteria for initiating treatment in sputum negative cases are not well defined. As a result of not identifying correctly smear-positive and smear-negative cases, and newly diagnosed and previously treated patients, some patients may be treated with inadequate regimens. Sputum microscopy examinations are carried out with insufficient standards and microscopy laboratories are inadequately equipped. A TB laboratory network assuring equipment, training and quality control is not in place.

Rationalization of treatment is required. There are currently too many alternative treatment regimens and the conventional regimens are of unnecessary long duration and low effectiveness. Short course chemotherapy regimens of higher cost-effectiveness are slowly being implemented but insufficient priority has been given to ensuring effective treatment of infectious patients, particularly during the initial intensive phase of chemotherapy.

The present system of recording and monitoring patient identification and progress during treatment to ensure health service concentration on achieving cure of infectious cases is seriously deficient. The present system does not allow the systematic evaluation of the results of treatment at health facility or block level. Neither does the registration system permit the use of cohort analysis of patients to assess cure rate as the main indicator of programme efficacy.

Drug supplies are occasionally interrupted by lack of timely funding and of buffer stocks. Additionally, the quality of the drugs supplied is not controlled. The extensive network of multipurpose health workers (MPHW) has not been sufficiently utilized at the community level to prevent defaulting and achieve treatment completion.

The present training system relies mainly on the National Tuberculosis Institute (NTI) courses. The state-level demonstration and training centres do not function. District Tuberculosis Centres (DTCs) are not adequately prepared to provide in-service training for dissemination of policy and standards. It does not make adequate use of training institutions and NGOs at the State level to transmit current policies and procedures. The curricula at medical colleges do not stress the basic principles of TB control and there is no systematic continuing education for medical practitioners.



In spite of extensive national experience in both operational and basic TB research, alternative methods to correct the extremely low proportion of cases diagnosed with bacteriological confirmation and of patients completing the prescribed treatment and cured have seldom been implemented. The findings of previous programme evaluations have not always been applied to improve existing programme procedures, nor has adequate use of the results of research and programme evaluation been made.

Nonetheless, the basic strengths of the India TB programme are considerable. The objectives on which the programme was established thirty years ago - integration, decentralization, free services, priority to treatment of infectious cases - are still valid today. They provide a sound basis for revitalization of the national TB strategy. In addition, the tuberculosis control programme can relatively easily build on its strengths: a well defined structure which provides services within general health care in an integrated manner; a basic managerial unit at District level with Central and State Governments providing support for diagnosis and treatment; experienced training and research institutions; and, a general health care system extended to the community through multipurpose health workers. An updated and strengthened programme can expect to reduce the magnitude of the problem by about half in each 10-15 years with the consequent savings in lives, human suffering and more effective use of financial resources. This will require a political commitment, initial investment and strong leadership, plus the rapid development of an efficient national model to serve as training ground and provide operational experience to programme managers at all levels.

#### RECOMMENDATIONS

1. The structure of the National Tuberculosis Programme should be strengthened by 1) establishing an apex policy making authority and an executive task force with managerial functions to implement programme reorganization, and 2) upgrading the central tuberculosis control unit in the Directorate to provide strong leadership and enhance the efficiency and effectiveness of the National Tuberculosis Programme.
2. The quality of patient diagnosis should be improved by 1) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment, 2) ensuring the quality of microscopy with adequate equipment, training and quality control, and 3) establishing criteria for diagnosis by radiological and clinical methods.
3. National and state tuberculosis programme resources should be directed to ensuring cure of tuberculosis patients, giving priority to infectious cases of tuberculosis by 1) adopting short-course chemotherapy, 2) establishing criteria for treatment completion, cure and discharge from medical care, and 3) ensuring an uninterrupted supply of drugs of good quality.
4. The current NTP system of registration and notification should be revised to emphasize the cohort analysis of treatment results (completion and cure, transfers, defaulters, died, treatment failures) as the main indicator of programme effectiveness.
5. Policies should be developed to ensure decentralization of treatment services closer to the community level to enhance access to care and patient compliance to recommended therapies.
6. Pilot projects should be implemented at block level to test the feasibility and results of different technical and organizational

strategies to be adopted by the tuberculosis programme -- i.e., to test the capacity to implement recommendations 2-5 above.

7. A medical officer or treatment organizer and a laboratory supervisor, with the necessary transport, should be added to the existing administrative structure at the sub-district level (about 500,000 population) to strengthen tuberculosis programme management and to facilitate decentralization of supervision.
8. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The current training infrastructure will need to broaden the scope of its training capabilities by utilizing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.
9. Operational research must be carried out as an integral part of the revised tuberculosis programme to evaluate programme performance, improve delivery of services, problem solving and obtain baseline epidemiological information to measure reduction in the risk of infection.



## INDIA - TUBERCULOSIS PROGRAMME REVIEW 1992

### 2. INTRODUCTION.

A review of the national tuberculosis programme was carried out from 9/1/92 to 9/17/92 as a collaborative effort of the Government of India (GOI), the World Health Organization (WHO) and the Swedish International Development Agency (SIDA). The purpose of the review was to evaluate present policies and practices, analyze their adequacy to reduce the tuberculosis problem and recommend organizational, technical, and administrative measures to improve the programme. The assessment included:

1. An overall description of the current programme achievements and problems,
2. An analysis of the tuberculosis burden, the programme resources and the programme structure,
3. Specific discussion of the leading issues facing the programme and their underlying causes, and
4. Recommendations for the next steps to improve the programme.

At the central level the team reviewed information relating to the magnitude of the tuberculosis problem in the country and epidemiological trends, programme structure, policies, technical norms and procedures relating to tuberculosis diagnosis and treatment, drug supply and logistics, supervision, monitoring and evaluation, education and training, coordination with other programmes and research. Meetings were held with the Ministry of Health, major referral facilities in New Delhi and voluntary organizations.

Following the review at the central level, the review participants divided into three teams to assess tuberculosis control activities at the State and District levels through facility visits and interviews with responsible staff in three selected States (Tamil Nadu, Gujarat, and Uttar Pradesh). Then the teams reconvened in Delhi for discussion of the review findings, conclusions and development of principal recommendations for submission to the Government of India. A draft summary of the conclusions and main recommendations was presented to the Secretary of Health at the end of the review.

A list of participants is attached in Annex 1, and a list of persons contacted and institutions visited as part of the review is in Annex 2.

This document summarizes the findings of the review. Background information on India can be found in Annex 3.1.

### 3. LIST OF ABBREVIATIONS

ADGHS	-	ASSISTANT DIRECTOR GENERAL OF HEALTH SERVICES
BCG	-	BACILLI CALMETTE & GUERIN
CHC	-	COMMUNITY HEALTH CENTRE
DGHS	-	DIRECTOR GENERAL OF HEALTH SERVICES
DHO	-	DISTRICT HEALTH (MEDICAL) OFFICER
DOT	-	DIRECTLY OBSERVED TREATMENT
DTC	-	DISTRICT TUBERCULOSIS PROGRAMME
DTO	-	DISTRICT TUBERCULOSIS OFFICER
DTP	-	DISTRICT TUBERCULOSIS PROGRAMME
EPI	-	EXPANDED PROGRAMME OF IMMUNIZATION
GH	-	GENERAL HOSPITAL
GNP	-	GROSS NATIONAL PRODUCT
GOI	-	GOVERNMENT OF INDIA
GP	-	GENERAL PRACTITIONER
H	-	ISONIAZID
ICMR	-	INDIAN COUNCIL OF MEDICAL RESEARCH
IMA	-	INDIAN MEDICAL ASSOCIATION
IMR	-	INFANT MORTALITY RATE
MBTC	-	MASTER BOOK OF TREATMENT CARDS
MC	-	MYCROSCOPY CENTRE
MCH	-	MATERNAL AND CHILD HEALTH
MO	-	MEDICAL OFFICER
MOH/FW	-	MINISTRY OF HEALTH AND FAMILY WELFARE
MPHW	-	MULTI-PURPOSE HEALTH WORKER
NGO	-	NON-GOVERNMENTAL ORGANIZATION
NRR	-	NET REPRODUCTIVE RATE
NTI	-	NATIONAL TUBERCULOSIS INSTITUTE
NTP	-	NATIONAL TUBERCULOSIS PROGRAMME
PHC	-	PRIMARY HEALTH CENTRE
PHI	-	PERIPHERAL HEALTH INSTITUTIONS
PPD	-	PURIFIED PROTEIN DERIVATIVE
R	-	RIFAMPICIN
RC	-	REFERAL CENTRE
RI	-	RISK OF INFECTION
RS	-	RUPEES
S	-	STREPTOMYCIN
SCC	-	SHORT COURSE CHEMOTHERAPY
SIDA	-	SWEDISH INTERNATIONAL DEVELOPMENT AGENCY
STO	-	STATE TUBERCULOSIS OFFICER
STTDC	-	STATE TUBERCULOSIS TRAINING AND DEMONSTRATION CENTRE
T	-	THIOACETAZONE
TAI	-	TUBERCULOSIS ASSOCIATION OF INDIA
TRC	-	TUBERCULOSIS RESEARCH CENTRE
VHAI	-	VOLUNTARY HEALTH ASSOCIATION OF INDIA
XC	-	X-RAY CENTRE



#### 4. TUBERCULOSIS IN INDIA

Prevalence of infection. A number of studies over the past 30 years, mainly in rural southern India, have shown the prevalence of infection among children 0-9 years old to be between 3.1% and 11.2% (Table 1). In the early 1960s, more than 50% of the population 20 years and older was infected with *M. tuberculosis* and most infections occurred before 15 years of age. By the late 1960s there was no evidence of change in this pattern. Since that time, there is no clear evidence of substantial changes in prevalence of infection among children beyond that which might have been expected from secular trends.

Table 1. India: Prevalence of tuberculosis infection among un-vaccinated children 0 to 9 years old and estimated annual Risk of Infection (RI)

Prevalence of infection	RI	Year	Location	Source
4.9%	1.0%	1961	Tumkur	NTI
9.6%	2.0%	1969	Tiruvallore	TRC
10.1%	2.1%	1983	Bangalore	NTI
10.4%	2.2%	1984	Dharmapuri	NTI
3.1%	0.6%	1985	Bangalore	NTI
9.0%	1.9%	1989	Kadambatmur	TRC
11.2%	2.3%	1989	Thiruvelangadu	TRC
6.7%	1.4%	1989	North Arcot	TRC

Annual risk of infection. The intensity of disease transmission in the community is best reflected by the annual Risk of Infection (RI) which represents the probability of a previously uninfected individual becoming infected with tuberculosis during a one year period.

RIs calculated from prevalence studies presented in Table 1 range from 0.6% to 2.3%. These data are difficult to interpret because methods vary among surveys but they clearly indicate wide variation within limited geographical areas and provide no clear evidence of a substantial decrease of the risk of infection over the last 30 years. This stagnant situation is substantiated by two recently published studies conducted in rural areas of Southern India. One showed that the RI decreased from 1.0% in 1961 to 0.61% in 1985, equivalent to an average decline of 3.2% per year. The other study showed no decrease in the risk of infection between 1969 and 1984 (RI of 1.7% in both years). These results would be consistent with a poorly functioning programme which would be creating chronic cases of tuberculosis and drug resistance.

Because most adults were infected in their youth, a small decrease of the RI would not have any rapid impact on the prevalence of infection in the adult population. It is safe to estimate that at least 50% of the population above the age of 20 years is infected and will remain at risk of disease and death from tuberculosis for their lifetime. A conservative estimate is that, currently, the RI for India is still between 1% and 2%.

Disease prevalence. The Sample Survey of tuberculosis conducted between 1955-58 remains the major source of information used by the NTP to anticipate



the tuberculosis situation in the country. The survey showed wide variations in prevalence of disease among persons aged 5 years or more (sputum-positive tuberculosis by smear or culture), ranging from a low of 229/100,000 to a high of 813/100,000. The overall prevalence was 398/100,000.

In 1960-61 and in 1972-73 surveys conducted by NTI showed the prevalence of radiological disease to be 1900 and 1100 per 100,000 respectively. In 1990, in an area near Madras, the rate was estimated to be 1700/100,000. In the first of these studies, the prevalence of sputum-positive tuberculosis was 410/100,000 and in others studies conducted by NTI between 1961 and 1968 in the Bangalore area the prevalence of bacteriologically confirmed tuberculosis (smear or culture-positive) ranged from 337 to 406/100,000 over the age of 5 years. About half of these cases (45% to 52%) were smear-positive. In a number of surveys and studies since that time, there is no evidence of a significant decrease in TB during the last three decades and there remains a very wide range of prevalence of TB in India. In the 1972-73 follow up of the 1960-61 study, the prevalence of bacteriologically confirmed disease was 440/100,000. Two studies conducted in 1989 and 1990 in two areas near Madras in the population above the age of 15 years found prevalence of bacteriologically confirmed disease of 1090 and of 430/100,000 (58% and 69% of confirmed cases were smear-positive).

The only clear exception to this stagnant situation is recent data from the Tuberculosis Prevention Trial<sup>1</sup>, in which a 350 000 population of South India is being followed prospectively. This study indicates a decrease in prevalence and incidence of both radiologically active and sputum-positive tuberculosis between 1968 and 1985. Most of the decrease, however, occurred during the first few years of the study. Data from 1978 to 1985 show stagnation with a prevalence about 1700/100 000 above the age of 10 years old (by X-ray or culture) and an incidence of about 450/100 000 over the age of 10 years (X-ray or culture). During the same period, 50% of all cases had bacteriologically confirmed (culture-positive) tuberculosis.

Among the many factors influencing prevalence of disease, the effectiveness of treatment is important. Poor treatment completion significantly increases the prevalence of disease. A recent retrospective cohort study conducted under programme conditions by the Tuberculosis Research Centre (TRC), Madras, illustrates the potential impact of poor treatment completion. It showed that among patients on short course chemotherapy who collected less than 50%, 50% to 79% and 80% or more of their drugs, 44%, 37% and 21% respectively were still sputum smear-positive after the end of treatment<sup>2</sup>.

Low effectiveness of the treatment programme explains much of the stagnation in disease trends over the last three decades. Further, with the current treatment completion rate it is probable that chronic and partially treated patients represent a large proportion of patients diagnosed by the programme.

Current tuberculosis rates. Age specific incidence rates (NTI, 1974) estimates suggest that about 870 000 new smear-positive cases of tuberculosis may have occurred in 1992. This number is very similar to the 850 000 estimate obtained on the basis of incidence data from the Tuberculosis Prevention Trial<sup>3</sup>. If the current average annual risk of infection is 1.7%,

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<sup>1</sup> S.P. Tripathy, personal communication, 1992

<sup>2</sup> TRC Annual Report, 1990

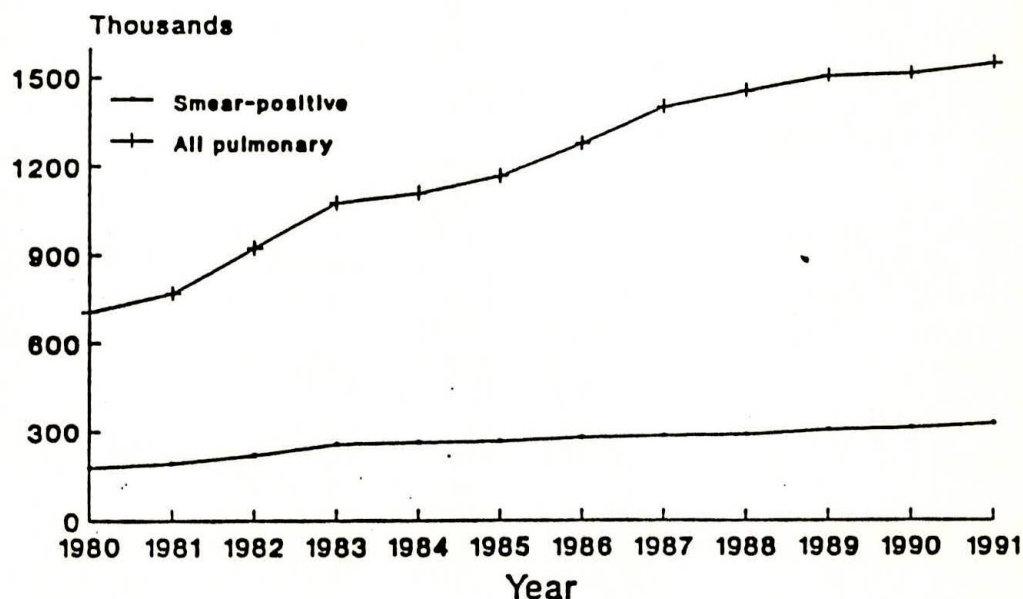
<sup>3</sup> S.P. Tripathy, personal communication, 1992



1.6 million new cases (all forms) and 714 000 new smear-positive cases of tuberculosis may occur annually. About a third of the total tuberculosis burden of India is borne by the urban conglomerations consisting mainly of towns, cities, and their suburbs.

**Notifications.** Based on the average case notification from districts with existing tuberculosis programmes (with about 83% of the population of the country), NTI estimated more than 1.5 million newly registered cases of pulmonary tuberculosis in 1991. 21% of them were smear-positive. The trend in notification, presented in Figure 1, reflects the increase in the number of districts integrated in the tuberculosis programme from 320 in 1980 to 387 in 1991, and also an increased proportion of cases not confirmed by smear examination. The proportion of smear-positive cases has decreased from 25% in 1980 to about 20% in the late eighties. Relapses, failures and partially treated patients are often inappropriately included in these notifications.

**Figure 1. India: Notifications of cases of tuberculosis, 1980-1991**



Extra-pulmonary cases are not reported  
Source: NTI, 1992



Age and sex distribution. The majority of tuberculosis cases in India occur below the age of 45 years, with about 75% of the diagnosed cases between 15 and 44 years old. Age-specific estimates of incidence from 1974 applied to the 1992 population, would imply that about 58% of all cases today occur between 15 and 44 years old. Two thirds of the cases are estimated to occur among males but tuberculosis takes a proportionally much larger toll on young females than among young males. More than 50% of female cases occur before age 34.

Mortality. Total mortality due to TB is uncertain but by any estimate poses a huge economic burden for India. Tuberculosis mortality is estimated by NTI to have been 69 to 95/100 000 in 1961-68 and 41/100 000 in 1977-81, or over 350 000 tuberculosis deaths annually (Table 2). Data from the Survey of Cause of Deaths yield a more recent parameter by which to estimate current mortality, resulting in 400 000 deaths, about 75 000 deaths in the 15-24 age group, 95 000 in the 25-34 age group and about 160 000 deaths in the 35-44 age group. Using the 1955 Sample Survey estimates of incidence, if all cases were diagnosed and at the present treatment completion rate of 30%, there would be about 657 000 annual deaths of tuberculosis. A large proportion of these deaths occur among women and it has been estimated that maternal mortality and tuberculosis claim approximately the same number of lives. For the decade of the 1990's, any of these estimates implies a staggering cumulative burden for the disease.

**Table 2.** India: Estimates of probable tuberculosis mortality

Source & year	Estimated mortality per 100 000	Annual deaths	Approximate (1) cumulative deaths 1990-2000
NTI			
77-81	41.0	346 000	3 460 000
Causes of deaths survey			
92	50.0	422 000	4 220 000
Sample Survey incidence estimates (2)			
55-58	77.8	657 000	6 570 000
"Styblo model" of incidence with 1.5% RI (2)			
92	50.1	432 000	4 320 000

- (1) Mortality rates from surveys applied to 1992 population structure and cumulative burden not adjusted for age structure within the decade.
- (2) Assuming no improvement from the current treatment completion rate of 30% and assuming 100% coverage of new cases.

Using the number of cases of tuberculosis currently notified by the NTP, the reported completion rate (30%), a case fatality of 10% among patients who complete treatment, 48% among smear positive-patients who did not complete treatment and 24% among smear-negative patients, it can be estimated that about 345 000 tuberculosis patients today diagnosed in the programme die. Almost all of these deaths are preventable. Increasing the treatment completion rate to only 85% would prevent close to 200 000 deaths annually, a 57% decrease in mortality.



**Table 3.** India: Number of Tuberculosis deaths which could be expected among cases officially reported in 1991 at different rates of treatment completion and potential reduction in mortality.

Completion rate	Expected deaths among		Reduction in mortality (all cases)	
	Smear positive	Total cases*	Lives saved	Percentage reduction
30% (current)	121 000	345 000	Base line	-
40%	109 000	309 000	36 000	10%
70%	71 000	202 000	143 000	41%
85%	52 000	148 000	197 000	57%

\* Pulmonary. As extra-pulmonary cases are not reported, they are not included in this calculation

Cumulative mortality during the decade to the year 2000 will probably exceed 3.5 million deaths, an enormous burden for society. A large share of these premature deaths can be avoided with a well-functioning programme. Given the ages at which deaths from tuberculosis are now occurring and the low costs for tuberculosis programme inputs in India, it is probable that the discounted cost per healthy year of life gained as a result of a well-functioning tuberculosis control programme will be well under US \$10, making tuberculosis control one of the highest priority interventions for the State and central governments.

**AIDS and tuberculosis.** HIV began to spread in India only in the latter part of the 1980s and there is no evidence yet that HIV infections are having an impact on the tuberculosis situation. Only recently HIV testing has become more common in a few research and academic institutions. A survey conducted among all newly diagnosed smear-positive tuberculosis patients in 1990 in Madras found 15 confirmed positive HIV cases among 2165 patients tested (0.7%). In Vellore, there were 16 confirmed HIV positives among 906 patients newly diagnosed with pulmonary tuberculosis (1.8%). In 1992, 12 of 183 (6.3%) tuberculosis patients admitted to a hospital in Bombay were HIV-infected. In a follow-up study of 220 HIV infected individuals conducted in Madras, 115 (52%) had radiological evidence of tuberculosis and 34 (15%) were culture positive. Other studies of HIV-prevalence in the general adult population have revealed prevalence varying between 0.1% in Calcutta to 1% in Bombay. The AIDS programme estimates that currently there are 750 000 persons infected with HIV in the country and that there will be 5 million in the year 2000. Assuming half of these people are also infected with tuberculosis, and that the breakdown rate from tuberculosis infection to disease among dually infected individuals is 10% per year, more than 35 000 HIV-related tuberculosis cases will occur in 1992. There may be as many as 250 000 HIV-related tuberculosis cases annually at the end of the decade. Virtually all of these cases will be in addition to the expected incidence. As important as these cases will be, they will continue to represent only a fraction of the cumulative cases of tuberculosis during the decade.

**Tuberculosis drug resistance.** Only a few laboratories can conduct drug sensitivity testing in India. Although data on drug resistance is scarce and resistance is not systematically monitored, available information (Table 4) is cause for concern. The very high rate of secondary resistance to both rifampicin and isoniazid is particularly serious, with long term implications as these patients will transmit a virtually incurable form of disease within the community.



**Table 4:** India: Primary and Acquired Drug Resistance in selected areas.

Type of patient and sample size	% Resistance to				
	S	H	R	HR	SHR
<b><u>Failure</u></b>					
81      Delhi Centre (1)	-	50.7	-	33.3	-
354     Delhi Suburbs (1)	-	78.8	-	61.5	-
560     North Arcot (2)	30.0	65.0	16.0	6.0	9.0
<b><u>Previously Treated</u></b>					
37      Madras (2)	35.0	62.0	13.5	5.4	8.1
111     Raichur (2)	11.7	52.7	17.1	5.4	11.7
<b><u>New cases by history</u></b>					
241     Madras (2)	7.3	12.6	1.6	0.8	0.8
244     Raichur (2)	11.0	19.1	3.2	2.0	1.2
324     Delhi (1)	-	18.5	-	0.6	-

(1) : Ind. J. Tub. Vol.39 No.2 pp 121-124

(2) : TRC Annual Report and M. Datta, personal communication

### **Conclusions:**

The burden of tuberculosis in India is staggering by any measure. About 1.5 million cases are notified every year, more than half of the adult population is infected, and there are at least 300 000 tuberculosis deaths annually. Social and economic consequences of tuberculosis for individuals and for the society are enormous in human suffering, economic loss, and decreased productivity. Recent trends are discouraging, indicating a programme which does not have any measurable impact and which appears to function far below its potential. While further study and improved analysis are needed to rigorously document the epidemiological situation, it will not change the broad conclusion that tuberculosis is one of India's most serious and still neglected health problems.

### **5. ORGANIZATION OF THE PROGRAMME**

1. **National Level.** The Ministry of Health and Family Welfare (MOH/FW) is divided into an administrative arm headed by the Secretary of Health and a technical arm headed by the Director General of Health Services (DGHS). The Secretary of Health is assisted by Additional Secretaries and the DGHS by Additional DGHSs and several Deputy DGHSs. One of these Deputy DGHS supervises the NTP as well as several other programmes. The responsible officer for the TB programme is an Assistant DGHS (TB). The NTP is located within the technical arm of the MOH/FW and on the administrative side, it is coordinated by a Joint Secretary who is responsible for its financial and administrative control.

**National Tuberculosis Programme Policies.** The long term objective of the NTP is to reduce tuberculosis in the country to the level where it ceases to be a public health problem. To accomplish this objective, the NTP focuses on 1) the BCG vaccination of infants, 2) the detection of the maximum number of tuberculosis patients among out-patients attending health institutions, and 3) the efficient treatment of identified tuberculosis patients, all as an integral part of India's general health services.



Central Structure of the NTP The central unit of the NTP has a staff of about 10 people. In addition to the Director, there are two physicians and 6 administrative officers for drug procurement, international assistance, monitoring of monthly reports, annual planning and coordination with the National Tuberculosis Institute (NTI)<sup>4</sup>. Currently, the post of programme director (Assistant DGHS-TB) and one of the two medical officer posts are vacant. The level of the programme director is lower than that of other programme directors (EPI, Leprosy) and below the level of the director of NTI. This, plus the fact that two out of the three central level posts are vacant reflect the low priority given to the NTP and show the absence of strong national leadership. This situation, if maintained, would jeopardize any attempts to revitalize the programme.

The Central Unit is responsible for drugs forecasting, purchase and allocation, the annual planning and participation in the discussions of the MOH/FW with the planning commission to determine the annual and 5-yearly "plan budget" of the NTP, and for liaison with international agencies (WHO, SIDA), with NTI, and with state TB programmes. The central unit does not play any significant role with respect to tuberculosis control technical policy, training and manual preparation, monitoring and supervision. These responsibilities have been progressively taken by NTI. NTI management, however, is virtually independent of the NTP. Additionally, State Tuberculosis Officers are State employees, and they are not accountable in practice to the ADGHS (TB).

NTP budget. The MOH/FW budget is composed of a "non-plan budget" used for personnel, salaries, hospitals, etc and a "plan budget", allocated by the Planning Commission for future investments or creation of new posts. The "non-plan budget" is not controlled by the NTP and fluctuates minimally from year to year. No detailed information could be made available to the review team about the proportion of the NTP budget corresponding to the "non-plan" budget nor a breakdown by States of the NTP budget and its trend. The 1992 (March 92 - February 93) plan-budget of the NTP is R 145 million (US\$ 5.3 million) of which R 110 million - more than 75% - are used to purchase drugs and 25 million for other expenses such as X-ray units and films, microscopes, vehicles, etc. Anti-tuberculosis drug costs are shared on the average on a 50:50 basis between Central and State governments. Within the overall NTP budget, the Central government also provides anti-tuberculosis drugs to voluntary organizations, and supplies, equipment, and drugs to the Union Territories.

Other resources. The Swedish International Development Agency (SIDA) has provided funds through WHO. These funds have been used to purchase x-ray units with Odelca cameras, miniature x-ray film rolls, vehicles, anti-tuberculosis drugs and microscopes. Occasionally, District and State tuberculosis associations provide anti-tuberculosis drugs, materials and equipment to specific district programmes or local tuberculosis facilities.

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<sup>4</sup> National Tuberculosis Institute (NTI). The National Tuberculosis Institute (NTI), located in Bangalore, is responsible for training NTP personnel, monitoring the programme and conducting operational research studies. Each year, NTI organizes two 10-week courses. In 1991, for example, 166 health professionals were trained. Apart from training DTC teams, the NTI also provides refresher courses for persons working for district tuberculosis control programmes and reorientation/retraining seminars for senior health administrators and teachers from medical colleges, etc. Lastly, the NTI collaborates with the World Health Organization (WHO) for international training efforts.



2. State level. India is administratively divided into 25 States and 7 Union Territories. In the State MOH/FW, the NTP is under the Director of Medical Services, Health and Family Welfare and the Director of National Programmes. All States have a State Tuberculosis Officer (STO), usually assisted by a staff of 6 to 10. The vast majority of STOs have been trained at the NTI. In principle, there is a meeting of all STOs at the central level once a year.

Responsibilities of the State Tuberculosis Officer (STO). The STO is responsible for negotiating for the State the amount of drugs provided by the central government and monitoring drug distribution to the Districts. He is responsible for the overall supervision of District Tuberculosis Officers (DTO) and through them of Peripheral Health Institutions (PHI). Lastly, he should organize and coordinate training activities at the State level, in conjunction with the State Tuberculosis Training and Demonstration Centres and with NTI.

State tuberculosis demonstration and training centre (STDTC). Seventeen states have training and demonstration centres. These centres were created in the early sixties to supplement NTI. They have an average staff of 100 people with about 30 professionals. In addition to training, they have responsibilities in diagnosing and treating patients and have, in some instances, research activities. In practice, however, the vast majority of these centres do not have an organized training programme or research activities and operate solely as District Tuberculosis Centres (DTC).

3. District level. The District is the basic demographic, economic, administrative and political unit in India. The District is further divided into Taluks and Community Development Blocks. One District encompasses 1,800 to 2,000 villages, has an average population of about 1.5 million, and a land area of 10,000 square kilometres. Health institutions in the District generally include:

1. One district hospital in the headquarters town.
2. Community Health Centres (CHC). Usually one in each Taluk, with several doctors and specialized services (about 10 CHC per district).
3. Primary Health Centres (PHC). In principle, one in each community development block (about 40 per district).
4. Varying number of sub-centres (180), other peripheral health institutions, dispensaries, maternity and child welfare centres, employee dispensaries, and private hospitals.
5. Specialized tuberculosis institutions. Tuberculosis clinic, DTC where the DTC has been implemented, sanatorium (about 100 beds per district).

With one CHC per 100 000 population and one PHC per 30 000 population, an average district may have about 10 to 15 CHCs and 50 PHCs. The country is covered by a network of 21 805 PHCs and 137 683 sub-centres (Figure 2).



Figure 2

## ADMINISTRATIVE ORGANIZATION AND HEALTH SERVICES

<u>ORGANIZATIONAL LEVEL</u>	<u>HEALTH SERVICES</u>
<ul style="list-style-type: none"> <li>- Number</li> <li>- Average Population</li> </ul>	
<div> <u>National</u> <ul style="list-style-type: none"> <li>- 850 000 000</li> </ul> </div>	Institutes
<hr/>	
<div> <u>State</u> <ul style="list-style-type: none"> <li>- 25</li> <li>- 34 000 000</li> </ul> </div>	Hospitals Sanatoria State TB Centre (STDC)
<hr/>	
<div> <u>District</u> <ul style="list-style-type: none"> <li>- 438</li> <li>- 1 500 000 - 2 000 000</li> </ul> </div>	District Hospital District TB Centre (DTC)
<hr/>	
<div> <u>Taluk</u> <ul style="list-style-type: none"> <li>- appr. 15 per district</li> <li>- 100 000</li> </ul> </div>	Community Health Centre (CHC) Central Hospital
<hr/>	
<div> <u>Community Development Blok</u> <ul style="list-style-type: none"> <li>- appr. 40 per district</li> <li>- 30 000 - 40 000</li> </ul> </div>	Primary Health Centre (PHC) Maternal and Child Welfare Centres Employee and Panchayat Union Dispensaries
<hr/>	
<div> <u>Villages</u> <ul style="list-style-type: none"> <li>- 1800 - 2000 per district</li> <li>- 700 - 800</li> </ul> </div>	Subcentres (each 4-5 villages) with Multipurpose Health Workers



In addition to these services, it is estimated that there are 330 tuberculosis clinics in operation in urban areas to provide services for the local residents. Approximately 47,000 hospital beds are available in the country for the in-patient care of seriously ill tuberculosis patients.

In the district, curative medical services and hospitals are managed by the District Medical Officer (DMO) and preventive services and primary health care by the District Public Health Officer. Although the District Tuberculosis Officer (DTO) works under the authority of the DMO, he has no formal control or authority over the district hospital and specialized institutions. Conversely, he controls and supervises tuberculosis activities in PHIs although these institutions are under the administrative authority of the District Public Health Officer. This situation means that the DTO cannot exercise leadership to improve the quality and coordination of tuberculosis control activities in hospitals and does not have the line of authority required to properly manage control activities in peripheral institutions.

District Tuberculosis Programme (DTP). In 1991, District Tuberculosis Programmes were in existence in 378 districts out of 438 districts in the country (86%). In a district, all health institutions which undertake case-finding and treatment for tuberculosis are considered as participating units of the DTP. These institutions are classified as either DTCs or PHIs. Each district participating in the DTP has one DTC. Sub centres do not have medical officers and are not considered as part of the DTP network.

District Tuberculosis Centre. DTCs maintain the patient case registers, manage the recording and reporting system and are responsible for supervising the TB activities of the PHIs. The DTCs also serve as referral centres to PHIs for X-ray examinations. They have X-ray units, microscopes and vehicles. They receive funds for drugs, gasoline, car maintenance, etc. from the State. Anti-tuberculosis drugs are supplied by the national Central Unit to all districts including those where the NTP has not yet been implemented. Most DTCs receive additional drugs directly from the State. DTCs have a staff of 15 to 20 persons including the District Tuberculosis Officer (DTO), one to three tuberculosis medical officers, one radiology technician, one laboratory technician, one to five treatment organizers, one statistical assistant, one pharmacist, and one or two drivers.

Peripheral Health Institutions (PHI). In the District, most CHCs and a number of PHCs staffed with at least one doctor are selected as PHI to implement the NTP and conduct diagnosis and treatment of tuberculosis. There are 3 types of PHIs:

1. X-ray centres, offering X-ray and microscopy
2. Microscopy centres, offering microscopy only
3. Referring centres, preparing sputum smear for or referring patients to the nearest microscopy centre.

No special staff is posted at PHIs and the Medical Officer in charge is responsible for tuberculosis activities. In some instances, one of the health workers of the centre (microscopist, X-ray technician) takes responsibility for tuberculosis patient management.

Multipurpose Health Workers (MPHW). In all PHIs there are multipurpose health workers who represent the most peripheral level of health care. They are usually based in subcentres, in pairs. With respect to tuberculosis, they are to maintain a list of all patients on treatment, to visit them regularly and to refer symptomatic patients to the nearest PHI or the DTC. They are not currently responsible for distributing or administering anti-tuberculosis drugs.



Urban tuberculosis control. There are a multiplicity of urban organizations and institutions involved in tuberculosis control activities, both public and private. These organizations, however, rarely coordinate their efforts and often work in isolation and/or overlap activities. Consequently, areas and/or population pockets needing tuberculosis services may be overlooked and manpower and financial resources are not well utilized. Since 1975, city tuberculosis programmes are to be organized in a similar fashion to DTPs, with the stipulation that each city programme would be tailored to the administrative, operational and social conditions of the specific city. Currently, however, only a few large urban areas have well-functioning tuberculosis programmes. Voluntary organizations and tuberculosis associations have been able to augment city tuberculosis programmes in many instances by providing technical and financial support, health education, and community outreach.

### Conclusions:

The NTP has a very weak central structure, which for a long time has not provided leadership in establishing and updating policy and technical procedures and assuming programme direction. As a result, programme procedures have stagnated and the original philosophy of the NTP has not been fully implemented, or revised to make full use of the development of PHC. The functions and resources of the State level, in particular training, have not been developed and properly utilized. In most large urban centers the coordination of activities among different institutions, under the guidance of the STO and STDTC, have not yet been implemented. In a similar way, the curative services (hospitals, etc.) and preventive services (PHIs) are not coordinated at District level in a single network for TB control, and the lines of authority of the DTO are not clearly established. The extension of TB diagnosis and treatment activities to the community through the MPHWS has been slow, and that valuable human resource is not sufficiently utilized to enhance access to care and patient compliance to recommended therapies. There is no technical and policy advisory body to lend credibility and promote visibility of the programme to government agencies and potential donors and to provide support to the national team in the preparation and periodic updating of national policies, technical and administrative procedures, and monitoring and evaluation of the programme.

## 6. CASE FINDING AND DIAGNOSIS

Diagnostic services provided by the NTP are free of charge for the patients. A major stated objective of the NTP is to detect the maximum number of tuberculosis patients in the community and among outpatients attending health institutions with symptoms suggestive of tuberculosis, giving priority to sputum positive patients. According to NTI manuals, the principal approach of case finding should be routine screening by sputum smear examination of chest symptomatic patients attending health centres, and symptomatic patients be referred for x-ray only after a negative sputum examination has been repeated. In practice, however, this policy is not followed.

Patients with respiratory symptoms attending a public outpatient facility are investigated with chest x-ray and generally one sputum smear examination. Patients who have to come back a few days after their initial exams are not routinely requested to bring an overnight sputum sample. Often diagnostic smears are not done or the results are not recorded on the treatment card. PHIs without x-ray facilities refer sputum negative patients to a peripheral x-ray centre or to the DTC. Looking for better care or because of public transport facilities, which directly link to urban centres, many patients bypass the microscopy centre and go directly to an x-ray centre or hospital, adding to their workload and increasing the proportion of cases diagnosed through x-rays.



Most facilities with X-rays diagnose the patients and initiate TB treatment on radiological evidence, in spite of a negative smear examination. Very few facilities indicate further sputum examinations, or treat smear negative tuberculosis suspects with non-specific antibiotics and follow-up the patient's clinical and radiological evolution prior to initiating anti-TB therapy, suggesting overdiagnosis based on x-rays. Overall, approximately 20% of patients diagnosed with tuberculosis have at least one positive smear, a very low proportion compared to the expected capacity of smear examination of diagnosing 40-60% of all TB cases. The practice of doing generally only one diagnostic smear examination is probably resulting in infectious cases being treated as noninfectious (with inadequate regimens and supervision) or not diagnosed at all. Official data published for one state tuberculosis programme showed that between 1969 and 1987 the total number of tuberculosis cases almost doubled whereas the proportion of smear positive cases decreased from 61% to 28%, suggesting that clinical practice is relying less on bacteriology and further separating from the policies recommended by the NTP.

Unfortunately, outpatient facilities run by non-government organizations (NGOs) generally follow the same routines. Moreover, NGO institutions and municipal health facilities were found to charge registration fees for each visit. In private practice, patients have to pay for consultations, smear examinations by private laboratories and the prescribed medication.

It is estimated that up to 50% of tuberculosis patients are identified and at least partially treated by private practitioners. These patients do not initially enter the NTP and are not registered. Many patients then move to the public sector because of the cost of care and drugs. Thus, a large proportion of patients attending a health service facility have previously been seen by a private practitioner.

Due to the high number of PHIs in the district, the maintenance of an updated cross indexing system at DTC is complex. Patients may not be able to provide a complete address due to illiteracy or type of dwelling or because TB has a social stigma and the patient does not want to receive mail from the DTC or visits from DTC staff. Unless they present an identity card issued by a public institution, patients previously treated outside the public system or which are not found in the DTC cross index are diagnosed, registered and notified as "new" cases. This practice correctly incorporates new cases initially detected outside the public system, but duplicates notifications if the patient was detected by a public institution outside the District.

A more serious problem is that the classification in "new" or "old" bears no relation to the previous treatment history and is not useful to decide on patient therapy. If the patient is not found to have been previously indexed in the DTC, he is considered "new" and is given a regimen for new cases. The insufficient definition of "new" and previously treated patient leads to the prescription of wrong regimens. A significant proportion of previously incompletely treated cases is known to have acquired resistance to isoniazid and streptomycin. The efficacy of "conventional" chemotherapy for such cases, who are most likely still symptomatic and smear-positive, is very low.

#### Laboratory facilities

Most laboratories visited were equipped with monocular, rather than binocular, microscopes without an electric light attachment. Some of the microscopes were in poor condition and the light source appeared to be inadequate. The quality of slides varied and some slides were found to be uneven and poorly stained. Acid fast bacilli could not always be found in smears read as positive. An ocular magnification ratio of five or six was routinely used rather than the usual 10 ratio. As definitions for data entry



are irregular, laboratory registers do not permit determination of the proportion of new cases, retreatment cases and follow-up examinations. Sputum smears are not routinely used for monitoring of treatment outcome.

Many laboratory technicians working in peripheral microscopy centres have been trained for the malaria control programme and are not familiar with sputum smear examinations. Malaria smears are often given a higher priority and may constitute a high case load. The number of sputum smears to be read by one technician per day is usually considerably less than 20 except in larger institutions such as DTCs and major hospitals. The rate of positive smears varies between 1 and 10%. These low positivity rates may be partly a result of poor selection of symptomatics, poor quality of the samples, low quality microscopes, weak laboratory practices, inadequate training and an excessively limited exposure to tuberculosis smear slides due to a small catchment area. The supply of chemicals was adequate and no shortages were reported. Slides with negative smear results are often reused, as indicated in the NTI manual, with a risk of false positive results.

Quarterly or semi-annual supervisory visits are made by the DTC team to assess the performance of the laboratory staff. The supervisors check usually only all the positive slides, retained at the microscopy centre for reading. Notes on the supervisory observations made, such as the proportion of false positive and false negative readings, were not available for scrutiny. There is no system of quality control through sending slides to the DTC or to a State reference laboratory. Laboratory staff are often in need of re-training and staining is of varying quality. Few States have functioning reference laboratories to train District staff, supervise DTC laboratories, carry out systematic quality control of smears and do sputum culture and sensitivity testing when necessary. In one State it was observed that the STDTC laboratory had different procedures for smear examination than those recommended by the NTI manuals and utilized by the DTC laboratories in the State.

### X-ray practices

With very few exceptions, diagnosis in clinical practice is based on the chest x-ray. Even with one negative smear or no smear result, tuberculosis treatment is initiated if the x-ray appears suggestive of active pulmonary tuberculosis. The x-rays taken in referral centres are usually kept at these facilities. The referring PHI only receives a note with the x-ray result. The standard equipment in most x-ray units is an ODELCA camera with 70 or 100 mm films. In some hospitals, standard size films are used. Chest clinics at the district level use both small and standard size x-ray films. Most of the technicians are sufficiently trained and the chest films are of a good quality, but complaints were expressed about the quality of the domestic films. X-ray centers had well functioning x-ray units and usually sufficient film to handle the tuberculosis caseload within the centers, although temporary shortages of x-ray films are commonly experienced by PHIs. 93% of x-ray machines were in working order at the DTCs as of 1991 (13). Assessment by an inexperienced reader of the small size x-ray films widely used for diagnostic x-rays or use of slightly inferior quality films can lead to an increase in overdiagnosis.

### Conclusions:

The NTP has an infrastructure of microscopy and x-ray centres, integrated into the primary health care system and staff are available to perform case finding activities down to the village level of health care delivery. Major weaknesses of the NTP with regard to case finding are that usually only one or no sputum smear is obtained before a tuberculosis diagnosis is made, and that diagnosis is primarily based on the results of a



chest x-ray. This practice results in significant underdiagnosis of smear positive cases by smear examination and in treatment of infectious patients as smear negative cases with inappropriate regimens, and discourages monitoring of treatment outcome by sputum smear results. Patients with respiratory symptoms are often inadequately assessed and treated before the diagnosis of smear negative tuberculosis is made. The lack of vigorous procedures for patient management increases the tendency to rely on x-ray examinations resulting in the overdiagnosis of smear negative tuberculosis. Inadequate case history and the impractical case registers result in multiple diagnosis of defaulters and overnotification.

The primary aim in case finding should be the identification of sputum smear positive cases. Before the diagnosis of tuberculosis and decision to treat are made, the results of at least two sputum smears should be available. The role of the sputum smear examination in tuberculosis diagnosis should be greatly emphasized and the role of radiological examinations should be reconsidered. For differential diagnosis, the ODELCA cameras and miniature films for diagnostic chest x-rays may be phased out and replaced with equipment based on the specifications for the WHO Basic Radiological System, after carefully working out the cost considerations. For screening of symptomatic attendees in hospitals of large urban areas to select patients for bacteriology, small size X-rays may be useful.

The NTI laboratory manual should be revised, used for training at State level and distributed as a reference to the laboratory staff of PHIs. Wall posters with the basic procedures for microscopy, as were seen in one of the States visited, should be made available to all peripheral microscopy centres. Supervision of DTC laboratories should be undertaken by State reference laboratories. Supervision at State and at District levels should include a system of quality control whereby samples of positive and negative smears are systematically sent to a reference laboratory for confirmation. Acceptable quality binocular microscopes should be made available. All diagnostic centres, including those outside the State health services, must adhere to uniform programme guidelines.

## 7. TREATMENT

The manuals for the District Tuberculosis Programme (NTI, 1990) include the current national policies for the treatment of tuberculosis. The Introduction Manual states that free chemotherapy should be provided to self referred tuberculosis patients. The highest priority is given to treatment of sputum positive cases to reduce the transmission of infection in the community. Five regimens of "conventional chemotherapy" of 12-18 months duration for all forms of tuberculosis are recommended. In a phased manner, two short course regimens of 6-8 months duration are to be provided for sputum positive cases. Patients are "allowed to collect drugs from the nearest PHI and are motivated to consume drugs for prescribed duration regularly".

In Annex 4.1 the regimens found to be most frequently used in the DTP are presented according to the currently recognized category of patient and priority given if drugs are available. The categorization used in the following sections of this report corresponds to that used in the WHO Guidelines for Treatment of Tuberculosis in NTPs. However, in the India NTP manuals, the seven recommended regimens do not always refer to the specific category of tuberculosis patients and the choices of regimens are not prioritized.



### Treatment practices.

Patients are mostly treated by "conventional" regimens on an ambulatory basis and oral drugs are self administered by the patient. In some States (mostly in the South of the country) the regimen of HT is rarely utilized due to the reported high frequency of side effects. There, most patients are treated with HE for 18 months or SH twice a week. In some States of the North where thiacetazone is well tolerated, the drug is not supplied in sufficient quantity because of shortages in the national market attributed to the low profit margin on the drug for the pharmaceutical companies.

SCC regimens for pulmonary smear-positive patients are theoretically implemented in approximately fifty percent of the districts in the country, but in reality only a minority of patients are treated with SCC so far. SCC is being implemented slowly, mainly because the expansion of SCC has not been given high priority in the NTP. The selection of patients eligible for SCC observed during the review is quite strict, probably because the medical officers of the DTP have doubts about the compliance of patients in self-administration of the SCC regimens. SCC drugs are often kept at the DTC or selected PHIs and patients living far away cannot come twice a month for the drug collections.

The treatment is usually prescribed by a medical officer of the DTC or PHI, and provided free of charge. Anti-tuberculosis drugs for the recommended regimens, in particular for SCC, are periodically out of stock, reducing the motivation of the patient to regularly attend the institution and contributing to the prescription of a non standardized regimen. Patients attending private clinics are required to pay for their medications. They may go to governmental institutions when they are unable to continue to pay for treatment, but do so only when they are very sick. In a limited number of situations, treatment may be supported by voluntary organizations. Often when there is a shortage of one or more drugs in the health centre, patients are required to buy the missing drugs. In one State, streptomycin, part of the "conventional" regimen, was presently missing in most centres visited by the review team due to a 50% budget reduction from the previous year's budget.

Patients with severe forms of tuberculosis (e.g. meningitis), those with complications of tuberculosis (e.g. pneumothorax, hemoptysis), those with tuberculosis complicated by other diseases and failure of an initial regimen requiring retreatment are hospitalized. Places of hospitalization are referral hospitals including sanatoria and medical colleges. Seldom are tuberculosis patients hospitalized in CHCs or district hospitals. Hospitalized patients frequently receive "conventional" chemotherapy that has low efficacy for critically ill and retreatment cases. Existing hospital beds for tuberculosis are utilized for advanced disease and not fully utilized to prevent treatment failure. Hospitalized patients often receive weak regimens and the beds are therefore not utilized in a cost-effective manner.

In the DTC, drug collection is done once a month for "conventional" therapy and twice a month for SCC regimens. The frequency of drug collections by the patient is similar during the initial and the intensive phase of chemotherapy. Streptomycin is administered in the health institution nearest to the patient home or by a private nurse. Usually the patient does not see the medical officer during the follow-up. He may be asked to see the MO if he has drug side effects. The monitoring of side effects is not systematic and there is little information regarding the percentage of patients who may have experienced major side effects.



Guidelines for changing regimens during chemotherapy or for prolongation of the duration of a regimen have not been issued by the NTP, creating confusion, particularly for MOs in the PHIs. Unnecessarily long conventional regimens are a burden for the patient, causes an unnecessary workload for the staff, and results in drug wastage. The decision to discharge from treatment is made by the MO on the basis of the treatment card and on the clinical condition of the patient. Criteria for discharge from chemotherapy are not clearly specified in the NTP manuals. The patient is permitted to stop chemotherapy when he has completed 80% of his prescribed regimen. If he has not completed such a course, he has to continue the treatment for the duration of time for which he has not collected drugs. Due to the high incidence of defaulting, most patients receive unnecessarily long regimens. In addition, the definition of treatment failure is not clearly specified nor is practice uniform among MOs working in the PHC centres with regards to how to manage a failure case.

After treatment completion and discharge, the patient is instructed to return every 3-6 months for follow-up. This practice is unnecessary and results in wasting of effort for both the patient and health staff.

#### Treatment organization.

Smear examinations are not repeated during conventional chemotherapy, to confirm that the patient is really sputum negative or to determine sputum conversion in smear positive patients. For SCC regimens, NTI recommendations do not require sputum examination at the end of the intensive phase of chemotherapy nor are criteria specified for prolongation of the 2 months initial intensive phase if the patients remain smear-positive. Smear examination after the initial intensive phase of SCC is required in some centres participating in the Tuberculosis Research Centre operational trial, but is done in approximately 20% of the patients only. The insufficient monitoring by sputum examination during chemotherapy does not allow for evaluation of the outcome of the initial intensive phase of SCC chemotherapy. Patients who are still smear-positive at the end of the initial phase should receive special supervision by the DTP staff because they may not have strictly adhered to the prescribed medications. These patients may still be cured by the same regimen for new cases if the drugs of the initial intensive phase are continued for an extra month and the staff fully supervises the patient.

National policies require that pulmonary patients be monitored by x-ray examination after six months and at the end of conventional chemotherapy. This requirement is not necessary in smear-positive patients and is not cost-effective in smear-negative patients. In practice, only a fraction of pulmonary cases are followed up by chest x-ray films in the DTP. Extrapulmonary tuberculosis patients are monitored by physical examination and by appropriate clinical tests.

The decentralization of the treatment of tuberculosis patients to PHIs, as recommended by the NTP, is not fully utilized for the administration of SCC regimens. The lack of decentralization results in a high percentage of dropouts. A significant percentage of patients diagnosed in DTCs are defaulting the first drug collection. The treatment card is not opened nor are the name and address of the identified smear positive cases in the community communicated to the PHI closest to the patient's home to retrieve the patient. Name and address of patients under treatment by the DTC or other institutions are also not routinely communicated to the PHI.

In PHCs, the MO at the beginning of treatment and the pharmacist during follow-up should provide patient motivation. At present, the same effort is made for all categories of patients, without sufficient focus for smear-



positive cases of TB that are the priority for cure. In DTCs, the DTO and MOs should provide motivation at the beginning of treatment and the treatment organizer should do so during the follow-up. Sometimes, in training and demonstration centres, health education and motivation is provided to small groups of patients. There is no formal monitoring of the effectiveness of such practices. There is no special effort to re-motivate patients who are still smear-positive at the end of the initial phase of SCC, when there is still a high probability of smear conversion and cure if the drugs are taken regularly. Effectiveness of health education practices among the patients and among the community are seldom evaluated and health education material is rarely available among patients, family members and health staff. Not enough emphasis is put on informing the patient and the health staff about the importance of sputum examination.

Follow up of defaulters is not practical because the staff is required to take action for a large number of patients, without focusing on those who remain smear-positive during chemotherapy. The current guidelines recommend that priority be given to sputum positive patients, leaving to the DTO the decision of excluding sputum negative patients from defaulter action. If home visits cannot be done, guidelines require that letters be mailed twice: after three days of defaulting and after 11 days if the patient is still delinquent. During the review it was found that letters are the most common action to retrieve defaulters. However, a large number of patients provide incomplete addresses and therefore reminder letters cannot reach them. In the PHC, the multipurpose health staff are sometimes asked to retrieve the patients, but such action is probably not stressed enough by the medical superintendent and Chief Medical Officer. The village health worker is often not informed about the TB patient(s) living in the village. The PHC is also not systematically informed by the DTC about new patients diagnosed and remaining under treatment by the DTC or hospitals.

The reasons for defaulting are well identified by the tuberculosis programme staff. Among the most important is the fact that the patient loses interest once he becomes asymptomatic. Disruption of drugs stock, incomplete provision of the first line drugs for "conventional" and SCC, long waiting time, inability of the system to adjust to the patient needs, distance of DTC or hospitals from the patient's home are the other most common reasons for defaulting. Some patients go to a health institution different from where they are registered with the hope of receiving better care. This increases default as well as making it more difficult to retrieve them. The DTC and other specialized institutions do not use auxiliary staff (MPHW) to retrieve defaulters and do not inform PHC of the existence of patients on treatment from that area.

Among defaulters, approximately 30% to 50% miss drug collections before the fourth month of chemotherapy. 5% of patients default after diagnosis is made and before therapy is initiated. In some instances, the patient is not informed that he has tuberculosis and should be treated. Lack of motivation of staff, weak leadership of the medical officer and little accountability to the chief medical officer for tuberculosis have been identified by the supervisory teams as additional reasons for patient defaulting.

In the policies of the NTP there is no target for treatment completion and cure of pulmonary smear-positive patients. In such patients the fatality rate is known to be high and irregular chemotherapy leads to drug resistance. The present policies and practices are insufficient to reduce the spread of the infection, particularly of drug resistant mycobacteria, and the mortality due to tuberculosis. The observation of the assessment teams show that the TB programme objectives are not efficiently prioritized. The existing health infrastructure and resources available are not fully utilized to sterilize smear-positive patients as quickly as possible. In a significant proportion



of the sources of infection diagnosed by the DTP, the chemotherapy is not started, and a large percentage of smear-positive patients put under treatment drop out during chemotherapy.

The decentralization of the programme is not achieved. Guidelines for patient management are not present at the level of peripheral health institutions (PHC and CHC for a population of 100,000 to 200,000) where most of the patients could benefit from the existing health services. Medical officers working in PHCs and CHCs are generally not trained for the proper management of the tuberculosis patient. Supervisory visits to PHI from DTC and chief medical office are not targeted to improve treatment outcomes.

### Conclusions:

NTP policies and procedures on treatment do not reflect the WHO recommended emphasis on short course chemotherapy and patient registration systems which facilitate the monitoring of completion and cure rates of patients on anti-tuberculosis treatment. The tuberculosis programme at the delivery level does not adequately emphasize the importance of treatment completion as the main index for programme evaluation. During the programme review, the teams observed that DTP practices depart from what should be done to effectively treat tuberculosis patients. Service delivery focuses on case finding activities and not on treatment completion and cure. Tuberculosis staff are not optimally utilized to enhance treatment completion activities. Additionally, there is no good system to evaluate treatment results. NTP policies and procedures should be revised to ensure that the most efficacious and current treatment regimens are recommended, including fewer regimens and short course regimens where appropriate. Registration systems should solicit data to monitor completion and cure rates, with particular focus on smear-positive tuberculosis patients. The main goal of the NTP should be to ensure that patient completion of anti-tuberculosis treatment and cure be reflected in all policies and procedures and that such be carried out in the current integrated health care delivery system. Guidelines for treatment organization are attached in Annex 4.2.

## 8. PROGRAMME MANAGEMENT

### 8.1 CASE NOTIFICATION

Tools for programme monitoring are the treatment card, the laboratory register, the master book of treatment cards (MBTC), the cross index card, the patient identity card and the report on treatment results. The use of register books and report forms is in accordance with the NTP guidelines in DTCs where the statistical assistant is in position and has been trained at NTI. However, training courses have been rarely repeated and trained staff have been transferred to other programmes within the district. The format of the treatment registers is not always standard, as they are copied by hand and not printed, and the content does not include all the data required to analyze the results of treatment. The card is sent from the PHI to the DTC when the patient completes treatment, defaults or dies, so the MBTC is the only source of data on treatment left at PHI level.

The usefulness of the recording and reporting system does not appear to be well known at all levels of the system. Consequently, evaluation of programme outcome and actions are missing, and the evaluation by cohort analysis of results of treatment is often not done. Cross checking of patients registered in the laboratory register, the treatment card, and registrations in the MBTC is not operating efficiently. Therefore no action is taken for smear positive patients registered in the laboratory register who default from the first drug collection, data on initial defaulters are not available and the information in the cards and MBTC is not complete.



### Conclusions:

The current reporting and recording system for the NTP is cumbersome and does not address the main WHO recommended objective of the programme, i.e. the monitoring of the cure rate among smear-positive cases of tuberculosis. Cohort analysis does not cover all smear-positive cases diagnosed and is not done at the PHI level. The current NTP system of registration and notification should be revised to facilitate recording of essential data, such as previous history of TB treatment, and emphasize the collection and cohort analysis of treatment results as the main indicator of programme effectiveness.

A printed copy of the laboratory register and patient register books should be made available to each PHI implemented to provide tuberculosis care. These registers should be kept by a PHI staff trained in record keeping and should be supervised at least every two months by the DTC supervisor. Supervisors should cross check the records in the registers to assess the consistency of the data. Standardized reports on the indicators of programme performance should be filled out at the end of each quarter and forwarded to the DTC. The DTC will consolidate the reports from the PHIs and forward them to the state TB Office. DTC team supervisory visits to PHIs should be prioritized on the basis of performance.

### 8.2 SUPPLIES AND TRANSPORT.

#### Anti-tuberculosis drugs

Anti-tuberculosis drugs used by the NTP are manufactured or compounded by pharmaceutical companies within the country. In principle, 50% of the anti-tuberculosis drugs for the NTP are purchased by the national government and 50% by the States. The national government negotiates with the states its financial contribution for drugs based on the capacity of the State to complement the central government contribution. The amount of drugs needed by each state is determined annually by the central unit from the number of patients reported the previous year, the population, and the requests received from districts. These requests are initially scrutinized at the state level. The central unit negotiates the purchase of drugs with the pharmaceutical industry but it must buy from semi-public corporations as long as the drug price is no more than 20% higher than the price of private companies. The distribution of drugs to the districts is the responsibility of the Medical Store Organization.

The State portion of the anti-TB drug supply is generally purchased by the District from manufacturers selected in State bids, using allotted State funds and sent to the District directly by the drug manufacturer. Monitoring of stock supply, reserve stock, and usage is left to the District. Although the districts send notification of supplies on hand, usage, and drug projections to the STO, it is unclear whether analysis of usage patterns is regularly undertaken at the State level. Facilities are likewise unaware of drug supplies available in neighboring facilities or institutions.

At the district level, the DTO usually estimates the needs of anti-tuberculosis drugs on the basis of the previous year's consumption. He receives the drugs purchased directly by the central government and the budget allotted by the state through the chief medical officer. In some situations, the budget obtained from the State to purchase anti-tuberculosis drugs was sufficient for only a fraction of the needs, due to increases in drugs costs (approximately 20% compared to the previous year). In some districts, the funds were sufficient, and if additional funds were necessary, they could be requested from the state. In some instances, shortages were corrected by using funds from TB associations, Interrupted supply of some



anti-tuberculosis drugs at district level were noted as being due to late or incomplete supply by the production laboratories of approved orders or due to the absence of reserve stocks at the state level. The state does not purchase or receive drugs directly nor does it maintain a buffer stock.

The rifampicin used by the NTP is not a combination capsule. Fixed dose combinations of rifampicin with isoniazid, and with isoniazid and pyrazinamide are however available in the market. The quality of such single drugs and combination drugs is not currently being monitored by the NTP.

### Conclusions:

Ensuring an uninterrupted supply of anti-TB drugs to the tuberculosis patient should be a key function of the national and State tuberculosis programmes. Shortfalls in funding and delay of drug supplies from the pharmaceutical industries can be compensated by 1) closer monitoring of usage patterns, drug purchase projections and stocks by the STO and 2) establishing a buffer stock at the State level sufficient to ensure at least a 6 month supply of uninterrupted drug distribution to the districts. Similarly, districts and PHIs should maintain internal buffer stocks of three months as an additional preventive measure. Estimations of the amount of buffer stock should be based on the number of patients reported during the previous year. In addition, drug quality should be monitored by the National Unit and the States through a selected scientific institution.

### Transport

The non-availability of road worthy vehicles and poor budget allocations for fuel have been cited as reasons for limiting the number of supervisory visits by the DTC team to PHIs. At District level, fuel quotas were clearly insufficient, in view of the increased number of PHIs to supervise and distances to cover. As a result, supervision of PHIs is not done with the frequency required, or several PHIs are supervised in the same trip with insufficient time allotted to each one. Adequate provision of fuel should be provided to the DTC for supervision, and transport should be provided to district supervisors based at subdivisional level to reduce mileage and fuel costs.

## 8.3 SUPERVISION, MONITORING AND EVALUATION

According to NTP policy, the District Tuberculosis Officer and his team of laboratory technician, x-ray technician, and treatment officer, etc. are responsible for the supervision of all personnel within their District involved in tuberculosis activities. The team is expected to visit each of their PHIs on a quarterly basis. They are to evaluate diagnostic and treatment procedures, validate laboratory results, monitor record keeping activities, check on defaulter actions taken, and monitor anti-tuberculosis drug supplies and support equipment. In addition to their supervisory duties, the team is expected to do on-the-spot training and/or retraining of staff, collaborate with other disease control programmes on topics of mutual interest, and offer continuing education to the general public. Supervisory checklists have been provided by the NTP to guide the supervision of DTCs and PHIs. At PHI level, Medical Officers have been made responsible for the supervision of laboratory technicians and multipurpose health workers.

When the NTP was operationalized in 1962, the District demographic unit was designated as the basic unit for the NTP. All NTP activities were conceived and organized at the District level. In the three intervening decades, the District has grown in population, and the number of government health services has grown at least in proportion to the population growth.



It is increasingly difficult for the DTC team to operate under the organization conceived thirty years ago, to feasibly supervise and manage at the District level. In one District visited, with a population of 4 million, 119 out of 148 Peripheral health institutions have implemented the DTP. The DTC staff would have to make 20 visits per month, supervising 2 facilities per trip in order to provide quarterly coverage for its implemented centers. This schedule of activities does not include the general hospitals, voluntary organizations, etc. which also treat tuberculosis patients and should benefit from regular supervision.

The assessment team noted that the District Tuberculosis team did make visits to PHIs. The quality of the visits was difficult to assess, and the frequency and regularity of the visits were difficult to validate, as supervisory reports were not available for scrutiny. Records were not in order at facilities where recent supervisory visits were noted.

Alarming, there has been a steady decline in the proportion of PHIs supervised by the DTC team, from 51% in 1983 to 41% in 1991. In 1987 only 84% of functioning DTPs sent quarterly reports. Of these only 72% (60% of functioning DTPs) gave information on supervisory visits. Of the 60% of DTPs giving information, they had supervised only 45% of their PHIs. Thus only 27% of the PHIs have been reportedly supervised. The quality of the supervision is not known (5).

Currently, supervisory visits are primarily used to evaluate record maintenance, laboratory performance, assess defaulter retrieval activities, and monitor the supply of anti-tuberculosis drugs and other equipment. Not only are the supervisory objectives poorly fulfilled, but very little time is devoted to the evaluation and supervision of programme performance with regard to the accuracy of case-finding and to patient completion of treatment.

The National Tuberculosis Institute (NTI) has been responsible for the monitoring of the National Tuberculosis Programme since 1978. Information on DTP activities is recorded through a system of records kept at the facilities and periodic reports sent to the NTI. Peripheral health institutions report case finding and treatment activities on a monthly basis to the DTP. The DTP prepares quarterly and annual reports for the NTI, inclusive of data received from the PHIs involved in tuberculosis activities.

Programme monitoring and evaluation has been largely limited to review and analysis of notification data and regularity of reports. The current information system does not provide for the monitoring of treatment outcome or programme outcome indicators. Management indicators and monitoring procedures focus attention on case finding but exhibit very little emphasis on case treatment and cohort analysis. Additionally, patients who are hospitalized in the more than 40,000 tuberculosis hospital beds are not registered in the NTI information system. Likewise, the large number of patients receiving initial care through the private sector are not registered with NTI. Consequently, it is estimated that less than 57% of all cases of identified tuberculosis are registered with the NTI (1).

In 1991, only 378 districts out of 438 with DTPs had registration in place (86.3%). Of those with DTPs, only 278 out of 378 sent reports (74%). Of the DTPs which reported to the NTI, they only received reports from 8502 out of 12,338 PHIs. Results from the 1987 "In Depth study on the NTP of India" (1) showed a general lack of awareness among tuberculosis staff of the importance of records and reports. Very few officers have readily made use of them. Data in the reports was not useful for programme management activities. Supervising officials rarely checked records and reports or gave guidance regarding their proper maintenance. Reports were very often



incomplete and unreliable. Although on site evaluation of case management is reported, it is acknowledged by supervisors that the monthly and quarterly reports sent to the DTC are not analyzed nor are the sending institutions given any feedback as to performance as reflected in the written reports.

### Conclusions:

There needs to be a clear emphasis placed on supervision if the NTP programme is going to succeed. Tuberculosis programme personnel need to be retrained about supervisory methodologies as well as supervisory content which emphasizes programme performance parameters. In order to address the increase in population and health care facilities at the periphery, a medical officer or treatment organizer and a laboratory supervisor should be added to the District Tuberculosis team at the sub-divisional level (about 500,000 population) in order to facilitate decentralization of supervision, staff training, monitoring and evaluation, and management of tuberculosis programme activities at the level of PHIs. To reduce travel time and cost, these staff should be based in a hospital or X-ray centre and they should be provided with transportation.

Monitoring of case finding and treatment results has not been prioritized, is still centralized and is not used at health facilities to evaluate the quality of programme delivery and implement corrective actions when necessary. PHIs management staff should be retrained on monitoring and evaluation methodologies. They should be taught to analyze their own facilities performance indicators and to take corrective action promptly. DTC, State and national staff should analyze the quarterly and annual reports received and provide feedback to the health facilities on the priority indicators of programme efficacy.

### 8.4 EDUCATION AND TRAINING

Since 1962, the National Tuberculosis Institute (NTI) at Bangalore, India has been the main training institution for tuberculosis programme staff. The various members of the District Tuberculosis Center (DTC) team (medical officers, x-ray technicians, laboratory technicians, pharmacists/treatment organizers, and statistical assistants) undergo a 10 week training program at the facility, with special emphasis on their areas of responsibility. The NTI also conducts seminars for state tuberculosis officers, university faculty, and district medical officers, as well as refresher courses for DTC staff.

In theory, in addition to NTI, the State Tuberculosis Training and Demonstration Centers (STTDC) are responsible for training BCG supervisors, orientation training of health visitors, and training of medical students and ancillary health care providers on the clinical aspects tuberculosis control. Continuing education for the private physician is often undertaken with assistance from the Indian Medical Association and voluntary organizations.

The review teams found, however, that the training given by STTDCs was neither comprehensive nor consistent with NTI policies and procedures with regards to diagnosis and treatment recommendations, i.e., x-ray reading, procedures for procuring and preparing sputum for smear microscopy, treatment regimen recommendations, etc. Training materials were not available for scrutiny. Instruction in the STTDC is provided on the basis of observations of clinical procedures, focusing on clinical aspects rather than programme operations.



Since the emphasis on primary health care and the push for integration of health services, medical officers and MPHWs have, in principle, become part of the tuberculosis control effort. The training and orientation of these health personnel in NTP policies and procedures varies widely. In some districts, the DTO and his staff provide systematic, but brief (two-day) training to medical officers and MPHWs using NTI training materials. In other areas, the training has been delegated to institutes of Public Health which provide general courses ranging from one year to eighteen months for health workers and one month for medical officers, where the tuberculosis content is a component of the course curricula. Medical officers of PHCs are also expected to train their staff in tuberculosis activities. Many of them, however, have yet to be trained themselves. The majority of medical officers interviewed in the field stated that they did not carry out any training activities for their staff.

Since 1962, over 4,800 team personnel or roughly 900 full teams have been trained by NTI staff. However, as the number of districts implemented has increased, and as senior personnel are promoted or attain superannuation, not all of the district teams currently have a full complement of trained persons. As of 1991, only 24% of DTCs had a fully trained team, while 66% had the services of a trained district tuberculosis officer (DTO), 76% had trained x-ray technicians, 78% had trained laboratory technicians, 88% had trained treatment organizers, and 59% had trained statistical assistants (13).

### Conclusions:

Training is vital to the successful implementation of the review team's recommendations for the NTP. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The needs for training of tuberculosis personnel for DTCs, PHIs and other health institutions exceeds the present training capacity of the NTI. The current NTP training should be decentralized by utilizing the existing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. These institutions should receive NTP training materials and "train the trainer" courses to maintain standardization of training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

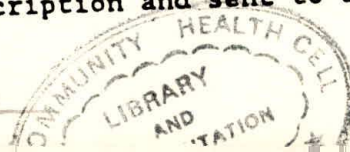
The NTP manuals should be revised to reflect the recommendations of the Review, and standardized educational materials should be developed by NTP for different categories of personnel involved in tuberculosis control activities (including medical students, general practitioners, etc. in private practice) and for patient motivation.

### 9. PRIVATE SECTOR

According to a study of 102 private doctors practicing in Bombay, 60% to 70% of patients bypass the public health system and seek care by private physicians when they become chest symptomatics (6). Review team field observations suggested that the proportion of patients seeking care in the private sector was slightly lower than evidenced in the Bombay study, but still represent about probably half of the new TB cases. Although many of those patients later move to the public sector, private practitioners have a major role and their management of TB cases influences also the results of the NTP. It appears that private physicians do not adhere to any set regimen for TB care. As in the public sector, dependence on x-ray diagnosis was evidenced. Case finding methodology and treatment regimens for tuberculosis patients vary widely and are usually more costly than regimens recommended by the NTP. Patients are usually given a prescription and sent to a pharmacy

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for drug purchase, with very little monitoring of patient compliance. Defaulter action is rarely taken.

The training of general practitioners is currently not adequate and has not been updated to incorporate recent advances in knowledge and strategies of the NTP. The capacity and organization of medical associations (IMA, Anti-tuberculosis associations) have not been tapped to provide continuing education and programme awareness to the private sector. Interviewed members of the Indian Medical Association (IMA) at State and District level showed strong support for the NTP efforts. IMA members seemed well aware of the issues and challenges facing tuberculosis control and were willing to utilize the organization to promote tuberculosis health education efforts and distribute educational materials to its members on the topic of TB case finding and management. The use of health education messages targeted towards both the private physician and the consumer regarding correct treatment regimens and the importance of completing treatment should be tested as a method to standardize care provided by the private sector.

### Conclusions:

A large share of the provision of health services in the country, including tuberculosis diagnosis and treatment, is done by private practitioners. They are, however, not currently included in the NTP system, either for notification of patients or standardization of diagnostic and treatment procedures. The role of the private sector in the care of the tuberculosis patient needs to be further clarified by the NTP. If indeed it is found that a large share of tuberculosis patients seek care in the private sector, improved training in medical schools and education of private practitioners must be implemented to ensure proper diagnosis and treatment and augment cure rates for patients under private care.

### 10. RESEARCH

India has a long history of tuberculosis research to improve programme delivery and treatment efficacy, and much of the information and experience obtained has been applied successfully in other countries. The research institutions can be utilized to analyze the functioning of the programme and to test alternatives to improve programme results, in particular organization of treatment delivery to increase the cure rate. To ensure that the studies provide relevant information for programme improvement, and that this information is opportune and utilized, this research should be planned and supported as an integral part of the NTP. Some operational research projects have already been discussed before the Review mission. Two major institutions currently involved in TB research are briefly described below.

The Tuberculosis Research Centre (TRC) in Madras was established in 1956, under the joint auspices of the Government of Tamil Nadu, the Indian Council of Medical Research, the British Medical Research Council and the World Health Organization, for studying initially the efficacy of domiciliary chemotherapy, in comparison with conventional sanatorium treatment. The centre was taken over by the Indian Council of Medical Research in 1965 and made a permanent research establishment. It established that a well-organised domiciliary chemotherapy with a daily regimen of isoniazid plus PAS produced results closely approaching those obtained in sanatorium with the same regimen; a satellite study established that there was no extra risk to the close family contacts from the infectious case after the start of treatment. Subsequently, the Centre investigated various regimens of chemotherapy in controlled clinical trials, backed up by in-depth laboratory investigations and solid statistical methodology. Clinical trials of various regimens of shortcourse chemotherapy that would be suited to Indian conditions were carried out, and more recently a study on implementation of



shortcourse chemotherapy under programme conditions in 18 districts selected from different parts of the country was initiated. In recent years, a strong department of immunology and cardiopulmonary function have been added to the Centre. Finally, the epidemiological unit that undertook a large trial of BCG vaccine in South India has now been integrated with the Centre. The Tuberculosis Research Centre has the capacity for undertaking training programmes that could complement the efforts of the National Tuberculosis Institute in Bangalore.

The National Tuberculosis Institute was established in Bangalore in 1960 with the objective of developing a suitable programme for tuberculosis based on operational research studies, training medical and paramedical workers for the District Tuberculosis Programme and monitoring the Programme through periodic reports received from the Districts. Based on studies on awareness of symptoms and action taken and on the Madras TRC studies demonstrating the efficiency of domiciliary chemotherapy, the NTP was evolved and launched at the NTI. In subsequent years, operational studies were undertaken on methods to improve case-finding, techniques for enhancing patient motivation and thereby enhance case-holding efficiency, and programme organization. Concurrently, large-scale field studies were initiated to provide information on epidemiological indicators such as prevalence and incidence of disease, fate of newly-diagnosed cases under programme conditions, and on the prevalence of tuberculous infection and infection with other atypical mycobacteria. Thereafter, and in view of conflicting reports about the efficacy of BCG vaccine, the largest BCG trial ever undertaken was launched in Chingleput, South India, to determine the efficacy of two strains of BCG vaccine at two different strengths.

#### Conclusions:

As a step towards the reorganization of India National Tuberculosis Programme activities, the research potential of the various research institutions should be evaluated in light of the findings and recommendations of this review and needs of the NTP for operational research studies. Operational research to test the feasibility and results of different technical and organizational strategies to be adopted by the tuberculosis programme should be an integral part of the revised tuberculosis programme.

#### 11. SITUATION ANALYSIS

Even after three decades of National Programme activities, the tuberculosis burden on Indian society remains enormous - something on the order of five million premature deaths in a decade, half of which are among women, mainly in the reproductive age. This mortality must affect at least twice that number of Indians with consequent lowered productivity, disability and perpetuation of poverty. Excellence in research, early successes proving the advantages of some modern treatments, availability of powerful and effective antibiotics, a well established TB structure at the State level and, in the last two decades, extensive development of the institutional structure for primary health care in the rural areas, have not yielded the progress against the disease which India could have expected. Decline in the annual risk of infection (and in incidence) has been agonizingly slow in many areas. Well over half the population is infected with TB and the risk of infection is far too high at between 1 and 2% per year. An aging population structure, increasing HIV prevalence and apparently rising levels of drug resistance mean that without a reoriented and vitalized public TB control effort the disease will pose an increasingly serious health and developmental constraint for several decades to come.



The main factors to be addressed in making real progress against TB fall in four main categories - organizational, managerial, technical and developmental. Elements of the present health care system, and many parts of the current TB control programme provide the basis for implementation of major improvements. Strengthening and reorientation of policy and program execution in each of the problem areas offer sound prospects of improvement in curing TB patients in numbers which will result in 8-10% annual decline in the risk of infection and effectively halve the tuberculosis burden in about a decade while ensuring much lower disease and infection rates for decades into the future.

The state TB control programs are well structured and have direct intervention capabilities at the district level and below in about three quarters of the country. In contrast, the national TB control programme has languished with ineffective terms of authority and budgets and an exceptionally low executive position within the Ministry of Health for such an important disease. Monitoring, critically examining and adjusting national policy for effective state performance has consequently atrophied.

In the absence of a strong central Ministry unit, power for TB policies has been ceded to the National TB institute (NTI) in Bangalore. The NTI has had preeminence in training and some types of research for TB but now suffers serious institutional weaknesses. Budget shortfalls, unfocussed direction of research, training program content which is not replicated at state level and lack of experience with making and implementing policy have left a gap in national TB leadership. The absence of a national policy body for TB at central level, supported by a strong executive TB unit within the Ministry, has meant that no revision of policy has been made in spite of repeated evaluation showing poor results, and therefore NTI has not changed or developed alternative TB Program procedures.

Further, the content of their training has stagnated in relation to recent TB control success elsewhere. In the absence of a strong central program, NTI has been forced to assume program management and standard-setting functions which are inappropriate for a training/research institution. This is particularly true as NTI does not have the staff and executive authority to monitor and enforce compliance of the states with policy.

Below the State level, TB has been indicated as a priority for integration into the key health services. However, the TB program's effective cooperation with health service providers at the primary level and willingness of the providers, under current policies, to devote substantial attention to TB, remains doubtful at best. The ambivalence resides both in lack of strong and focussed national program direction and in the absence of policies responsive to the legitimate interest at the local level for a clearcut, standard, easy to follow program which is effective for cure. Strong direction, some decentralization below the district level, training, increased funding and a comprehensive policy package are needed.

Technical problems confronting the NTP are both historical and the result of some isolation. There remains traditional emphasis on case-finding activities when only a minority of discovered cases are being cured. Technical practices emphasize radiographic methods which are sensitive, but not specific, rather than concentrating on high-quality microscopy which with a good quality control system can be both specific and sensitive. Too frequently, one sputum smear is examined rather than several, leading to inappropriate treatment of infectious cases. Microscopes are often monocular and of poor quality, training is uneven and quality assurance systems seldom function. Protocols for appropriate use of radiography and clinical diagnostic methods need to be prepared and disseminated.



Treatment for diagnosed patients is chosen from too many regimens and adequate short-course chemotherapy is yet infrequently used and is completed in only a minority of cases. Repeated sputum smears during the course of treatment are not regularly taken to monitor effectiveness of therapy. Provision of services is often too remote or inconvenient to encourage patient compliance, and providers lack adequate motivation and training for patient supervision. Improved treatment protocols, training, adequate supplies of only SCC drugs, and adaptation of practices to provide some degree of supervised initial chemotherapy, whenever feasible, are needed.

Recording and reporting procedures do not permit rigorous supervision of the system as a whole or at the institutional level. Case definitions are not adequate. Criteria for completion of treatment and discharge do not exist. Laboratory registers and patient treatment registers do not contain the information necessary to perform cross checking or to monitor the performance of states, districts, blocks or individuals providers. Conversion status of smear positive patients cannot be documented. Cohort analysis to ensure and measure program effectiveness cannot be satisfactorily done with present registry formats and procedures. Therefore, adaptation of existing TB Program policies and resources to implement and improve recording and reporting system is required.

Developmental constraints include both institutional and financial issues. Operational research to test and improve on program performance is not currently an integral part of the TB program. Training materials and objectives are in need of revision to support a revitalized program and pedagogical content may need improvement. Medical college curricula need additions to provide both theoretical and practical exposure to the elements of TB control as doctors graduating now will continue to see TB throughout their working careers. Present private medical practitioners need to be educated about modern treatment and policies of the program. This can be done through existing NGOs. To do this, strengthening of the NTI, of the state level training centre, and studies and technical assistance at both the national and state levels will be needed. Opportunities for overseas training and experience will accelerate adoption of effective new experience in TB control elsewhere.

The government has recently decided to increase funding for TB control and is for now continuing to provide for the treatment of all TB patients diagnosed in the public system. The present high number of overdiagnosis and treatment of patients which now appears to be occurring offer scope for savings in an improved program. Overall though, financial resources for TB appear to have declined in real terms in recent years because of inflation and rising import costs, despite the government's recognition of the trend and efforts to counteract it. Moreover, only a fraction of patients today requiring treatment receive it in full.

A strengthened program will require increased resource allocations at both the central and local levels for drugs, supervision (including transport), training and operating cost. Given the demonstrated cost-effectiveness of TB control programs compared to other health sector interventions, revision and expansion of India's TB program with external financial assistance would appear to be fully justified.



*Critique* : Funding : State level ; dist level ; - A social control : popul + linkage i  
*Hypoth* : private sector ; wages + trad. med ; TAF ; ↓ decant / PR  
 : intra public sector diff  
 : calcu. technical - context cont. context  
 : rel to broader factors such as housing + epidemiology not considered.

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## 12. RECOMMENDATIONS

1. The structure of the National Tuberculosis Programme should be strengthened by 1) establishing an apex policy making authority and an executive task force with managerial functions to implement programme reorganization, and 2) upgrading the central tuberculosis control unit in the Directorate to provide strong leadership and enhance the efficiency and effectiveness of the National Tuberculosis Programme.
2. The quality of patient diagnosis should be improved by 1) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment, 2) ensuring the quality of microscopy with adequate equipment, training and quality control, and 3) establishing criteria for diagnosis by radiological and clinical methods.
3. National and state tuberculosis programme resources should be directed to ensuring cure of tuberculosis patients, giving priority to infectious cases of tuberculosis by 1) adopting short-course chemotherapy, 2) establishing criteria for treatment completion, cure and discharge from medical care, and 3) ensuring an uninterrupted supply of drugs of good quality.
4. The current NTP system of registration and notification should be revised to emphasize the cohort analysis of treatment results (completion and cure, transfers, defaulters, died, treatment failures) as the main indicator of programme effectiveness.
5. Policies should be developed to ensure decentralization of treatment services closer to the community level to enhance access to care and patient compliance to recommended therapies.
6. Pilot projects should be implemented at block level to test the feasibility and results of different technical and organizational strategies to be adopted by the tuberculosis programme -- i.e., to test the capacity to implement recommendations 2-5 above.
7. A medical officer or treatment organizer and a laboratory supervisor, with the necessary transport, should be added to the existing administrative structure at the sub-district level (about 500,000 population) to strengthen tuberculosis programme management and to facilitate decentralization of supervision.
8. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The current training infrastructure will need to broaden the scope of its training capabilities by utilizing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.
9. Operational research must be carried out as an integral part of the revised tuberculosis programme to evaluate programme performance, improve delivery of services, problem solving and obtain baseline epidemiological information to measure reduction in the risk of infection.



## ANNEX 1

PARTICIPANTS IN THE COMPREHENSIVE PROGRAMME REVIEW NATIONAL TB PROGRAMME  
INDIA 1992

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27. Dr J. Veen  
WHO Consultant  
The Netherlands

*Analysis of composition*

*No NTI sep. / No ICNR / chengapat / TAI  
TRC - 7 (25% of total participants, 35% of Indians)*

*Internat - 8/27*

*Directorate (Central) - TB div poorly rep*

*Finance Ministry*

*Sam/NATL*



INSTITUTIONS VISITED AND PERSONS INTERVIEWED  
CENTRAL LEVEL

INSTITUTIONMAIN PERSONS INTERVIEWED

-TB Association of India <i>1/2 hr short meeting where their views were not really solicited / heard.</i>	Dr D.R. Nagpaul Vice President and Hon. Technical Adviser. TAI, New Delhi
	Dr S.P. Pamra Former Hon. Technical Adviser TAI, New Delhi
-Ministry of Health	Dr P. Kumar I/C ADG TB, Nirman Bhavan, New Delhi
-Planning Commission	Prof. I.C. Tiwary Adviser (Health), Planning Commission New Delhi
-National Malaria Eradication Programme	Dr Narasimham, Director NMEP, New Delhi
-Universal Immunization Programme	Dr (Miss) Jotsna Sokhey Dep. Commissioner (MCH), Nirman Bhavan New Delhi
-Medical Stores Department	Dr Biswas, Medical Stores Division R.K. Purman, New Delhi
-Central Health Education Bureau	Dr Hiramani, CHEB, Kotla Road, New Delhi
-National Institute of Communicable Diseases	Dr T. Verghese Director, New Delhi
	Dr R.C. Sharma Epidemiologist, NICD, New Delhi
-LRS TB Hospital, Aurobindo Marg New Delhi	Dr R.C. Jain Medical Superintendent, LRS TB Hospital, New Delhi
-New Delhi TB Centre J.L. Nehru Marg, New Delhi	Dr Govind Prasad Director, NDTB Centre, New Delhi
-National Aids Control Org. Red Cross Road, New Delhi	Dr L. Khodakevich Medical Officer, Global Progr. on AIDS WHO, India
-National Task Force on Malaria	Dr Harcharan Singh, Chairman (Former Adviser, Planning Commission)
-Indian Council of Medical Research (ICMR)	Dr S.P. Tripathy, Director General



TAMIL NADU STATE  
MADRAS

INSTITUTIONMAIN PERSONS INTERVIEWED

-Ministry of Health	Mr K. Inbasagan Health Secretary
-Anti-TB Association of Tamil Nadu	Dr Susila Raj Director of Medical Services I/C and Vice Chairman
-Institute of Thoracic Medical Association	Dr Panchamurthy President of the Madras City I.M.A. etc.
-Central Medical Store	
-Government TB Sanitorium Thambaram	Dr R. Paramasivam Superintendent
-Institute of Public Health Poonamallee	Dr A. Ramalingaswara Rao Director of Public Health
	Dr Prithivi, Director
-State Tuberculosis Division	Dr A. Subramaniam (STO)
-Medical and Health Services	
-Indian Medical Association	Dr Bhaktavalsalam

SALEM

-DTC Salem	Dr T. Arunagiri (DTO)
PHI - Nainampatti and subcentre	
PHI - Karipatti and subcentre	
PHC - Vzhapadi (RC)	
GH - Athur (XC)	
PHC - Vinaitheerthapuram and subcentre	
GH - Rasipuram (XC)	
PHI - Sengalandapuram (RC)	
GH - Omalur (MC) Leprosy Centre	
Relief Rural Centre - Chettipatti	
PHI - Sarkapalliyur (MC)	
PHI - Sirkar Kollapatti (RC)	
GH - Mattur Dam	

THANJAVOOR

-DTC Thanjavoor	Dr Mohan Raj -DTO
	Dr G. Govindarajalu- Deputy Director Medical Services
	Dr R. Elango Deputy Director Health Services
-Indian Medical Association Thanjavoor District	Prof. V. Thiyagarajan, President T.M. Thanjavoor



-District Collectors Office

PHI - Nadu Cauvery and Sub-centre  
 PHI - Budalur and Sub-centre  
 PHI - Vallam and Sub-centre  
 PHI - Melattur (XC)  
 Panchayat Union Dispensary - Sengipatti (RC)  
 Panchayat Union Dispensary - Vaduvor (RC)  
 GH - Mannargudi (XC)  
 GH - Thiruvaiyary (RC)  
 GH - Kumbakonam (XC)

GUJARAT STATE

-Ministry of Health

Mr Bhanujan  
 Health Secretary

Mr Sugathan  
 Commissioner, Health

Dr N.G. Ghasura  
 Addl. Director , Health Services

-State Tuberculosis Division

Dr B.M. Soni  
 State Tuberculosis Programme Officer

-State Tuberculosis Demonstration  
 and Training Centre

Dr P.P. Mehta  
 Director

-State Tuberculosis Association

Dr Patel  
 Chairman

-Indian Medical Association  
 Gujarat State Branch

Dr I.C. Shah

BHAVNAGAR

-K.J. Mehta TB Hospital  
 Amargadh - Bhavnagar

Dr M.D. Gandhi  
 Medical Superintendent

-District Medical Office

-Government Medical College

-District Tuberculosis Centre

Dr Shah (DTO)

Community Health Centre (XC)  
 Mandvi - Surat

PHI - Kathor (MC) and Sub-centre

Civil dispensary Gadat - Surat (RC)



UTTAR PRADESH STATE  
LUCKNOW

-Ministry of Health and Family Welfare	Mrs Sunita Khandpal Principal Secretary
-Ministry of Health and Family Welfare	Dr Bacchilal Additional Secretary
-Department of Health	Dr P.D.P. Mathur Director General, Health Services
-Department of Health	Dr B.N. Saxena Director General, Health Services
-Department of Health	Dr P.K. Tandon Director National Health Program
-Department of Health	Dr Brijendra Singh, JD (TB)
-Department of Health	Dr J.K. Agarwal (CMOH)
-Thakurganj TB Hospital	Dr Saxena (CMOH)
-RFPTC - Indira Nagar	Dr V. Kumar, Epidemiologist
-Kanpur General Medical College	Dr Sharma, Acting Principal and Professor of Paediatrics
-Kanpur General Medical College	Dr M.S. Agnihotri Professor of TB and Chest Diseases
-Uttar Pradesh TB Association	Dr Sinha President

VARANASI

-District Tuberculosis Centre	Dr Gyanendra Singh, DTO
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AGRA

-State Tuberculosis Demonstration Training Centre	Dr V.K. Tewary Director and Professor
-State Tuberculosis Centre	Dr M.L. Mehrotra Ex - Director
	Dr Gupta, CMOH
	Dr K.D. Gautam, Statistician

KANPUR

-District Medical/Health Services	Dr Ram Babu, CMOH
-District Tuberculosis Centre	Dr S. Nath, DTO
-General Practitioner	Dr Singh
-Kanpur Medical College ML Chest Hospital	Dr Katiyar Professor of TB



### ANNEX 3.1

#### BACKGROUND INFORMATION

The National Tuberculosis Program (NTP) of India must be viewed within the context of India's political and socio-economic profile.

257. India is the second largest country in the world and contains nearly a fifth of the world's population. The present population is derived from six main ethnic groups, dispersed unevenly between urban and rural areas, with roughly 75% of the population residing in rural regions of India. Crude birth rates, death rates and infant mortality rates are higher in the rural parts of the country. Thirty seven percent of India's rural population is below the country's poverty line, consisting largely of the landless, marginal and small farmers and other marginal workers. Although great strides have been made in the universalization of primary education in recent years, adult literacy rates remain low because of lack of universal free availability of formal education in the previous decades.

India has experienced clear periods of economic growth, evidenced by a rising gross domestic product, gains in per capita income, and growth in agriculture, industry and in consumer goods production. The economic gains are however unevenly distributed within the country, despite welfare schemes implemented to alleviate poverty and unemployment. Steady gains in per capita income and gross national product have been offset by poor balance of payments and inflation.

A network of air services, railway system, and roads provide linkages for the vast populations of India. A spreading network of telecommunications facilities complement the transportation systems, facilitating within country business transactions and implementation of health and family welfare programmes.

After gaining independence in 1947, India has become a multi-party democracy, with a federal structure reflected in both the central and state governments. Local self governments are in place in cities (municipalities) and in villages in the form of panchyat raj institutions. A strong bureaucracy lends continuity and stability to gubernatorial administrations throughout the country.



## HEALTH SECTOR

## Principal health problems:

Morbidity statistics with regard to the incidence and prevalence of diseases are not available for the country as a whole. The main sources of such statistics are health care institutions, community surveys, and ad-hoc studies conducted on specific subjects. 1986 data depicting the five leading causes of deaths due to major communicable diseases in descending incidence are as follows: tuberculosis, tetanus, viral encephalitis, viral hepatitis, and meningococcal influenza. 1986 morbidity data in descending incidence are as follows: influenza, tuberculosis, enteric fever, whooping cough and viral hepatitis (11). Data on causes of death in all major cause groups lists asthma and bronchitis, clubbed together, as the leading cause of death, followed by tuberculosis, pneumonia, cardiovascular disease, and anemia.

Magnitude

Age-specific morbidity and mortality data indicate that the major causes of morbidity and mortality among children in India are infectious and parasitic diseases, and diseases of the respiratory system. Among adults, infectious and parasitic diseases are joined by diseases of the circulatory system, injuries, and poisonings as major causes of morbidity and mortality. Health policy and strategy:

The government of India has entrusted a specialized body, viz., the Planning Commission, the responsibility to be the Advisory Body for health care policy formulation, functioning at the highest policy level without, however, being involved in the responsibilities of day-to-day administration.

Not exactly true - consultation process

The Planning Commission's current Five Year Plan on the national health policy of the India government emphasizes political as well as administrative commitment to 'Health for All by the Year 2000' enunciated in the Alma Ata Declaration of 1978. The policy places emphasis on developing a rural health care system based on a combination of promotive, preventive, and curative health care services taking the village as a base, and de-emphasizing hospitals, super-specialities, and highly trained doctors practicing mainly in urban areas.

A large increase in the population of India as evidenced by the 1981 country-wide census is attributed to a fall in the death rate brought about by significant improvements in health conditions, effective control of epidemics and overall socio-economic development over the last three decades. The control and stabilization of population growth is considered essential in order to maximize gains in the socio-economic and health sectors.

Thus, national health policy demographic targets are aimed at achieving a net reproduction rate of one (NRR:1) by the year 2000 AD, with a crude birth rate of 21 per thousand and a crude death rate of 9 per thousand. The intention is to bring the population growth rate down to 1.2 per annum from the growth rate of 2.5 per annum recorded during the decade 1971-1981. The policy also stresses the need for close linkages at the primary level between health and family welfare programmes including MCH. It further lays down the Infant Mortality Rate of below 87 by 1990, and of 60 or less by 2000 AD from the 1980 level of 114 per 1,000. At present, the IMR is 96. Nutrition and immunization are considered essential to bring down the IMR. Children up to one year of age under the Expanded Programme of Immunization are targeted for vaccine coverage as well as prophylaxis against anaemia and vitamin deficiency.

in National Health Policy

The targets for 'Health for All by the Year 2000' include a statement on tuberculosis. Levels (percentages) of tuberculosis cases completing treatment out of those detected have been set for the years 1983, 1985, 1990, and 2000. Current data indicate that tuberculosis cases completing treatment are 25 percentage points behind projected figures.



## Health services and structure:

A parallel structure of political/administrative and technical advisors is in place at both the federal and state level of government to implement the country's general health services.

At the Central level, there is a Ministry of Health and Family Welfare consisting of two Departments namely the Department of Health and the Department of Family Welfare. Both departments are headed by the Secretary to the Government. The Secretariat functions under the direction, control and supervision of the Cabinet Minister who is usually assisted by the Minister of State. The Directorate General of Health Services serves as the technical wing to the Ministry and its activities cover the whole spectrum of medical care and public health apart from general administration.

Most health programs, with the exception of leprosy and family welfare, are integrated at the district level where a district medical officer/district health officer organizes the planning, implementation, and supervision of different health programmes, using a network of primary health institutions and multipurpose health workers.

Strides have been made to increase the numbers of health care personnel. Presently, there are 108 recognized medical colleges and 17 unrecognized medical colleges with an annual admission of 11,562 and out-turn of approximately 11,000 graduates. A majority of these institutions have facilities for post-graduate education, producing approximately 6,000 post-graduates annually.

In 1946, there were only 7,000 nurses in India, each serving a population of 43,000. It was recommended that there should be one nurse for every 500 of population. Facilities for training nurses were implemented, resulting in a net out-turn of 8208 nurses in 1986, up from 1282 in 1950. Currently the nurse to population ratio ranges from 1:1179 in urban areas to 1:6075 in rural areas.

The supply of pharmacists was extremely meager in 1951. There were only two institutions offering degrees in pharmacy in the country with an annual intake capacity of 70 and an out-turn of 38. It has increased to 12 institutions with an intake of 675 and an out-turn of 281 by 1961. No information with regard to total number of pharmacists registered with the Council are available.

There is a great variation in the distribution of health manpower e.g. the doctor population ratio varies from 1:820 to 1:1560, with demand greatly exceeding supply in rural areas. Reorientation of all categories of health care providers towards primary health care at the community level has helped to ease the demand at the periphery. In addition, the national health policy has established a goal of having one male and one female multipurpose worker for every 5000 rural population. Plans to convert existing unipurpose workers and integration of organization and structure of various health and family welfare programmes at the primary health centers are well under way.

## Health budget:

The current budget for health and family welfare (Seventh Plan 1985-1990) is 66 489 million Rs, roughly 1.9% of the total budget is for health and 1.8% for family welfare. During 1988-89 there has been a great emphasis on rural health and control of communicable diseases, reflected in funding to programmes for the eradication of malaria, leprosy, and tuberculosis.

$\frac{66489}{5} = 13297.8$  per year  
 50% for HHS + 6,645 million  
 Prof. TB (664 million)  
 all 3000  
 is actually  
 much less  
 92-93 TB 290 million



# POPULATION OF INDIA FROM 1901-1991

CENSUS YEAR	POPULATION IN MILLION	SEX RATIO F : M	POPULATION DENSITY NO./SQ.KM	URBAN POPULATION % AGE	DECADAL GROWTH RATE
1901	238	0.972	77	11	+ 5.7
1911	252	0.964	82	10.3	- 0.3
1921	251	0.955	81	11.2	
1931	278	0.950	90	12	+ 11
1941	318	0.945	103	3.9	+ 14
1951	361	0.946	117	17.3	+ 13
1961	439	0.941	142	17	+ 21.5
1971	548	0.930	177	19.9	+ 25
1981	685	0.933	216	23	+ 25
1991	840	0.929	256	27.5	+ 23.5

The different population health indices are listed below for the last 10 years.

CENSUS YEAR	CRUDE BIRTH RATE	CRUDE DEATH RATE	GROWTH RATE	GROSS FERTI RATE	INFANT MORTAL.	LIFE EXPECTANCY AT BIRTH RATE MALES	FEMALES
1981	33	12	21	156	110	55.6	56.4
1986	29.7	10.7	19	136	92	58	59
1991	26.7	9.3	17.4	118	80	60.6	61.7

## LITERACY RATES (PERCENT)

CENSUS YEAR	MALE	FEMALE	TOTAL LITERACY
1901	9.8	0.6	5.4
1911	10.6	1.0	5.9
1921	12.2	1.8	7.2
1931	15.6	2.9	9.5
1941	24.9	7.3	16.1
1951	25.0	7.9	16.7
1961	34.4	12.9	24.0
1971	39.5	18.7	29.5
1981	6.7	24.9	36.2
1991	63.9	39.4	52.1



ENROLLMENT IN SCHOOLS (PERCENTAGE)

CENSUS YEARS	PRIMARY SCHOOLS (6-10 YEARS)			MIDDLE SCHOOLS (11-14 YEARS)		
	BOYS	GIRLS	TOTAL	BOYS	GIRLS	TOTAL
1950-51	61	25	43	21	5	13
1960-61	83	41	62	33	11	23
1970-71	93	59	76	46	21	34
1980-81	99	66	83	52	27	40
1985-86	109	77	93	65	38	52

EDUCATIONAL INSTITUTIONS 1987-88

PRIMARY SCHOOLS	:	543 677
MIDDLE SCHOOLS	:	141 000
SECONDARY SCHOOLS	:	71 300
COLLEGES FOR GENERAL EDUCATION	:	4 329
PROFESSIONAL EDUCATION	:	876
UNIVERSITIES AND CENTRES FOR HIGHER LEARNING	:	190



## GNP TRENDS

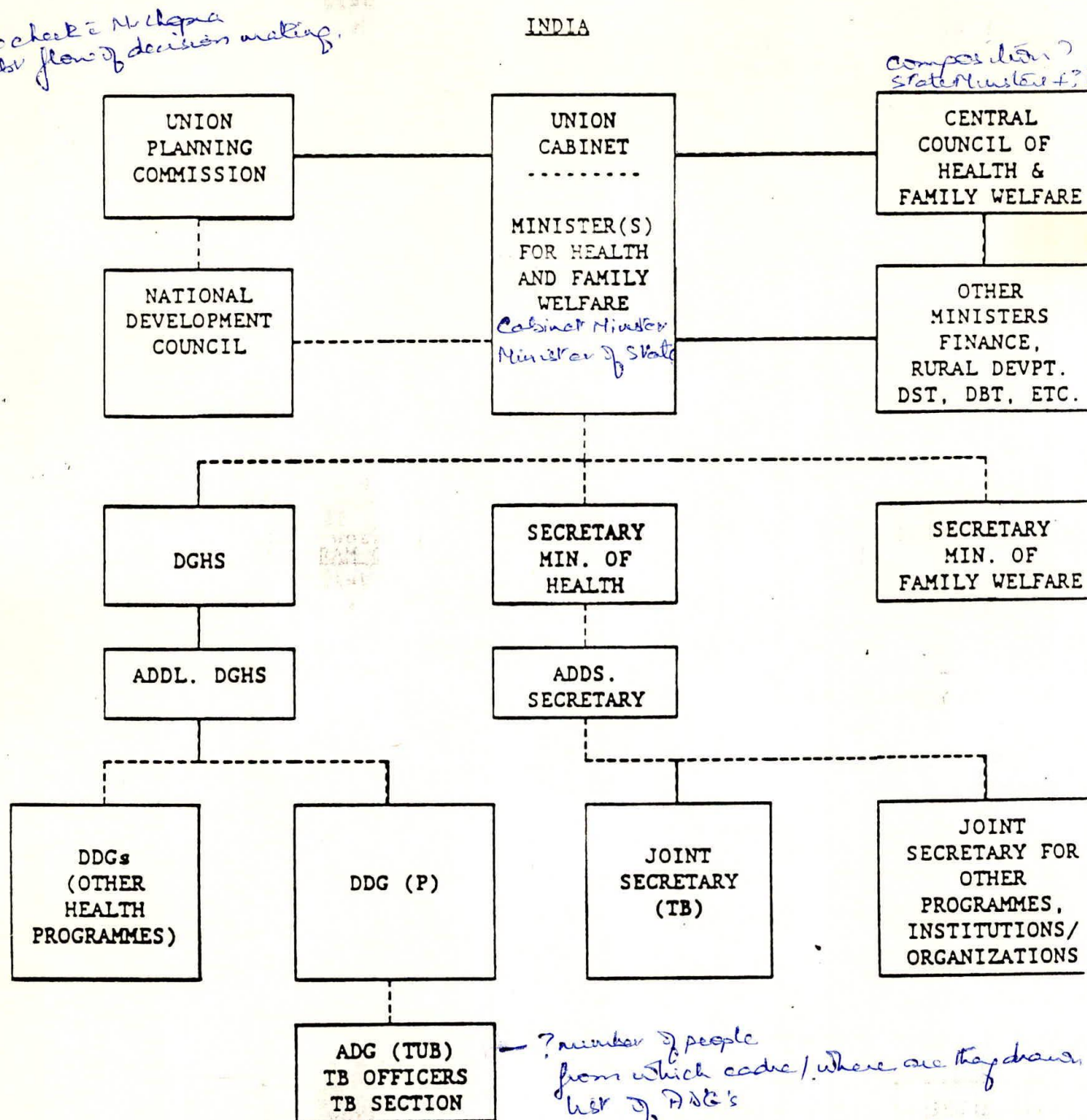
INDIA 1987-88

YEARS	GNP (IN 1000 MILLIONS AT CURRENT PRICES)	PER CAPITA NET NATIONAL PRODUCT
1950-51	91	254
1955-56	97	236
1960-61	140	306
1965-66	219	426
1970-71	365	633
1795-76	664	1026
1980-81	1226	1627
1985-86	2326	2734
1987-88	2915	3284

CATEGORY OF PERSONNEL	PRESENT ANNUAL NUMBER TRAINED	TOTAL NUMBER (1987)
1. Doctors		
a. Under-graduates	12 000)	330 000
b. Post-graduates	5 000)	
2. Dentists	850	9 800
3. Nurses	10 000	245 000
4. Auxiliary-Nurse Mid wives	15 500	132 000
5. Health visitors	660	16 000
6. Laboratory technician	2 200	
7. X-Ray technicians	800	
8. Pharmacists	12 000	
9. Multi pupose workers	8 200	182 000
10. Medical Statisticians, Statistical Assistants, and Medical Record Clerks	NA	NA



# ORGANOGRAM OF CENTRAL HEALTH MINISTRY & DEPARTMENT



List of Union Cabinet Ministers

1. Raj Kumar Amrikhwar

2.

3. Dr. Sushila Nayar

4. Dr. Karan Singh

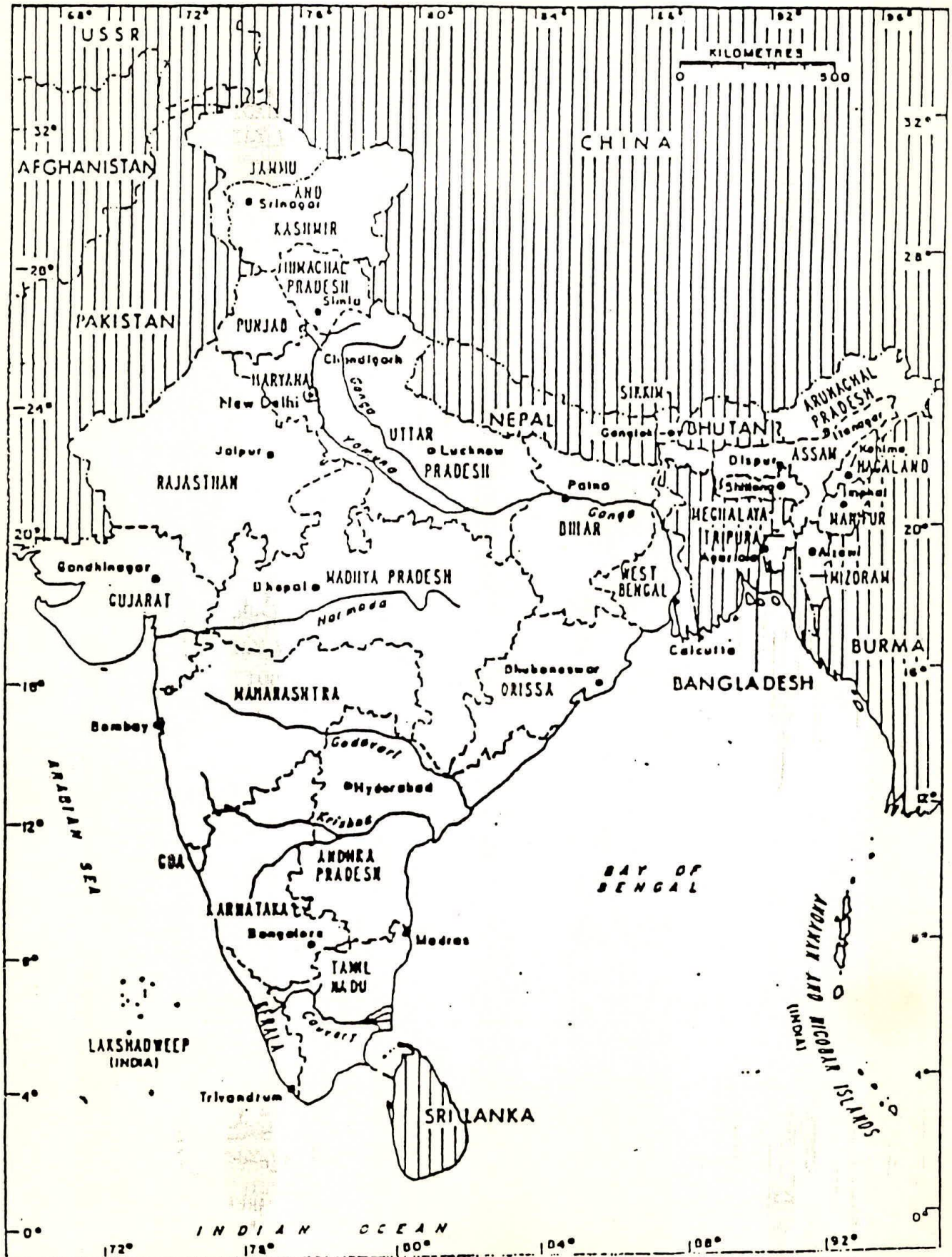
5. Raj Narain

6. Shan Karanand

7. Currently being held by PM, Nalabimbo Rao,



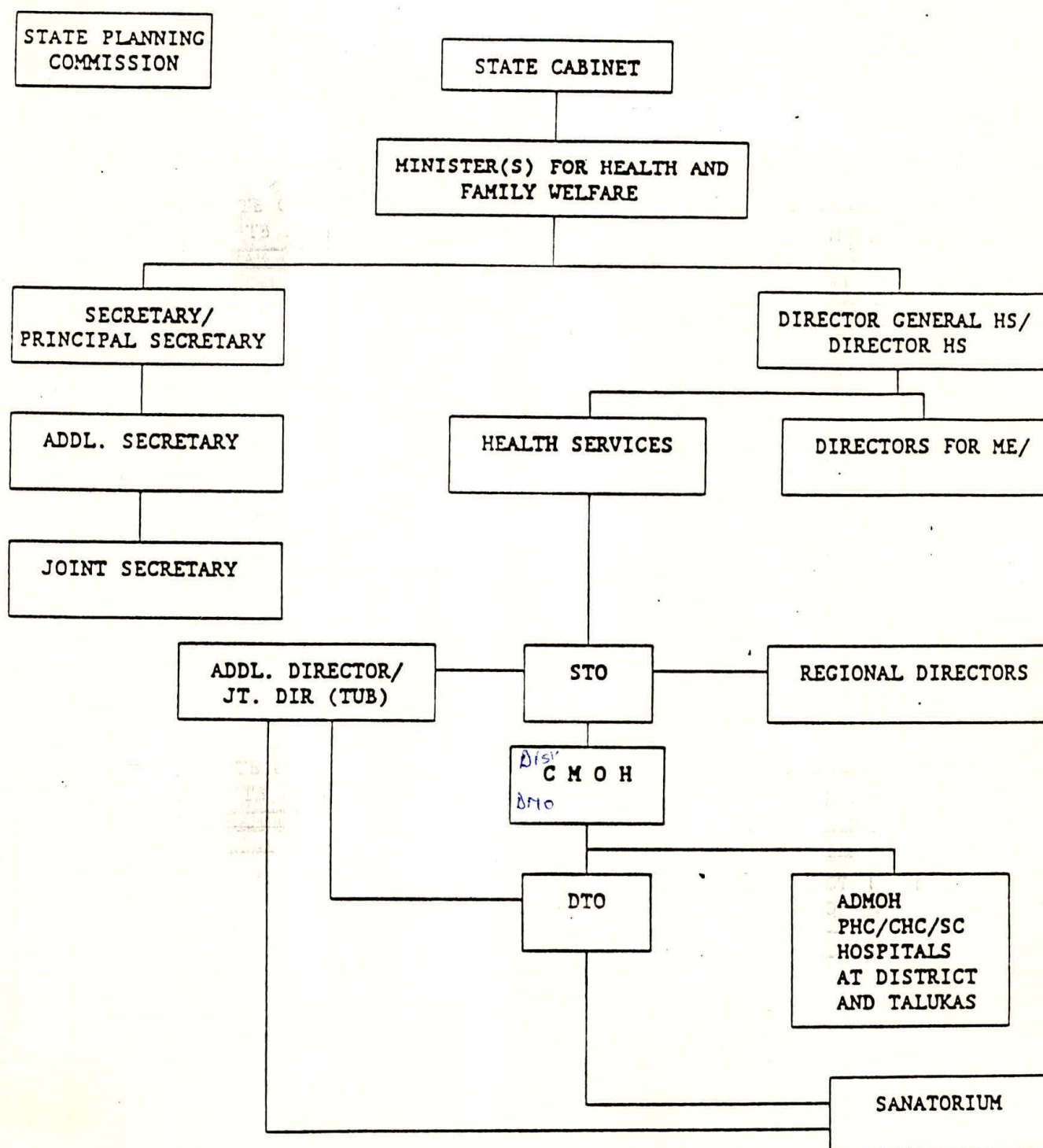
## MAP OF INDIA



The boundaries shown on this map do not imply official endorsement or acceptance by the World Health Organization



ORGANOGRAM OF STATE HEALTH MINISTRY & DEPARTMENT



STO	:	STATE TUBERCULOSIS OFFICER
CMOH	:	CHIEF MEDICAL OFFICER OF HEALTH
ADMOH	:	ASSISTANT DISTRICT MEDICAL OFFICER OF HEALTH
DTO	:	DISTRICT TUBERCULOSIS OFFICER
ME	:	MEDICAL OFFICER
MS	:	MEDICAL SERVICES
FW	:	FAMILY WELFARE



## ANNEX 4.1

## PRESENT TREATMENT PRACTICES

## 1. Case definitions

To report the regimens most commonly used in the NTP, patients are categorized according to the site of the disease (pulmonary or extrapulmonary), bacteriological status and history of previous tuberculosis treatment (see WHO Guidelines for Treatment of Tuberculosis in the National Tuberculosis Programmes).

## 1.1 Definitions according to the site of the disease.

Pulmonary smear-positive patients are those reporting one of the following cardinal symptoms: cough for two weeks or more, chest pain for one or more months, hemoptysis. They should be proved smear-positive by at least one sputum smear examination (10 bacilli or more seen in one hundred fields).

Pulmonary smear-negative patients are those with the cardinal chest symptoms with an x-ray of the chest suggestive of tuberculosis and smear-negative on two consecutive collections (usually one on the spot and one early morning). Patients with pleural effusion are categorized as smear-negative.

Extrapulmonary tuberculosis is tuberculosis of an extrapulmonary site diagnosed on clinical basis by a medical officer.

## 1.2 Definitions according to previous history of tuberculosis therapy.

New patients are those not indexed in the District Tuberculosis Centre (DTC) and not previously treated in the DTC. Patients previously treated or under treatment by an institution not reporting to the DTC are considered new.

Old patients are patients:

- receiving treatment in the DTC
- resuming treatment after being lost
- previously indexed in the DTC, have completed the prescribed regimen and are smear-negative at the end of chemotherapy, and they come back to the DTC with symptoms suggestive of tuberculosis (relapses). A relapse patient can be smear-positive or smear-negative.
- patients smear-positive after having completed the prescribed regimen (failures of a treatment for new patients and chronics)
- not attending the DTC for two or more months (lost)

## 2.1 Regimens for new patients:

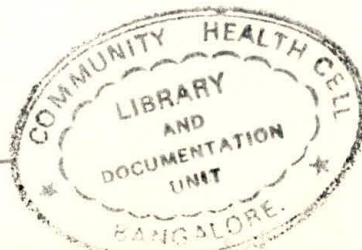
Pulmonary smear-positive

- conventional chemotherapy

- (1) 2SEH/10EH
- (2) 2STH/10TH

Patients clinically not improved at the end of the 12 months period receive 6 more months of EH or TH.

DIS-319  
05829





- Short course regimens

- (1) 2HRZ/6EH
- (2) 2HRZ/6TH
- (3) in sanatoria and chest hospitals: 2 EHRZ/4HR

Pulmonary smear-negative (including pleurisy and hilar adenopathy):

- conventional chemotherapy

- (1) 2S<sub>2</sub>H<sub>2</sub>/10EH
- (2) 12EH or 12TH
- (3) in sanatoria and chest hospitals: 3STH/12TH

Patients clinically not improved at the end of the 12 months period receive 6 more months of EH or TH.

- Short course regimens (for cavitary or miliary tuberculosis)

- (1) 2HRZ/6EH
- (2) 2HRZ/6TH
- (3) in sanatoria and chest hospitals: 2HRZ/4HR

Tuberculosis in children (0-5 years old)

Pulmonary forms: 12 HR (HE)  
Extrapulmonary forms: 18 -24 HR (HE)

Extrapulmonary tuberculosis of lymph nodes, bones, abdomen:

- (1) 2STH/10TH
- (2) 12 EH (TH)
- (3) 2SEH/10EH

Meningitis and other extrapulmonary patients seriously ill:

- (1) 2HESRZ/6HR

2.2 Old patients:

Relapse and failure (all forms)

- (1) in sanatoria: 2STH/18TH
- (2) in DTC: 3STH/18TH

Chronics: TH lifelong

When possible smear-positive failure and relapse patients are referred to a specialized institution for drug sensitivity tests and appropriate treatment. If possible the patient is prescribed treatment according to the results of sensitivity tests. If possible two additional drugs are prescribed to which the patient is still sensitive.



## ANNEX 4.2

## GUIDELINES FOR TREATMENT ORGANIZATION

Correct treatment should include the following:

- Patients should be provided a standardized regimen according to the type of disease and treatment history
- All pulmonary smear-positive patients detected in the district should be monitored by sputum smear examination during chemotherapy and at the end of chemotherapy
- It should be ensured that pulmonary smear-positive patients are cured (that they complete drugs collection and remain smear-negative until the end of the prescribed regimen)

It is essential to prepare a new national policy and structural reform package and a workplan for the new programme implementation, starting in States in which there is a sufficient political commitment for improving the tuberculosis programme. Reliance on "conventional" chemotherapy is inadvisable because the cost of these regimens is approaching the cost of short course regimens (SCC) when ethambutol is used instead of thiacetazone. (The cost of ethambutol is approximately four times higher than that of thiacetazone and one dose of streptomycin costs approximately 2/3 of a daily dose of rifampicin). Simplified guidelines should be prepared for the prescription of appropriate regimens. It is advisable to recommend one regimen per category of tuberculosis patients, with few alternatives to adapt them to State specific situations. SCC regimens are the most cost-effective regardless of patient categories. Guidelines for case management of all forms of tuberculosis, linked to the resources made available for purchasing drugs, should be provided.

Priority for SCC should be given to new pulmonary smear-positive cases. Such cases should be identified by a proper treatment history taken by a medical officer, with clear guidelines on how to collect the information. During the interview, the patient should perceive that the type of drugs that he will receive will not depend on his answers. It should be emphasized that a smear-positive case of tuberculosis that becomes negative during the initial phase of treatment usually has a little chance of becoming smear-positive again during the continuation phase of chemotherapy. Cases that remain smear-negative are practically at no risk of developing acquired drug resistance.

Smear-positive relapses should be identified as the second priority category. These patients should be identified by a careful treatment history. Guidelines should specify key questions to differentiate "true" relapses from failure cases that have previously taken irregular chemotherapy. Such irregular smear-positive failure cases should have the lowest priority among smear-positive cases due to high risk of having already developed acquired drug resistance to the most potent anti-tuberculosis drugs (isoniazid and rifampicin). Treatment of failures should not divert resources from effective treatment of new smear-positive cases and smear-positive relapses.

Pulmonary smear-negative patients who are severely ill (with cavitary or miliary tuberculosis) and severe extrapulmonary cases should have the same regimen as the new pulmonary smear-positive cases. Tuberculosis meningitis cases require a regimen with the same initial phase as new smear-positive cases, with a continuation phase containing rifampicin and isoniazid for 6 months. Pulmonary smear-negative and extrapulmonary patients not included in the previous category (as lymphadenitis, pleurisy, childhood tuberculosis) may be offered different regimens.



Indicators of patient adherence to the prescribed regimen must be specified. The guidelines should emphasize the importance of assessing smear conversion after 2 months of the initial intensive phase for new smear-positive patients on SCC. Patients who are still smear positive after 2 months of therapy should continue the same combination of drugs for an extra month. Re-motivation of these patients is an essential component of their therapy. Smear-positive patients should be considered cured only after confirmation of sputum smear negativity in order to make available the data to monitor the cure rate among all new smear-positive cases diagnosed. Pulmonary smear-negative and extrapulmonary cases may be discharged after completion of the prescribed number of monthly drug collections.

Patients who are smear-positive before chemotherapy should be rigorously educated about the importance of sputum examination during the follow-up of chemotherapy. Responsibility for ensuring the regularity of drug pick-up during the initial phase of the regimen for these smear-positive cases should be given to the staff of PHIs and subcentres. Supervisors should assess if the target of 80% smear conversion after 2 months of SCC chemotherapy and more than 90% at three months, among patients that started chemotherapy 3 to 6 months before, has been achieved. If the target is not achieved, full patient supervision should be considered.

New smear-positive patients unable to attend ambulatory therapy (because they are too sick to walk or are living in a place unsuitable for fully supervised treatment) should be hospitalized for 1 to 2 months in the nearest TB hospital.

Guidelines for accomplishing tuberculosis programme activities should (1) aim to improve the supervisory capacity of DTC, (2) encourage patient's diagnosis and treatment at PHI level, (3) assign to the staff at block level clear responsibilities for ensuring patient treatment and follow-up. Their main target should be the achievement of high smear conversion for new smear-positive cases at the end of the initial phase of SCC (80% at two months and 90% at three months) and a high cure rate (in the first two years of the programme more than 70 % and then 85% among new smear-positive cases).

TB sanatoria and hospitals should be more involved in the DTP and their activity should be focused to achieve the same objectives as the PHI at block level. Policies for the use of hospital beds should give priority to ensure smear conversion among new infectious cases and failure cases.

At state level districts with the best performing staff and in a logistically favorable position for frequent supervisory visits should be selected to implement the new programme. The number of districts to be involved and the plan for expansion should be proposed by the state TB Office and revised by the national TB Unit. In each district only the best performing PHIs should be initially involved and frequently supervised by the DTC staff. The implementation of the plan should ensure that no lack in drug stocks will occur. The expansion of the programme in the district should be rapid enough to avoid the fact that patients from blocks not included in programme will be attracted to the implementing PHIs. The expansion should be based on smear conversion rates achieved among the total number of new smear positive patients and smear positive relapses diagnosed and put on treatment.

Training courses for MOs working in the DTC and in the PHIs involved in the programme should be planned and the training programme approved by the national TB Unit. Retraining of the microscopist and provision of binocular microscopes should be a requisite for implementing the district programme.

The following guidelines for programme management at district level should be issued by the NTP and approved by each state before extra resources for programme implementation are allocated to the programme.



**A. Guidelines for patient and programme management, including:**

1. Case-definitions and regimens
2. Frequency of patient's follow-up by smear examination
3. Methods for ensuring patient adherence to the prescribed regimen
4. New recording and reporting forms and registers
5. Programme evaluation methods
6. Drugs procurement and stock

**B. Guidelines for preparing a workplan for the implementation of the new district tuberculosis programme.**



## ANNEX 5.1

## COORDINATION WITH OTHER PROGRAMMES

## AIDS Control Programme

1991 estimates show India as having at least 750,000 HIV infected individuals. Studies of prevalence show rates varying from 0.1% in Calcutta to 1% in Bombay. The National programme has an active health education arm aimed at the population at large as well as high risk targets e.g. prostitutes.

Initially, surveillance was carried out at two sites, the National Institute of Virology in Pune and the Christian Medical College in Vellore. An AIDS cell has been established in the Directorate General of Health Services to coordinate all activities pertaining to AIDS control in the country. At present, 20 states have AIDS programme cells, 40 surveillance centers have been established (mainly at medical colleges and universities) and 4 referral centers are available for AIDS control efforts. The programme is directing efforts to provide surveillance and notification at the District level, and laboratory testing of blood specimens at peripheral levels in order to protect blood donations.

In light of a growing awareness of the importance of tuberculosis as an HIV-associated disease, health care personnel in the AIDS programme are advocating the drafting of a joint AIDS/Tuberculosis programme policy document on case management, diagnosis and treatment. A suggestion has been made by AIDS programme personnel to include a tuberculosis advisor in the AIDS programme at both the central and state levels of health care delivery. In turn, it has been suggested that an AIDS staffer be present in the tuberculosis control programme for coordination and collaboration on areas of mutual interest, i.e. surveillance of dually infected individuals, counselling, HIV testing, and promotion of preventive chemotherapy efforts for HIV individuals infected with tuberculosis.

## Expanded Programme on Immunization

EPI is one of the most cost-effective public health programmes and is an important component of the primary health care services. Its impact is related to programmes of maternal and child health and family planning. The EPI programme has targeted 85% vaccination of infants against vaccine preventable diseases and 100% of expectant mothers against tetanus. The coverage is being extended in a phased manner by immunizing about 18 million infants and 24 million mothers every year to achieve the set targets. The immunization services are provided through the existing health care delivery systems and are available in hospitals, dispensaries, and MCH clinics in the urban areas and the primary health centres in rural areas. Currently, the programme is in place at all Districts in India.

The vaccination of children with BCG became a responsibility of the EPI programme in 1981-82. The programme ensures vaccine supplies and monitors coverage from the central level. The programme purchases BCG vaccine produced locally by the BCG Vaccine Laboratory at Madras, India.

## Leprosy Programme

The leprosy programme of India is a vertical programme. The programme has a system of leprosy control personnel decentralized to sub-center levels, with specific disease surveillance and control officers for every 20,000 population. The Leprosy Programme in India has been highly successful in reducing both the incidence and the prevalence of leprosy in the country. As an example, one high endemic state evidenced a reduction in prevalence from



The success of the programme has been variously attributed to 1) the successful implementation of multiple short course drug therapy, 2) stringent strategies for case detection and treatment, 3) intensive health education, and 4) active case finding activities.

Leprosy staff are still required to ensure case detection and management, but the continuing reduction in incidence and prevalence of leprosy is placing less demand on the leprosy staff. Proposals for better utilization of the leprosy manpower need to be explored in light of the decreasing demands on personnel time. One such proposal is to utilize leprosy personnel to augment tuberculosis activities at the community level.



VOLUNTARY HEALTH ORGANIZATIONS

In India, health care services can be divided into two distinct components, the public sector or government sector of health care and the private sector. The private sector can further be classified into a commercial sector and a voluntary sector. The voluntary sector encompasses hospitals and health care institutions registered as non-profit societies. They are operated primarily by Churches and other charitable trusts and associations.

An important voluntary organization in India is the Voluntary Health Association of India (VHAI). The organization provides for nursing education with emphasis towards rural and primary health care, rural community health education, and promotes people's participation in health care. Voluntary organizations specific to tuberculosis include a tuberculosis sanatorium opened in 1907 by missionaries at Bhowali and the Union Mission Tuberculosis Sanatorium started in 1911 by Dr Frimodt-Moller at Madanapalle.

In 1934, with the active support of the Indian Government, the Tuberculosis Association of India was created to coordinate curative services as well as train doctors and para-medical workers in tuberculosis work. Currently, the Association has placed its emphasis on 1) providing health education to the general public, 2) channeling funds to persons and institutions for research opportunities, 3) coalition-building of tangential voluntary organizations to provide a united effort towards the elimination of tuberculosis, and 4) augmenting government tuberculosis control efforts with voluntary support e.g. providing alternative hours TB clinics to increase access to health care services and providing incentives to health care staff involved with case-holding activities. TB seal fund raising activities continue to be a major focus of the Association. Members and executives of the TB associations tend to be officials of the Health department, either in active service or retired. Administratively, this membership structure can facilitate tuberculosis programme delivery by sharing close collaboration with governmental efforts and augmentation in areas of need.

State anti-tuberculosis associations are actively involved in tuberculosis activities at the State and District level. The associations derive funding from the sale of TB Seals and from interest earned on investment capital. They fund operational research activities, provide facility construction and maintenance, augment anti-tb drug supplies to districts experiencing shortfalls, are actively involved in the training of health care personnel involved with tuberculosis control efforts, and provide monetary incentives to patients on anti-tb chemotherapy. Health education activities aimed at the general public are also underway. The associations appear to have great flexibility in their financial expenditures.

The director of the Association is also the State tuberculosis officer. This dual role may be perceived as an asset in terms of coordination of tuberculosis efforts between a voluntary organization and a government programme. The Association has the infrastructure in place and a philosophy in line with the overall goals of current tuberculosis control efforts that can facilitate future collaborative ventures.

The Swedish International Development Agency (SIDA) has been providing assistance for the National Tuberculosis Control Programme since 1979. SIDA supplies funds for equipment (x-ray units, film), anti-tuberculosis drugs (Rifampicin and Pyrazinamide) and other needs to the programme in accordance with an agreement signed jointly by the Government of India and SIDA in 1985.



## ANNEX 6.1

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## ANNEX 6.2

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