A STUDY OF

POLICY PROCESS AND IMPLEMENTATION

OF THE

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

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of the University of London
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ABSTRACT

TB, a major public health problem in India since the 1900s, has a current prevalence of 14 million and an estimated annual mortality of 500,000 persons. Nation-wide government sponsored anti-TB public health measures introduced in 1948, developed into the National TB Programme in 1962. Despite gains, implementation gaps between programme goals and performance, over 35 years, have been of a magnitude sufficient to cause concern. This study aimed to understand explanatory factors underlying the implementation gap.

A policy analysis approach was adopted, focusing on the policy process and specifically on implementation, at national, state, district and local levels. It undertook a historical review with a two-tiered framework covering the period 1947-97. In the first tier the historical narrative is woven around a framework of context, content, process and actors. The nature of the problem and policy relevant technical dimensions of intervention measures are discussed, as are effects of pharmaceutical policies and financial resource flows on TB policy. The second tier applies a framework of implementation factors to national policy development and implementation at state and district level. Interviews were conducted with TB patients, elected representatives, front-line health workers, doctors, district and state staff, national programme managers, researchers and representatives from international agencies. Documents were reviewed. Thus the study incorporated an integrative bottom-up cum top-down approach.

Findings highlight that interests of patients, medical and allied professionals, pharmaceutical and diagnostic industries and the state are interdependent, but often conflictual. Unequal societal relations affect not only the development and transmission of TB, but also the implementation of control programmes, particularly for the impoverished, among whom high levels of indebtedness due to the disease and difficulties accessing private services were noted. Techno-managerial approaches to TB control often mask societal and policy process factors accounting for the implementation gap. The importance of leadership, institutional development, capacity at the patient provider interface and accountability and need for sustained policies were noted, within an affirmative framework embodying social justice and safeguarding the interests of the majority of patients.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF ABBREVIATIONS

ARTI - Annual Risk of Tuberculous Infection

AIDAN - All India Drug Action Network

ADHO, TB - Assistant District Health Officer, Tuberculosis

BCG - Bacille Calmette Guerin

CAG - Comptroller and Auditor General

CBHI - Central Bureau of Health Intelligence

CDRI - Central Drugs Research Institute

CGHS - Central Government Health Scheme

CHEB - Central Health Education Bureau

DHO - District Health Officer

DGHS - Directorate General of Health Services

DH&FW/O - Department of Health and Family Welfare/Office

DOTS - Directly Observed Therapy, Short Course

DTP - District Tuberculosis Programme

DTC - District Tuberculosis Centre

DTO - District Tuberculosis Officer

DSS - *Dalit Sangharsh Samiti* (Committee for the Struggle of the Oppressed)

ESI - Employees State Insurance

FRCH - Foundation for Research in Community Health

FREHM - Foundation for Research and Education in Health Management

GOI - Government of India

GOK - Government of Karnataka

GP - *Gram Panchayat* (Village Council)

HA - Health Assistant (earlier MPW or Multi-Purpose Health Worker)

HAL - Hindustan Antibiotics Limited

HDK *Taluk* - *Heggade Devana Kote Taluk* (study *taluks*-subdistrict administrative region)

HIV - Human Immuno-deficiency Virus

ICMR - Indian Council of Medical Research

ICORCI - Institute of Communication, Operations Research, and Community Involvement

ICSSR - Indian Council of Social Science Research

IDMA - Indian Drug Manufacturer's Association

IDPL - Indian Drugs and Pharmaceuticals Limited

IMA - Indian Medical Association

INH - Isoniazid/ Isonicotinic Acid Hydrazide

IUAT/IUATLD - International Union Against Tuberculosis/ and Lung Disease

JD-TB - Joint Director, Tuberculosis

KSTA - Karnataka State Tuberculosis Association

LA - Legislative Assembly

LT - Laboratory Technician

MDR - Multi-Drug Resistance

MFC - Medico Friend Circle

MO - Medical Officer

MOH/&FW - Ministry of Health /and Family Welfare

MSTA - Mysore State TB Association

NGO - Non-Governmental Organisation

NIHFW - National Institute of Health and Family Welfare

NTP - National Tuberculosis (Control) Programme

NTI - National Tuberculosis Institute

ODA (UK) -Overseas Development Administration (United Kingdom)

OPPI - Organisation of Pharmaceutical Producer's of India

PHI - Peripheral Health Institution

PHC - Primary Health Centre

PHU - Primary Health Unit

PKTB & CD Hospital - Princess KrishnaJammani Tuberculosis and Chest Disease Hospital

RNTP/RNTCP - Revised National Tuberculosis (Control) Programme

Rs. - Rupees

SCHARA - Society for Community Health Awareness, Research and Action

SCC - Short Course Chemotherapy

STC - State Tuberculosis Centre

SIDA - Swedish International Development Authority

TAI - Tuberculosis Association of India

TB - Tuberculosis

TCC/TRC - Tuberculosis Chemotherapy (later Research) Centre

TNC - Trans-national Company

PAS - para-amino salicylic acid

UN - United Nations

UNFPA - United Nations Family Planning Association

UNICEF - United Nations International Children's Emergency Fund

UNIDO - United Nations Industrial Development Organisation

UNRAA - United Nations Relief and Rehabilitation Administration

USAID - United States Agency for International Development

VGKK - Vivekananda Girijana Kalyana Kendra (Tribal Welfare Centre)

VHAI - Voluntary Health Association of India

WB - World Bank

WHO - World Health Organisation

WHO- SEARO - WHO South-East Asia Regional Office

ZP - *Zilla Parishad* (District Council)

CHAPTER ONE

TUBERCULOSIS AND ITS CONTROL IN INDIA: UNFOLDING PROBLEMS A PROCESS OF CONSTRUCTION AND RECONSTRUCTION

1.1 Introduction:

Tuberculosis (TB) received official recognition as a major public health problem in India from the early 20th century (Wilkinson 1914, TAI 1956, GOI 1961). Limited efforts towards TB care and cure were initiated primarily by the voluntary sector in the 1920s and 1930s, a time when effective curative and preventive technology had not developed. TB control measures[1] at national level were introduced in 1948, with the new Government of independent India taking responsibility for interventions (TAI 1956). This period coincided with increased use of BCG as a preventive intervention and rapid developments in TB chemotherapy globally.

Implementation problems in the TB programme were encountered almost from inception (Andersen and Banerji 1963, TAI National Conference Proceedings 1968-78). National assessments consistently reported gaps between expected performance and outcome (ICMR 1975, ICORCI 1988, GOI/WHO/SIDA 1992). Only approximately 8-16% of expected cases of tuberculosis received complete treatment from the public health services annually (Radhakrishna 1988). Evaluations led to little apparent change in performance.

Renewed global interest in tuberculosis control in the 1990s resulted in a global policy strategy (WHO 1994-1997). Termed the Revised National TB Control Programme (RNTCP) in India, it has techno-managerial components, along with appeals for increased political will and funding. This study argues that unless deeper underlying explanations for the implementation gap[2] are understood and acted upon, renewed inputs and modified strategies of the type suggested in the RNTCP may face the same fate as the National TB

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[1] TB control involves introducing planned interventions in the relationship between tubercle bacilli and man to render the epidemiological situation more favourable to man (Nagpaul 1984).

[2] Difference between policy statements, promises, expectations and subsequent performance.

Programme in the long term. A policy analysis approach has been used to study policy process and implementation of the NTP at national, state and district levels. The analytical model is based on concepts of context, process and actors, besides policy content (Walt and Gilson 1994) and has developed a framework to study implementation factors. This study explicitly focuses on access to services under the NTP by the impoverished, comprising approximately 40% (360 million people) of the population below and around the poverty line[3] (Patel 1995, Reddy 1997). This is because the poor bear the burden of TB disproportionately (ICMR 1959) and have less access to general health care services (Chatterjee 1988). The policy analysis approach in this study also derives from a value base of social justice and equity in health and health care (Ganapathy 1985, Barker 1996).

This chapter starts with a brief historical account of TB in India, discussing issues concerning problem definition of TB for policy purposes. It highlights how incremental additions to incomplete knowledge regarding the problem affected policy content and strategy, and outlines the series of related, interlocking problems that unfolded during implementation. This leads to a discussion of the implementation gap in the TB policy over the years, which is the problem being addressed by this study. Recognising that policy content dominates scientific and academic discourse, excluding other critical elements of policy process (Walt and Gilson 1994), this chapter provides a background to the main findings and discussion regarding policy implementation in later chapters (4-8). Technical aspects of policy content are discussed in Annexe 1. Chapter two builds a conceptual framework for the study from the policy science literature and Chapter three discusses study design and methods. Chapter four and five reviews historical policy development at national level, including related financial and pharmaceutical policies. Chapter six debates current policy changes in the 1990s. Chapter seven and eight discuss implementation issues at state and district level. Chapter nine draws conclusions from the entire study regarding explanatory factors for the implementation gap.

[3] The poverty line used in India presently is the level of per capita total expenditure by families at which basic food requirements in caloric terms are met (Krishnaji 1997).

1.2 A Brief History of Tuberculosis in India:

Tuberculosis has had along history in India. Tuberculosis-like conditions are recorded in ancient Indian texts (Stead and Dutt 1994), the *Ayurvedic Samhitas* (Gothi 1982). The disease is reported to have occurred in domesticated elephants in India prior to 2000 BC (Metcalf 1991). It was written about in Sanskrit *Vedas* suggesting that pulmonary tuberculosis was known in 1500 BC, the approximate date of the earliest written records, the *Rigveda* (*ibid*), and in later works by noted physician Sushruta in 500 AD (*ibid*, CHEB 1960, Gothi 1982). It was and still is called *Rajya-Roga,* the 'king of diseases' (Manjunath*[4]1995). The disease evidently existed in the region since ancient times, was recognised and named by Indian systems of medicine, which also developed therapeutic guidelines (*ibid*)[5]. It is not known whether the disease was sporadic, endemic or epidemic (Nagpaul 1978).

Despite its early presence, Wilkinson (1914) commented on the rarity of tuberculosis in India in the first half of the nineteenth century and its progressive increase in the middle years of that century as industrialisation and population density increased. Other authors report that as late as 1880 tuberculosis was relatively uncommon in India (Daniel *et al* 1994). It is probable that the present secular epidemic was brought to the Indian subcontinent from Europe, as has been recorded to have occurred in South Africa and among the indigenous peoples of the Americas (Packard 1989). Population movement is an old, well-established method of spread of infectious disease.

In 1910, the growing magnitude of the problem of tuberculosis in the country was first officially noted by Sir Pardly Lukis, Director General of the Indian Medical Service (Gupta 1985). The All India Sanitary Conference in Madras in 1912 recorded a rapid increase of tuberculosis among the population (TAI 1956). Dr. A Lancaster studying the tuberculosis problem in the country from 1914-16 for the Government of British India, found prevalence alarmingly high in large areas which 40 years previously were 'virgin soil' to TB (CHEB

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[4] A star following a name indicates that the source of information is an interview.

[5] Recent studies suggest immuno-modulating effects of traditional medicinal preparations given alongside modern chemotherapy (TAI 1996).

1961;1). He noted that though phithis was possibly present for centuries in cities, even there considerable increases occurred during the period, with spread to smaller towns and villages 'following development of commerce and industry', being most marked in centres with greatest commercial development and in villages linked to them by direct lines of communication *(ibid;*1). Rogers studying post mortem reports in the 1920s suggested that 17% of total deaths in Calcutta were due to TB (Gupta 1986). Social forces possibly primed the population for the current epidemic of tuberculosis, a disease strongly linked to poverty and overcrowding (GOI 1946, Dubos and Dubos 1952). These included: *'looting and laying waste the land of defeated enemies,..extorting very high land revenues... in the last half of the eighteenth century'* (Jeffery 1988;17); increasing landlessness among sections of the population resulting from colonial policy (Spear 1978); impoverishment; the frequent occurrence, every 3 years, of famine, drought and scarcity in the 19th century (Jeffery 1988); and other epidemics such as plague, reported to have caused a mortality of 15 million persons in British India and 18 million in the princely states over 20 years following the 1896 epidemic. Severe, countrywide famines occurred in 1877-78; 1897-98 with the plague epidemic; in 1919-20 preceded by an epidemic of influenza and in 1943 (*ibid*). Large scale movement of refugees around 1947 exacerbated the problem (GOI 1961).

These social forces operating over a prolonged period could have lowered the resistance of the population, increasing susceptibility to epidemics of disease (McNeill 1976). Growing industrialisation and urbanisation, associated with worsening living and working conditions, provided the ecological setting, as occurred during the industrial revolution in Europe and the USA (Dubos and Dubos 1952).

In summary, TB has been known in India for many centuries, although relatively rare until the mid-19th century. Adverse social conditions led to widespread disease, evident in rising and high rates of infection and disease in the early 20th century. Today, with 40% of India's population living in similar adverse social conditions, including poor access to health services, the possibility of rapid epidemiological decline seems unlikely (Quadeer 1994).

1.3. Problem Definition: An Epidemiological Construct of TB

As scientific methods of measurement and diagnosis developed, the problem of TB became defined in predominantly biomedical terms, while consideration of its social dimensions receded. Policies developed around this dominant framework. The evolving understanding of the biomedical/epidemiological aspects of TB in India, developed from over two decades of research, are summarised. This is followed by a brief overview of broader, inter-related problems that developed during the policy process.

1.3.1 Prevalence and Incidence of Infection[6]: From 1930, high proportions of reactors to tuberculin testing/cuti-reaction (70-88% in those above 15 years, and 11-40% in children) in studies by Ukil (1930), Benjamin, Rao and Lal (cited in CHEB 1961), revealed the magnitude of the problem. Tuberculin testing during the nation-wide Mass BCG Campaign in the 1950's detected widespread infection both in rural and urban areas, challenging prevailing views that TB was an urban problem as in Europe (CHEB 1968). This had resulted in a concentration of TB services in urban areas (TAI 1970). Implications of this distribution of infection, confirmed by the National Sample Survey (1955-58), were enormous, as 82% of India's population was rural and under-served by health care services (ICMR 1959, CHEB 1961). The rural thrust of the National TB Programme derived from this finding (*ibid*). Prevalence of infection in 1961 was 52%[7] (Subramanian 1963). Infection rates were substantially higher among adults, necessitating a shift in focus from children through school BCG programmes, to providing TB services for all age groups. An NTI study in Tumkur district found 38.3 % of the population infected (induration more than 9 mm considered positive) (Raj Narain *et al* 1963).

Studies observed two types of reactions and distribution curves to Tuberculin tests. One with low degree, non-specific sensitivity (smaller indurations), due to non-pathogenic/

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[6] Prevalence of infection is the proportion of persons with significant tuberculin test results (eg. more than 10 mm) at any point of time, usually expressed as a percentage (NTI 1990).
Incidence of infection is the rate of new infection among non-infected persons of the earlier year *(ibid)*

[7] Comparisons to be made with caution due to different types of Tuberculin used, different dosages, varying levels of reaction/induration selected to indicate positivity, different age groups (Mayurnath *et al* 1991).

atypical mycobacteria is highly and widely prevalent in India (ICMR 1980, Frimodt-Moller 1960). The other with larger indurations caused by infection with *M.tuberculosis*. Animal and other studies show a slight protective effect following infection with some atypical mycobacteria, with an inverse relationship between prevalence of TB and of non-specific sensitivity (*ibid* citing Palmer and Long, Gothi *et al* 1976, Raj Narain *et al* 1984). However it was considered unlikely that non-specific sensitivity could account for the complete lack of protective effect of BCG in the TB Prevention Trial (*ibid*). Overall prevalence of infection in the early 1980s was estimated at 40% (Baily 1983) and currently is about 30% (TB Division 1995). Prevalence of infection among children 0-9 years old ranges between 3.1-11.2 %, with more than 50% of the population aged 20 years and above infected (GOI/WHO/SIDA 1992). There is a wide gap between the 30% infected and 2% ill with disease (NTI 1994c). The large pool of infected people, at life-long risk of disease, reduce probabilities for rapid TB control, requiring long term, sustainable policies[8].

NTI studies in Bangalore district report an average Annual Risk of Tuberculous Infection (ARTI)[9] (Annexe 1) of 1.1% in 1961 and 0.61% in 1985 i.e. a 37% decline occurred over 23 years or 3.2% per year (Chakraborty *et al* 1992). Studies in Chingleput district show no decline in the 1.7% ARTI, suggesting that regional differences occur (Mayurnath 1991, Chakraborty 1993). Differing ARTI's in two neighbouring *taluks* were attributed to socio-economic differences (*ibid*). A survey in a drought prone, deprived region of Rajasthan in 1991 reported an ARTI of 1.44 (Siddiqi *et al* 1996). Policy managers cite risks of 1-2% (TB Division 1995).

1.3.2 Disease Prevalence[10]: Frimodt-Moller (1960) cites prevalence rates of X-ray positive pulmonary tuberculosis from previous studies: 3.1% among labourers and 0.8% among Gurkha recruits (Aspin 1946); 1.2% among school children, factory workers and a section of Trivandrum's population (Hertzberg 1952); 1.4% in Faridabad near Delhi (Sikand and Raj Narain 1952); 2.3% among industrial labourers in Madras, with estimates

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[8] An important reason for integration with general health services.

[9] The probability of an uninfected person becoming infected with TB during a one year period (TB Div.1995).

[10] Differences in case definitions, diagnostic criteria and methods over time need to be kept in mind.

of 1.5% for urban Madras (Philip 1952)[11]. In the first community survey in Madanapalle town the prevalence was 6.8/1000 X-rayed, with 5.7 bacteriologically positive cases/1000 (Frimodt-Moller 1960).

The National Sample Survey of pulmonary TB, covering six zones of India, reported prevalence rates of 13-25/1000 of active and probably active TB and 2-8/1000 of bacteriologically positive TB, both increasing with age and lower in females than males, especially over 35 years (ICMR 1959). Some suggested that active abacillary disease was probably over-estimated (TAI 1970). An NTI study in Tumkur District (1960-61) found 2.5% of the X-rayed with probably active/active tuberculosis and 4/1000 of the X-rayed population aged 10 years and above sputum positive (Raj Narain *et al* 1963). A second survey in the same district after 12 years of the District TB Programme revealed no change in disease prevalence. However studies from Madanapalle, Bangalore and New Delhi over time showed a declining prevalence with increased concentration in older groups (TAI 1970).

Surveys in Delhi from 1962 to 1973 reported 12-15/1000 cases of active/probably active disease and 2.1-4/1000 bacillary cases (Pamra *et al* 1973 cited in Gothi 1982). In the Longitudinal Study (1961-68) of the National Tuberculosis Institute in Karnataka the rate of bacteriologically confirmed disease was 3-4/1000 (Gothi 1982). In the TB Prevention Trial prevalence of bacillary TB in persons 10 years and above was an estimated 9/1000 in Ponneri and 7.5/1000 in Kanchipuram of Chingleput district (ICMR 1980). A study by the Tuberculosis Demonstration Centre, Agra in 1978 in an urban population found the rate of bacteriologically confirmed disease to be 8.9/1000. In Kashmir prevalence of culture positive TB in 1978 was 3/1000 and of abacillary X-ray positive patients 14/1000, with differences between districts (Mayurnath *et al* 1984).

Regional variations continue to be reported. Prevalence rates of 4.38/1000 culture positive cases and 0.68/1000 of smear positive cases in age groups 10 years and above were reported from Bangalore district between 1984-86 (Chakraborty *et al* 1995). A large survey in

[11] Higher rates among labourers noted.

Wardha district, central India, between 1982-88 found a prevalence of 1.6/1000 of sputum positive pulmonary TB by smear or culture or both (Narang *et al* 1992), which is lower than the national average. Interestingly 56.2% were positive only on culture (with recommendations to increase use of cultures for diagnosis), 66.3% were males and 33.7% females. A high prevalence of 15/1000 of bacteriologically positive cases is reported among a tribal population in Madhya Pradesh (Chakma *et al* 1996).

An average prevalence rate of 4/1000 sputum positive pulmonary tuberculosis is used by the NTP as the basis for estimating numbers of expected cases in a district and for target setting. Differences between regions and over time could partly explain gaps between expectations and achievements and suggest a need for flexibility in deriving administrative estimates/targets.

1.3.3 Incidence of Disease: A review of Indian studies reports that disease incidence is approximately one third prevalence (Rangan *et al* 1997). With good TB services prevalence may be the same as incidence, or if services are not fully effective, approximately twice incidence (Murray 1994). Incidence of all active cases in the Delhi and Madanapalle studies were 340 and 410/100,000 (Sivaraman 1982). Incidence of sputum smear positive TB in the first NTI survey was 65/100,000 and 23 years later 23/100,000 in the same area, indicating a decline (Chakraborty 1993). In the TB Prevention Trial incidence of culture positive pulmonary TB was 250/100,000 per year, with incidence among males three times that among females, and increasing with age in both sexes (ICMR 1980). Programme managers calculate incidence of sputum positive TB at 1/1000, excluding children under the age of 5 years (TB Division 1995).

1.3.4 Mortality: Little is known about TB death rates in India in the 19th and early 20th century (Nagpaul 1978). Summary data from reviews and recent findings (Table 1.1) show declining trends[12].

[12] Readers are cautioned about differing quality of estimated data and regional variations (Nagpaul 1978).

Table 1.1 Mortality Rates Over Time due to Tuberculosis in India

Researcher	Year	Annual TB Mortality Rate	Comments
Leonard Rogers	around 1918	800/100,000	overestimation due to selection bias of post mortem record analysis
Lancaster	1920	591/100,000, Ahmedabad	speculated 400/ 100,000 for most Indian cities
Cummins *	1921	530/100,000	among Indian Labour Corps of British Empire Force in France
Benjamin *et al*	1939	462/100,000, Saidapet	15 TB deaths in 6,500 in 6 month survey
McDougal	1949	200/100,000 estimate	basis not clarified
Frimodt-Moller	1960	64/100,000 in 1953-54 21/100,000 in 1955, in Madanapalle	Steep decline from est. 263/100,000 after introduction of community based control programme. Initial figures overestimated extrapolation from hospital data
ICMR **	1955-58	77.8/100,000	estimated annual deaths in the country 6,570,000
NTI	1961-68	100/100,000	longitudinal survey findings
NTI **	1977-81	41/100,000	estimated annual deaths 346,000
Chakraborty *et al*	1978	84/100,000, Bangalore region	higher in males and older age groups
Goyal *et al*	1972-76	40/100,000 Delhi	congested urban area, low income with good domiciliary services

Source: Nagpaul 1978, Goyal *et al* 1978 Gothi 1982, *cited in Ukil, 1930, **cited in GOI/WHO/SIDA 1992.

Gothi (1982) attributes declining TB mortality to socio-economic improvement associated with increased availability and utilisation of anti-tuberculosis measures. Earlier rates may have been overestimates due to extrapolations from hospital data (Frimodt-Moller 1960), mis-diagnosis and presence of early tubercular lesions in deaths due to other causes (in rates

from post-mortem records). Current estimates range from 50/100,000 population (Datta 1994) to 84/100,000 (NTI 1994). TB mortality rates are not good indicators of disease dynamics in populations, as they can decrease while morbidity and infection rates remain almost unchanged. (Chakraborty 1993).

Case fatality among untreated patients was about 50% (NTI 1974). With chemotherapy this declined and is currently estimated to be 13% (NTI 1994). However a case fatality of over 25% was reported from a district using Short Course Chemotherapy under routine conditions (Datta *et al* 1993). Patients put on Standard Regimens and lost to treatment have outcomes similar to the natural history of the disease, with 49.7% dead in five years (Jagota 1995). These findings suggest poor functioning of the NTP, with case fatality among patients with irregular/incomplete treatment, comprising 66% of those treated by the public sector, remaining unacceptably high.

The Bhore Committee estimated 500,000 annual deaths from TB (GOI 1946). Current estimates range from 346-500,000 annual deaths (GOI/WHO/SIDA 1992, TB Div. 1995). Lowered mortality rates are compensated by demographic growth. Approximately 10% of total deaths in persons aged over 10 years are estimated to be due to TB (NTI 1994). It is plausible that higher rates occur among the impoverished. Globally TB is the largest cause of death from a single disease, accounting for 26% of avoidable deaths (Kochi 1991), 80% of which occur in productive adults aged 15-59 years (WHO/TB/94).

1.3.5 Natural History: Five year follow-ups of 126 sputum positive patients in rural Bangalore, without access to treatment for want of resources and facilities, showed that 49.2% died (with a higher proportion during the first 18 months), 18.3% remained bacillary/infectious, and 32.5% converted spontaneously (NTI 1974). Outcomes changed among newer infectious cases in subsequent surveys of the same population. At 18 months, mortality decreased to 14.3 %, sputum conversion increased to 52%, while 33% remained bacillary, increasing sources of transmission (Gothi 1982), indicating altered dynamics of the disease in populations.

A 30 month follow-up of infectious TB patients in Delhi, with good domiciliary chemotherapeutic services, showed 11% mortality, 74% sputum conversion, while 15% remained infectious (*ibid*). Prevalence did not vary significantly even after 15 years of providing good chemotherapeutic services (*ibid*). The same was noted by Frimodt Moller (1960) in Madanapalle. It was estimated that epidemiological impact of interventions would occur slowly, requiring three or four decades to show change (Banerji and Andersen 1963).

1.3.6 Magnitude Of Problem: In the 1950s 5 million people (1.3% of the population) were estimated to have active pulmonary disease of whom 1.5 million (0.4%) were infectious (ICMR 1959). With demographic change and continuing prevalence rates of 15/1000 (all forms) (ICMR 1959 and subsequent studies) current estimates are 14 million TB patients, including 3.5 million (4/1000) sputum positives (TB Div.1995). Based on an ARTI of 1.7% it is estimated that 1.6 million new cases (all forms) including 714,000 new smear positive cases of TB occur annually in India (GOI/WHO/SIDA 1992;11). In an average district of 1.5 million people the annual incidence is an estimated 750 sputum smear positive patients (Chakraborty 1993). The problem is widely dispersed with 2-3 sputum positive patients and 10-12 patients with radiologically active TB in each of the 600,000 villages in India (NIHFW 1988). TB is an adult problem with 93% of all cases occurring over 20 years of age (NTI 1994).

In 1970, 400,000 patients received treatment at government clinics (TAI 1970) rising to 700,000 in 1981 (NIHFW 1988). More recently 1.5 million TB patients are diagnosed annually by the NTP of whom 20% or 300,000 are sputum positive (Nagpaul 1989, GOI/WHO/SIDA 1992). Patients treated at organised sector public sector are not included (NIHFW 1988). An equal number are said to be treated by the private sector (Nagpaul 1989). Recommendations to make pulmonary TB notifiable (TAI 1970), giving an idea of the actual magnitude, have been consistently ignored by government.

1.3.7 Time Trends: Grigg's hypothesis (1958) of secular TB epidemics in countries spanning 200-400 years was accepted by NTP planners since the 1960's (Nagpaul 1978,

Chakraborty 1993)[13]. As epidemic waves in populations decline, the age structure of infected persons shifts towards older age groups. Longitudinal surveys in India indicate that this is taking place *(ibid)*. Earlier surveys found over 50% of cases in the over 40 year age group, while more recent surveys report 70-80% cases in this age group (*ibid*). Decline in infection rates and incidence of smear positive disease has been noted. The nature of the disease has changed from acute, fulminating, exudative presentations to more chronic, fibrotic forms with reductions in primary disease (Nagpaul 1978, Uke 1994). TB experts suggest on the basis of changing epidemiological patterns that the epidemic is in decline.

Impact of Intervention: In Madanapalle following intensive application of community based control measures, sputum positive morbidity reduced from 4/1000 in 1950 to 2/1000 in 1964, though prevalence of infection and disease incidence may not have altered (Raj Narain 1964). The decline in disease in 6 towns with a good TB service was not significantly different from 6 control towns without any special TB service (Frimodt-Moller 1981).

1.3.8 TB and HIV[14]

HIV infection rates in patients with pulmonary tuberculosis rose from 0.77% to 3.4 % between 1991-1993 in a sample of 1430 pulmonary tuberculosis patients in South India (Solomon *et al* 1995). In another series of 7000 patients 1% were HIV positive (Prabhakar 1995). Sixty percent of the approximately 450 AIDS patients reported by 1995 had active TB (TB Div.1995).

HIV seroprevalence among TB patients in Bombay is reported to have increased from 2% in 1988 to 10-15% in 1991 and 1992 (Snider *et al* 1994), though the basis of this data is unclear. WHO estimates a rise to 10% in Asia by 2000AD (WHO/TB/94).

1.3.9 Drug Resistance

The first ICMR multi-centric survey of drug resistance (1964-65) involving patients without history of previous chemotherapy, showed fairly high levels of drug resistance, 14.7% to isoniazid, 12.5% to streptomycin, and 20.4 % to one or more drugs (Fox 1990). Further

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[13] This comprises part of the explanation by them for only a marginal improvement in the epidemiological situation over 3 decades.

[14] Further discussion on technical aspects of drug resistance and HIV and TB in Appendix A, 1.5 and 1.6.

analysis at the TCC, Madras suggested that part of this was initial drug resistance and not primary drug resistance. The second ICMR multi-centric survey (1965-67) additionally involved patients with history of chemotherapy. Earlier findings were repeated, but resistance was found to increase with duration of chemotherapy, with resistance to isoniazid or streptomycin or both increasing to 46% at 1 month and 74% at 6 months, lower than findings in Hong Kong in 1962 (*ibid*). Others were more optimistic suggesting that data from Madras and Madanapalle in India between 1957-67 revealed low primary drug resistance despite drug and staff shortages and resultant treatment deficiencies (Toman 1979, 78). A review of studies (1968-1995) of Initial Drug Resistance (IDR) in India concluded it is low with less than 20% resistance to isoniazid, less than 10% to streptomycin, and around 1% to rifampicin (Rangan *et al* 1997). However acquired/secondary drug resistance resulting from irregular, inadequate TB chemotherapy is higher. In a retrospective cohort in North Arcot district between 1986-1988 31% of patients had active disease following treatment at government health facilities (Datta *et al* 1993). Among these 65% were resistant to isoniazid, 12% to rifampicin, 12% had combined resistance to isoniazid and streptomycin and 4% to isoniazid and rifampicin (*ibid*). In another study, of 2779 patients in North Arcot district 25% had resistance to one or more drugs including 2% to rifampicin while in Pondicherry 13% had initial resistance to one or more drugs (Paramasivan *et al* 1993). A high proportion of patients with initial resistance responded favorably to treatment (*ibid*). As a comparison recent studies in the USA reveal a 14.2% crude prevalence of any resistance (Reider 1994).

1.4 Societal/ Social Dimensions :

Health policy makers in the 1940s explicitly acknowledged the role of socio-economic factors by linking TB and its spread to *'malnutrition and undernutrition, insanitary and overcrowded housing conditions'* (GOI 1946;157). They specifically advised government that, *'the attack on the disease should be launched simultaneously in two directions..1) improvement of socio-economic conditions..to provide for a higher standard of living, better housing, adequate nutrition and... (better) environment in their homes, their work*

places and places of public resort, and 2) towards effective control of the spread of infection from patients to those who are healthy. (They) referred to the necessity for sustained State action towards the achievement of definite results in ....the amelioration of social conditions' for TB control (*ibid*;158). Need for government action towards improved housing, environment and nutrition, in relation to TB control, was re-emphasised in the 1960s by a government committee (GOI 1961). The '*social and economic repercussions'* of the disease affecting almost all families, directly or indirectly, was acknowledged (CHEB 1961;1). The voluntary sector too recommended action concerning poverty, overcrowding and nutrition (TAI 1956, 1970). It undertook public education concerning social customs such as the *purdah* system and habits like spitting in public places was undertaken (*ibid*). It thus focussed on individual behaviour.

The first government sponsored National Sample Survey (1955-58) reported greater TB prevalence among lower socio-economic groups living in poorer housing, with high prevalence rates of 4-5% among the poorest in urban slums (ICMR 1959). From a socio-political perspective, the study and TB control work from 1947-58 highlighted the inadequacies of institutionalised, technology-based, specialist TB work being conducted, to the socio-economic context of India, and strengthened the search for alternative, indigenous approaches to TB control (Nagpaul 1989, Banerji 1993). The central government established institutions with mandates to evolve policies based on public health principles and community based strategies (GOI 1959, 1961)[15]. The government proactively framed societal parameters for research and policy, commissioned studies and articulated the radical new National TB Programme (GOI 1962), influencing global policy (WHO 1964, 1982).

A sociological study in the early 1960s of symptom awareness and health seeking behaviour found 70% of sputum positive patients and 80% of X-ray positives, conscious of symptoms (Banerji and Andersen 1963). Motivated by their suffering, substantial

[15] The TB Chemotherapy Centre, instituted in 1956, tested the scientific basis and efficacy of domiciliary treatment pioneered in the 1940's at the New Delhi TB Centre (Banerji 1993). The National TB Institute,established in 1959, developed a nationally applicable, socially relevant programme within existing resource constraints (GOI 1961, Nagpaul 1989).

proportions of symptomatics (50% of sputum positives and 33% of radiologically active) took action, approaching health services for relief (*ibid*). This study formed the basis for adopting a felt need approach in the NTP with passive case detection and integration of tuberculosis with general health services (Banerji 1993). It formed part of the argument against house to house surveys/active case finding and use of Mass Miniature X-rays (*ibid*) promoted by some experts and an industrial lobby (interview 1995). Supportive arguments included unsustainable costs and poor reliability of X-rays as diagnostic tools (Raj Narain and Subramaniam 1962, Raj Narain *et al* 1964). It was hypothesised that non-specialised personnel using simple standard questions could identify symptomatics for further investigations (Banerji and Andersen 1963). Symptoms provided a simple mechanism for screening. Sputum smear examinations in patients with symptoms of chronic cough at peripheral health institutions provided a simple method for diagnosis of pulmonary TB (Baily *et al* 1967). Findings that 50% of symptomatics approaching health services were mis-diagnosed and treated with cough mixture, suggested that educational efforts be focused on the health system and the medical profession rather than on mass health education campaigns for patients (Banerji and Andersen 1963). It is argued that social science inputs interacting with interdisciplinary studies during policy formulation led to '*subordinating technology to the needs of people, deprofessionalisation (and) demystification*' (Banerji 1993,65).

Early studies from the NTI found irregularity in drug taking un-correlated with economic, social, educational and other status of patients and their families (Andersen 1962). A later study in Gujarat found greater utilisation of government District TB Centre facilities by the poor, scheduled tribes, Muslims and scheduled castes (Mankodi 1982). However District TB Programme services in general were under-utilised, despite adequate institutional facilities. Poverty was not found to be a cause for incomplete, irregular treatment and it was suggested that sociological problems of implementation needed greater attention (*ibid*). A study in Maharashtra on the other hand found a higher proportion of defaulters living in poor socio-economic conditions, lacking health information, social support and good relationships with health care providers (Barnhoorn and Adriaanse 1992). Problems of

distances and transport, inaccessibility of health institutions to the poor, particularly women among them were identified as causes for non-adherence in addition to poor drug supplies and apathy of doctors (Quadeer 1994).

After articulation of the NTP in 1962 explicit statements concerning socio-economic development were dropped from the TB control policy. Major directions of research in government institutions were towards case finding, case holding and defaulter action, chemotherapy and technical components. There was little work on effects of income and social class on TB, access to care, treatment outcomes and coping mechanisms of these groups. There was little work on general health services, a key component for the NTP. The societal dimensions were thus almost deconstructed.

In summary, the magnitude and complexity of the problem of TB is immense. Research regarding the extent and nature of the problem strongly influenced the development of treatment and control strategies and policies.

Problem of TB in India:

- Prevalence of infection decreased from 70-88% to 52-30% of the population. It is equally distributed in rural/urban areas, increasing with age.
- Incidence of infection is 1-2% per year. Gradual decline over time fits in with natural decline.
- Prevalence of disease is 16/1000 (all forms), including 3-4/1000 bacillary TB, increases with age, lower in women, higher in lower socio-economic groups, regional variations and declining prevalence noted.
- Incidence of disease is 1/1000/year (sputum smear positive), 1-5/1000 (all forms)
- Mortality is reduced but still high at 50-84/1000
- Magnitude of problem: 13.5 million TB patients of which 3.6 million are infectious. In absolute numbers it is larger than in 1947 due to demographic reasons. Widely dispersed, predominantly rural, adult problem affecting men more.
- The secular epidemic appears to be on the decline.
- Drug resistance, chronic excretors, and TB/HIV co-infection are additional problems.
- Socio-economic factors considered during policy formulation but overshadowed by technical components.
- Poor functioning of the programme is indicated by high case fatality rates, high ratios of prevalence to incidence, increasing proportions of chronic excretors and increasing drug resistance.

1.5 Policy Related Problem Definitions/Approaches to TB Control

TB control programmes conventionally frame the problem within epidemiological, bio-medical and public health/programmatic parameters described in 1.3 and also case finding, case holding, default, relapse, treatment failure (e.g. WHO 1964, 1974, Kochi 1991). Beneath epidemiological/public health articulations are conflictual societal relations and interests, more apparent in sectoral action/non-action and implementation. However societal and political economy issues were infrequently raised. This thesis views the problem of TB

and its control within societal and policy parameters in addition to the above. Finance, infrastructure, sectoral responses, and pharmaceuticals are referred to but are not specifically addressed by TB policy makers. These broader policy related problems even for single diseases like TB are not simple or static. The historical review (Chapter 4) revealed multi-layered complex problems unfolding over time, affecting and sometimes resulting from implementation (Table 1.2). Dominant paradigms and the power/powerlessness of various actors (policy makers, implementors and patients) influenced the understanding of the problem and choice of solutions.

Table 1.2 Layers of TB Related Problems and Policy Responses Over Time

Period	Multi-Layered Problems	Policy Response
1900-1940	a) TB recognised as a major public health problem and medically intractable; b) Knowledge gaps about problem, inadequate technology for public health intervention; c) No state responsibility for problem solving.	a) The family; voluntary sector; medical profession in predominantly private sector; b) An emerging public sector (local govt.), c) No organised national response.
1947-mid 1960's	a) Continues as major public health problem; b) Links to poverty recognised and stated; c) Inadequate health care infrastructure, resources and organisational mechanisms; d) TB drugs imported, expensive, in short supply e) TB redefined as a technical problem with techno-managerial solutions: mass application of BCG and domiciliary chemotherapy.	a) State responsibility, active intervention, b) Build up of knowledge through indigenous state sponsored research; c) NTP evolved mandated by central govt., d) Gobal development of chemo-therapeutics makes cure more possible; e) International public health players, UNICEF, WHO, become active.
Mid 1960 -1980's	a) Continues as major public health problem; b) Resource constraints continue; c) Competing interests (family planning within health) and underlying forces more obvious; d) Inadequate development and poor functioning of state run general health services.	a) Growth of private sector medical practice; b) Growth of Indian pharmaceutical industry reduces prices and increases availability of TB drugs in the market.
1990's	a) Absolute numbers of TB patients higher than 1947 due to demographic reasons. Continues as foremost public health problem; b) Continued focus on technical factors, societal/ policy process factors inadequately considered; c) Problems of chronic excretors and drug resistance created by poor implementation; d) Co-infection with HIV a new problem.	a) Re-emergence of international actors: WHO, World Bank, bilateral donors; b) Global policy linked to financial aid; c) National policy makers forget/ ignore indigenous research contributions and implementation experiences.

NB: This is discussed further in Chapter 4.

Changing and sometimes competing definitions of the problem often co-existed. TB was variously viewed as an intractable medical problem in need of simple, reliable diagnostic methods and an effective cure (TAI 1956); a social problem linked to widespread poverty, poor housing and under-nutrition requiring developmental effort (GOI 1946, 1961); a public health problem with techno-managerial solutions (GOI 1961); a behavioural problem requiring health education (CHEB 1961); an international problem and threat requiring urgent global solution and action (WHO/TB 1994); a symptom of inequitable societal relations demanding social justice or from the perspective of the poor with TB, a struggle for life (MFC 1984). With technology development public health and bio-medical constructions became dominant, driving policy nationally and internationally. Societal analysis and strategies (GOI 1946, 1961) receded from government's TB policy agenda.

In 1962 the NTP attempted accommodating sociological and epidemiological definitions[16] without acknowledging inherently different goals/interests. The sociological definition went beyond the medical domain with the problem of pulmonary TB understood as the *'total sum of all the suffering, discomfort and economic dislocation directly or indirectly brought about by the tubercle bacillus destroying human lung tissue.'* (Banerji and Andersen 1963). Reduced suffering being a goal, the programme was deliberately named the National Tuberculosis Programme (NTP) and not the National Tuberculosis Control Programme (NTCP), differing from other concurrent vertical disease control programmes (malaria, smallpox) (interviews 1996). Competing epidemiological definitions focused on reducing disease transmission and on control, the latter deemed to be achieved when prevalence of infection reduced to 1% at 14 years of age (WHO 1964, Gupta 1985). This indicator was said by a key policy maker to have developed *'from the top of one's head'* (interview 1995), an interesting insight into how measurable policy objectives developed in the abstract domain were imposed on implementors working in real life situations. Control was also

[16] Whether definitions, articulated by researchers, are meaningfully adopted becomes evident during implementation processes.

defined as reduced disease prevalence over time. The target was a 50% reduction in prevalence of excretors[17] over 20 years (Piot 1962).

Epidemiological arguments narrowed policy by focusing on infectious pulmonary TB thus implicitly favouring public health and state interests over patients interests. Patients with sputum smear negative, active pulmonary TB or with childhood and extrapulmonary TB[18], being non-infectious and consequently not threatening society, received cheaper, less effective drug regimens, though physically suffering as much or more (MFC, 1984). This group comprises over 50-60% of patients with TB. This approach continued in the 1980's with Short Course Chemotherapy (multidrug, shorter duration, better cure rates) available to infectious patients and Standard Regimens (longer duration, less effective, cheaper) to others (NTI chemotherapy guidelines) [19]. Justified by resource constraints, the policy was none the less discriminatory. The resource constraint argument, accepted for five decades represents societal relations and state priorities (Chapter 4).[20]

Despite acceptance of association of TB with socio-economic factors and poverty, there were few efforts to understand causal and mediating societal mechanisms, how these affect policies and services, or to propose strategies to engage with deeper causes. An initial model (Table 1.3) suggests need for linkages between different levels.

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[17] Infectious patients excreting tubercle bacilli in their sputum.
[18] TB is a systemic disease manifesting in different organs depending on the response of the immune system and other factors (Bloom 1994).
[19] The Revised NTP covering a small proportion of the population offers SCC to seriously ill sputum negative patients (TB Div. 1995).
[20] This study views TB (all forms) as a cause of human suffering and a major public health issue that is intricately linked to societal relations.

Table 1.3 TB and Society: Levels of Analysis and Solutions

Levels of Analysis of TB	Causal Understanding	Solutions/ Control Strategies
Surface phenomenon (medical & public health problem)	Infectious disease/ germ theory.	BCG, case finding and domiciliary chemotherapy.
Immediate cause	Undernutrition/ low resistance, poor housing, low income/ purchasing capacity	Development & welfare -income generation improved housing.
Underlying cause (symptom of inequitable relations)	Poverty/ deprivation, unequal access to resources.	Land reforms, social movements towards an egalitarian society.
Basic cause (international problem)	Contradictions and inequalities in socioeconomic and political systems at international, national & local levels.	More just international trade, finance and political relations etc.

Source: Modified from Ganapathy (1985)

1.6 Implementation Problems and Gaps

Delays and difficulties in implementing public policies are frequent worldwide (Lazin 1995), and differences between public policies and their performance, termed the 'implementation gap' are reported (Chapter 2). In India, concerns about the inability of the TB programme to achieve its objectives (Chapter 4), with consequent effects on potential programme impact were repeatedly expressed (Table 1.4).

Table 1.4 Implementation Gap in the National TB Programme

Year	Report	Indicators of an Implementation Gap
1956 1961	Second Five Year Plan; GOI, Mudaliar Committee.	*1st Plan* (1951-56) 5000 TB beds established of 10,000 planned, 55 new TB clinics started, the majority without laboratory/X-ray facilities & staff; *2nd Plan* (1956-61) 2,500 TB beds of 4000 established, 100 TB clinics set up against a target of 300, some without minimum requirements, utilisation of UNICEF supplied equipment behind schedule, integration of BCG campaign not possible because clinics, school health and other services did not develop as anticipated. Only 3 out of 10 planned State TB Training and Demonstration Centres established
1969-70	Fourth Five Year Plan.	Implementation by States was poor despite guidance/assistance by Centre By 1968, end of 3rd plan, only 170 out of 330 districts were covered by the District TB Programme, several districts had no TB beds as adjuncts to domiciliary treatment. Two major States had no State TB Centres.
1975	ICMR, NTP Assessment.	'the working of the NTP is far from satisfactory'; 2.1%-15.5% of eligible children given BCG, 19-44% of new bacillary cases detected against estimated incidence, 2.5%-33% of all forms of TB treated against estimated prevalence, very high proportion of patients discontinue treatment.
1988	ICORCI, In-Depth Study of NTP.	performance of this 'carefully planned programme' continued below expectations even after evaluations, causing concern. Case detection in 1987 was 1/4th the annual incidence of TB (too low for significant impact on the TB problem). Only 27% of those starting treatment made 12 or more monthly drug collections from 1982-86.
1992	GOI/WHO/SIDA TB Program Review	'the programme is not having a measurable impact on transmission and appears to function far below its potential'.

Sources: GOI,2nd & 4thPlan, GOI 1961, ICMR 1975, CHEB 1977, ICORCI 1988, GOI/WHO/SIDA 1992

Implementation[21] problems and gaps viewed from different perspectives (discussed below) were highlighted by researchers at the NTI (Andersen and Banerji 1963, Raj Narain 1964);

[21] Implementation is defined as the functioning of the NTP in accordance with its basic principles of integration, meeting felt needs, referral system, supervision, training, guidance and supplies etc. (ICORCI 1988).

by the voluntary sector (Bordia 1971, Deshmukh 1971, MFC 1984, VHAI 1984) leading to requests for evaluations by the TB Association of India; and by parliamentarians. The latter two resulted in government sponsored comprehensive research based reviews identifying operational, organisational and administrative bottlenecks (ICMR 1975, ICORCI 1988). While democratic processes elicited response, political processes prevented findings from being implemented.

The government (GOI 1961) acknowledged assessments of the first two plans that resources were inadequate for the institutionalised, vertical approach then pursued. Government resource constraints became an over-riding parameter within which the NTP was formulated. Implementation problems (e.g. 80% irregularity in chemotherapy) in the NTP, reported from a well resourced urban programme, predicting rising drug resistance, concluded that theoretical solutions of mass chemotherapy were small steps towards achieving the difficult goal of TB control (Andersen and Banerji 1963). *'Critical problems for achieving TB control within a reasonable time'* were identified as *'organisational and administrative...rather than medical and technical'* (Andersen 1962;1).

Others argued that the NTP using diagnostic and treatment techniques with inherent limitations, through minimal facilities at District TB Centres and elementary services at Primary Health Centres, could not be expected to achieve TB control in the near future (Raj Narain 1964). With about half the sputum positive cases positive by direct smear, and 50% of direct smear positive cases being symptomatic in some studies, the NTP had a maximum potential of reaching 30% of total bacteriologically positive cases (*ibid*). Isoniazid monotherapy (300 mg/day) would convert 60% of sputum positive cases, giving a maximum programme effect of sputum conversion of 18% of cases (60% of 30% possible to diagnose) (*ibid*;6). Most transmission to family contacts occurred before diagnosis, hence chemotherapy was unlikely to contribute much to TB control (*ibid*). Drug resistance and chronic excretors were predicted causing suffering and expense to patients and society (*ibid*). These unintended policy consequences where solutions became part of the problem. were later documented. In the fifth survey of the Chingleput BCG Trial only 29% of cases

found were new, with 71% being old cases detected in previous rounds but not yet cured (Jagota 1995). Others reiterated that poorly functioning programmes produce chronic excretors, increasing disease transmission and drug resistance (Grybowski 1993). Findings that peripheral institutions detect only 34% of all cases and that just 24% of cases detected by the NTP were bacillary, indicate that basic principles of the programme were not being practised by implementors (Sivaraman 1982).

The Indian Council of Medical Research report (1975) focusing on the public sector, dealt implicitly with issues concerning power such as apathy and lack of interest in Peripheral Health Institutions, need for authority and competence at district and state TB centres, poor implementation by states, and need for greater centralisation. It took on the medical profession by recommending that private practice by Government medical officers be banned, and suggested greater community participation. It pointed the way forward beyond a techno-centric approach. The report was released at a time of social and political unrest, when family planning dominated the health agenda and Emergency[22] was introduced (Chapter 4). Besides introduction of monitoring in 1978, most of the recommendations were not acted upon.

The 1988 report (ICORCI) viewing the NTP as part of the health system, found it was given low priority, with integration slow, incomplete and hampered by '*conflicting personal and group interests*' (*ibid;*190), with other programmes such as family welfare producing detrimental effects. Infrastructural inadequacies of staff, accommodation, equipment and facilities were highlighted while lack of supportive supervision at all levels was the weakest point. Staff discontent and conflict, with health workers *'almost on the point of revolt'* (ibid;209) in one State was reported. Case finding and case holding was low along with a paradoxical overdiagnosis and treatment of 'suspect' cases. Recording was '*incomplete and unreliable*' (*ibid*;222), monitoring was not used locally/meaningfully and pressures of targets for case detection led to over-diagnosis (*ibid*). The only action on the exhaustive report, commissioned by government, financed by WHO and submitted in November 1988,

[22] A national emergency was declared by the central government under which civil rights were curtailed (Chapter 4).

was circulation of the summary recommendations to the States (interview 1996). International approaches were being developed by WHO in 1989 (Kochi 1991) through which the TB programme in India was to receive World Bank support (Banerji 1993;78). This partly explains why the 1988 report was shelved.

The 1992 Programme Review (GOI/WHO/SIDA) identified a weak central structure, inadequate development of State resources, poor coordination at district level, insufficient utilisation of health assistants and no credible technical/policy advisory body. Problems in case finding, treatment practices and organisation, poor drug supplies and financing, training and supervision, and the role of private practitioners were raised. Recommendations however were in the old mode focusing on diagnostics, treatment and cure, recording and cohort analyses, training and operational research. Creating an apex making policy body and task force (a suggestion made earlier), strengthening the central unit, and additional staff at sub-district level were other recommendations (*ibid*). This review led on to the Revised NTP (Chapter 5). Till 1997, about 23 million people of 950 million were covered in phases by the Revised NTP, but no action was taken on critical issues raised.

All three authoritative, analytic reports involving experienced, committed national TB experts, were commissioned by government. Despite being incisive and comprehensive, these assessments and other critiques have not influenced implementation and performance, pointing to the role of deeper underlying factors.

An implementation gap in TB control was also observed globally. For instance,

> *'Inspite of sustained efforts made by WHO and IUAT to assist the implementation of realistic and effective TB control programmes..practical progress is still lagging behind. Achievements fall short not only of what could reasonably be expected even in unfavourable conditions, but also of what would be required to make an impact on the TB problem. Thus only a small proportion of the world's population benefits today from scientific advances in the prevention and chemotherapy of TB. This applies not only to developing countries; so far only a few of the affluent countries have taken any determined*

steps to rationalise their TB services' (Hitze, Chief, TB, WHO Geneva, 1971 quoted in USPHS 1976).

A decade later a WHO study group said, '*TB represents the prototype of a disease for which the natural history is known and substantially quantified and against which an effective, simplified, standardised, technology has been developed and organised into NTP's and yet there is a continuing gap between expectations and achievements which is creating concern'* (WHO 1982;7).

Problem analyses and policy for tuberculosis control during the past 4-5 decades, the phase of 'scientific optimism'[23], has been relatively apolitical. Questions concerning susceptibility of certain societal groups to TB, their reduced access to care, and underlying structural issues are raised by a few (MFC 1984, VHAI 1994, Farmer 1995, Rangan *et al* 1997). These questions are generally unheeded in the policy process in India. In the 1990's WHO reframed the problem in epidemiological terms (Kochi 1991). Its appeal for increased political will (WHO 1996, 1997), to governments with a variety of political systems and beliefs across the world, to initiate action on TB is important, but too general from a political science perspective, besides being merely a background to the main techno-managerial policy package.

In conclusion, the problem being addressed by this policy is intrinsically complex. Development of policy content was part of the policy process and cannot be seen as a separate technological entity. Societal factors/ forces and effects of poverty on TB in India, apparent from historical data, received insufficient policy consideration from policy makers. Rationalism and indigenous research helped understand the extent, nature and epidemiological aspects of the problem and to develop policy content along scientific principles. Limitations of this approach to understanding other crucial elements of policy process and implementation were not appreciated. Though sociological findings and national socio-economic context influenced policy strategy, the emphasis was on the epidemiological/public health approach. Research contributions were internationally

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[23] Exemplified by statements such as '*specific tools are now available for preventing and curing tuberculosis making it possible to plan and execute effective anti-tuberculosis programmes under practically any epidemiological or socio-economic conditions'*(WHO 1964;1).

accepted and basic policy principles considered sound by repeated evaluations, which however raised issues beyond the scientific domain to explain problems with implementation. Implementation gaps consistently persisted over forty years at levels such that epidemiological impact was elusive, reduction of suffering inadequate, and with unintended negative consequences. This study suggests that the NTP, while technically sound, is flawed in that policy process factors, particularly societal and political issues concerning power, alluded to in evaluation reports as affecting implementation are inadequately considered. These need to be seen as part of the problem requiring specific strategies. These are discussed further in later chapters.

CHAPTER TWO

POLICY PROCESS AND IMPLEMENTATION: BUILDING A CONCEPTUAL FRAMEWORK

2.1 Introduction

Policy studies as an academic discipline emerged in the 1950's, with 'The Policy Orientation' by Lasswell in 1951 (Sapru 1994, Parsons 1995), in response to development of public sector policies. From the 1940's, many governments invested substantially in national public sector social policies, including health, education, housing, water supply, sanitation and social welfare. International priority given during this period and until the 1980's, to the role of the state in the economy and development is widely recognised (Walt and Gilson 1994). This was exemplified in the USA by the New Deal initiatives under President Roosevelt, and in the UK, with nationalisation and the setting up of public services and utilities under the welfare state.

However by the 1970's, despite gains, dissatisfaction developed regarding a perceived 'implementation gap' (Dunsire 1978), or 'implementation deficit' in which 'the modern state promised programmes which it cannot deliver' (Hjern and Porter 1993;248). Delays, difficulties and failures in implementation were perceived as frequent (Lazin 1995).

In India, following political independence in 1947, ambitious development policies were formulated. They were to function through a public administration structure evolved in British India primarily for tax collection purposes and maintenance of law and order. They were embedded in an ancient society with its own institutions (family, caste, religion, *panchayats* or mechanisms of local governance, Indian systems of medicine), social relationships (some of which were hierarchical and stratified) and philosophical framework. Health sector policy documents written just before Independence articulated major social goals (Banerji 1985 citing the Sokhey report of 1939, GOI 1946) as did the Constitution of

India in 1950 and five year plan documents. Written during a phase of nationalism and deriving from the freedom struggle, they provided vision and direction to the health sector. They perhaps reflected the ideals of the authors and personalities involved, which may not have been shared or internalised by the system through which they were to be executed. Specific policies evolved subsequently to control major public health problems (tuberculosis, malaria, smallpox), develop health services, and train health personnel (Park 1994). From the 1960's expert committees, evaluation/ research studies and monitoring systems revealed implementation problems in health sector and tuberculosis control policies (Chapter 1;Table 1.4, ICSSR/ICMR 1981, Banerji 1982, 1990).

2.2 Understanding Policy

The meaning of the term policy as used in policy science and an understanding of its dynamics has been evolving. Varying definitions arise from different disciplines, schools of thought and ideologies. Definitions, frameworks and methodologies used, reflect assumptions about social relationships, and influence the way policy process is perceived. Some definitions are operational without reference to underlying assumptions and philosophies. Pressman and Wildavsky described policy in 1973 as a 'hypothesis containing initial conditions and predicted consequences'. Policies were formulated because of dissatisfaction with certain conditions (by the public or other interests) e.g. tuberculosis, poor health services or unemployment and also due to other politico-economic forces. Different interpretations and analyses of causes of conditions resulted in different policies. While predicted consequences from social policies sometimes did not occur, unintended consequences not uncommonly did (Leichter 1979).

Early work on policy making focused on the primacy of decision making as a rational choice between various options, often supported by policy research (Howlett and Ramesh 1995). Hogwood and Gunn (1984) refer to policy as being larger than a discrete decision, involving a series of decisions sometimes in a rational sequence, and also as specific activities undertaken as an expression of general purpose, a specific proposal or a programme. Health sector policy, defined as broad statements of goals, objectives and

means that create frameworks for activity, and developing rules to guide action or inaction (WHO SEARO 1989, Palmer and Short 1989), was apolitical with an implicit rationalism. The assumed linearity had the following sequence: problem- research- policy formulation- intervention/implementation- output/ outcome/impact- monitoring and evaluation- feedback and correction. Other analysts recognising the limitations of a rationalist approach, described policies as being more complex, and interactive (Walt 1994).

Walt (1994) drew attention to implementation and a broader set of actors. 'Health policy embraces courses of action that affect the set of institutions, organisations, services and funding arrangements of the health care system. It goes beyond health services, however, and includes actions and intended actions by public, private, and voluntary organisations that have an impact on health (*ibid*;41). Not creating agencies or organisations with authority and adequate budgets after policy decisions to act on problems, would suggest that government is not fully committed to the policy (Walt 1994 and 1994b).

Political dimensions received explicit recognition from some scholars. Dye (1972) for example suggested that public policy was anything that governments chose to do or not to do i.e. governments were politically motivated in policy formulation. Political system analysis of policy includes what governments do, why and the consequences that follow (Leichter 1979) and not merely the analysis of 'rational' policy processes (Jordan and Richardson 1987). Placebo or symbolic policies are 'not actually designed to solve societal problems, but introduced as a means of managing the political agenda' (*ibid*;233). Policies formulated because of the need to be seen to be doing something, may never be expected to be implemented. While policies may be expressed as explicit written documents, they may also be implicit or unwritten (WHO SEARO 1989). Very generally worded policy documents and widespread use of implicit goals and practices allow room for manoeuvre and hidden political agendas. Gaps between statements and action occur, between what governments say they will do, what they do, and what they decide not to do (Palmer and Short 1989, Walt 1994). Policy statements could become political tools to appease societal pressures and demands. Recognition that the state was not necessarily a neutral actor

working for the common good, but was influenced by strong societal forces reflecting the distribution of power in society, added to the use of political approaches to policy analysis.

Policy is affected by the political system within which it functions. Society centred approaches (Grindle and Thomas 1991) such as pluralism conceptualise the policy environment as several interest groups competing to exercise power and influence (Hill 1993). Negotiation, bargaining, compromise, formation of alliances and coalitions of interests characterise policy process including implementation. This school earlier assumed that distribution of power is more or less equal among interest groups functioning in an open, liberal democratic political framework. However later analysis recognised unequal distribution of power and influence in society (Barker 1996). In health care policies, medical professionals, medical insurance companies and producers of pharmaceuticals/medical technology have disproportionate power in comparison with consumers and the poor (Patel and Rushefsky 1996).

Other society centred approaches suggest that policies respond to and benefit different societal groups differentially. They do not assume homogeneity of 'people, populations or public'. Varying political strengths of groups (class, caste, gender, ethnicity, religion, professionalism/knowledge base etc.) are strong influencing factors in the policy process. In implementation it has been reported in the USA that 'the character of client treatment at the hands of street level bureaucrats reflects and reinforces class and ethnic divisions' (Hudson 1993;396). While the state theoretically could play a policy role in evening out inequalities, it could also serve the interests of dominant groups.

State centred approaches (Grindle and Thomas 1991) such as political economy/elitist theories conceptualise corporate/business and economic forces as predominant. The ruling class or elite control market structures, state functioning, resource allocation and political decision making through strategies of manipulation, information control and sanctions (Blowers 1993). Powerful networks of business, military, aristocratic, bureaucratic and political elite influence government agencies and decision making (Barker 1996). Political

and policy agendas and implementation processes are subservient to these deeper forces, with national and international capitalism as important determinants.

Public policies refer to those for which governments are primarily responsible (Palmer and Short 1989, Walt 1994). They affect public interest and are carried out in the name of people as a whole. They may restrict certain areas for the public sector while creating an environment for private sector growth in other areas, along with regulation and monitoring. National health policies are guiding principles for health sector efforts of the State, also setting the tone for the entire health sector operating in a country. However business and corporate interests exert a powerful influence on government policy (Blowers 1993). Market forces gained prominence in the dominant neo-liberal framework during the past two decades. Whether they are suitable for the health sector including pharmaceuticals is under debate, particularly in the context of ethics and values of social justice and equity.

For this study, tuberculosis control policy was defined as a series of related decisions, action or inaction, around a framework of goals and objectives, evolved and undertaken over a period of time, by several actors at different levels, explicitly or implicitly, impinging directly or indirectly on the problem, with intended and unintended consequences. It includes the creation of the means to guarantee execution and affects institutions, organisations, health personnel, services and funding arrangements within the health care system (adapted from Walt 1994). Implementation was seen as an integral part of policy process, related to political processes, societal structures and values.

2.3 Policy Analysis

Policy analysis is multi-disciplinary and multi-method (Williams 1982) and studies the policy process. Policy research provides policy makers with information and options to solve problems (Majchrzak 1984). A distinction is made between analysis for policy (provision of technical and economic information for policy making, monitoring and evaluation) and analysis of policy (focusing on processes and values affecting origins, intentions, constructions and conduct of policies) (Gordon, Lewis and Young 1993).

Theoretical approaches to policy analysis, using varying frameworks and disciplines have developed. Analysis for policy focuses on a linear, rational, problem solving, prescriptive approach (Majchrzak 1984). Others recognise the limitations of the rational choice approach (Schelling 1985, Grindle and Thomas 1991, Walt 1994). In the health sector, epidemiology contributes an understanding of the nature, magnitude and determinants of the problem (Levine and Lilienfeld 1987). Economic approaches have introduced concepts of efficiency, effectiveness, and value for money to make best use of scarce resources (Clegg 1993). They have been little used in the health care services sector in India, though are reported to be widely utilised in other policy areas. The limitations of an economic approach, especially in coping with political dimensions and value systems have been raised (Ganapathy 1985).

Several analysts using political science approaches focus on actors, institutions and societal groups involved in policy making. Studying the role of policy elites (Grindle and Thomas 1991), health bureaucracies (Justice 1986), interest groups and conflicting interests (Reich 1993a), economic and class interests (Navarro 1994) are typical of this body of analyses. Political mapping (Reich 1993a) and stakeholder analysis (Crosby 1992) study political resources, support for and opposition to policy. Banerji (1990) analyses health policies in India using a multi-disciplinary approach, a historical perspective, and a pro-poor value base. Differing ideological assumptions underpin all policy analyses explicitly or implicitly.

Walt (1994) and Walt and Gilson (1994) use a political economy approach, suggesting an analytical model for health policy analysis incorporating context (social, political and economic), process, actors (international, national, subnational) and content. Policy analysis can potentially be an intervention and input into policy making and policy change processes (*ibid,* Barker 1996). It has descriptive as well as prescriptive or normative aspirations. Caution regarding its prescriptive uses is suggested, given the complexity of policy processes and the political compulsions of the moment that drive policy makers (Howlett and Ramesh 1993). Concepts such as context are general, open to varying political interpretations.

The above analysts tend to focus on national/central actors with an inherent top-down approach, ignoring public perspectives and participation in the policy process. This could mask societal conditions and gloss over the human aspects of health policies dealing intimately with the lives of people. 'Critical Policy Analysis' as an alternative includes a critical reflection of social science methodologies used for policy analysis, recognising their values, interests, assumptions, and structural limitations (Ganapathy 1985). The method is explicitly committed to social justice, recognises issues of power and conflict, takes a historical and dialectical approach, uses different methods to get divergent perspectives, feels that public participation is essential to generate valid knowledge, sees policy analysis as an intervention building on critical reflection, dialogue and collective social action with demystification and repoliticisation of policy analysis. Generating multiple perspectives and undertaking a dialectical analysis of these perspectives supports a deeper understanding of reality. Every proposition is true only upto a point, hence multiple perspectives help overcome individual limitations (*ibid*).

As mentioned above the role of the public has been neglected in policy analysis, which takes the government or policy perspective as reference point. Representation of peoples' interests was assumed to be ensured by existing state and interest group mechanisms in a democratic framework. This may not occur for the weaker unorganised sectors given the inequalities of power in any society. Citizens are key stakeholders in policy process (Ganapathy 1985), not just passive recipients, dependant beneficiaries and objects of development/health services or of research. There is need for people to be participants, subjects and producers of meaning in policy analysis (*ibid*).

Most analysts tend to overlook the impact of the complexities of health problems (inherent biological features of TB for instance) on policy. Content too is often considered as predominantly technical and value free, though it may be as influenced by political factors as processes are.

2.4 Policy Process and Implementation[1]

Early policy studies focused on decision making and suggested linear stages of formulation, implementation, evaluation and termination in the policy process (Lazin 1995). In the stagist, policy cycle approach to understanding policy process, issues or problems first reach the political agenda. Decisions, laws or regulations are then made by policy makers. Implementation was expected to follow automatically and was considered part of public administration. Monitoring, evaluation and finally termination occurred. This model is a modified version of the seven stage model first articulated by Lasswell i.e. intelligence, promotion, prescription, invocation, application, termination and appraisal (Parsons 1995). These conceptual approaches reflected the perspectives of policy/decision makers/planners.

Inductive implementation studies identified different issues and interactive processes. Phillip Selznick's study on the Tennessee Valley Authority in 1949 is one of the earliest analyses on implementation (Parsons 1995). It indicated that organisations adapt, survive and thrive as complex organic systems interacting with their environment. Selznick showed how informal organisations developed within formal structures. Decisions often followed the interests and values of its members and not the formal policy goals of the organisation.

Pressman and Wildavsky's case study on unemployment in 1973 is a widely cited early study of implementation failure. Its central point was that policies/programmes requiring a number of decision points (at which agreements are to be made), clearances (at which participants have to consent), and with multiple actors involved, are unlikely to achieve their objectives. However their identification of failure strengthened their recommendations and support to a strong top-down approach. They stressed the need for clearly defined and understood goals, capacity to assemble and control resources, co-ordination, effective communication and control of individuals and organisations in performance of tasks

[1] 'Policy implementation covers the operationalisation of policy prescriptions into goals and actions that specify the agents, procedures, capacities and behaviors required to produce the intended outputs at various levels (national to local). Brinkerhoff (1997;205) deriving from Mazmanian and Sabatier's definition/top-down approach in 1989.

(Parsons 1995). Their later writings acknowledged implementation as a process, as evolution, learning and mutual adaptation (*ibid*).

Pressman and Wildavsky reinforced the linear stagist understanding of policy process (Hill 1993, Lazin 1995) by drawing a distinction between policy making and implementation. The top-down approach was critiqued by many as being policy-driven, hierarchical, concerned with effectiveness and control, with an emphasis on getting implementors to meet objectives. There is an assumption of power at the top and of significant control over political, organisational and technical factors (Williams 1982). Policy goals were assumed to be valid (Hogwood and Gunn 1984). However increasingly research suggested that policies were often altered/'subverted' by actions of local implementors, and that organisational and inter-organisational factors transformed policy (Hill 1993). Implementors coping with circumstances and field conditions that were difficult and continuously changing with 'the problem' presenting in different dimensions often made crucial decisions. They however rarely participated in the planning or in the design and analysis of research. Their perspectives, if considered, were represented or interpreted by others.

Other studies acknowledged implementation to be complex. It was called the 'missing link in the study of social policy' (Hargrove 1975, cited in Sapru 1994) and 'the Achille's heel of social policy' (Williams 1982). Disinterest and naiveté in implementation in the real world were found to be impediments in the policy process (Sapru 1994, citing Williams 1975). Regardless of rigorous plan formulation, build up of organisational structures and substantial resource inputs, gaps between intent and implementation were common (Hogwood and Gunn 1984). It became evident that a decision did not imply that implementation would take place. It was also realised that implementation was a crucial and intrinsic part of the policy process (Grindle and Thomas, 1991). A more inclusive and democratic approach to policy making and policy analysis seemed necessary.

Using a different research approach with a bottom-up perspective, other aspects of the policy process were identified. Rather than starting with policy makers, and policy

objectives and studying to what extent they were implemented, this approach started from street-level implementors. Lipsky in 1971 (cited in Parsons 1995) first argued that interaction between bureaucrats and clients at street level should be taken into account. His studies of urban policy and special education reform found that the rational model was not effective in practice or theory; that control over people was not the way forward to effective implementation; that services were maintained by coping strategies of committed and dedicated street level staff. Thus alteration of policy was not seen as subversion but as necessary adaptation.

Others too found local actors' personal motivation, goals and strategies, their re-interpretation of programmes, along with interorganisational interaction and the development of a network of contacts, substantially transforming and altering policies (Elmore 1982, Howlett and Ramesh 1995). Implementors often reinterpret policy in relation to local circumstances, requirements and demands of clients, personal preferences and styles. It was realised that the policy is not the only or major influence on the behaviour of implementors (Elmore 1982). Formal and informal relationships constitute policy networks and subsystems and influence policy processes (Howlett and Ramesh 1995). Several analysts found negotiation, bargaining, conflict, compromise and consensus building integral to policy process, acting as constraint or contribution according to circumstance (Jordan and Richardson 1987, Grindle and Thomas 1991). Policies and programmes adapted and adjusted to local political and socio-economic environments (Lazin 1995). Findings from studies reviewed indicated that: vague and conflicting goals are the norm, policy objectives are unstable, changing over time, interorganisational and intergovernmental structures are inter-dependant and interactive, constant change and reinterpretration of goals make programme evaluation almost impossible. It was suggested that policies or policy makers cannot solve problems, but those in immediate proximity, with problem solving skills and discretion can (Elmore 1982). Policies can only direct attention towards a problem and provide individuals an occasion for the application of skill and judgement. A major shift in power is implied by this approach. Hence relationships between the problem and the closest point of contact is a critical stage of analysis (Elmore

1982). However even here the perspectives and participation of the affected public is not considered.

Discretionary behaviour by those delivering services was characteristic of several programmes studied (Williams 1982). Workers' behaviour which controlled programmes and determined outcomes was shaped by organisational structure and processes of functioning that either supported and motivated workers or left them isolated. It was suggested that instead of discretion being viewed as illicit it should be seen as an asset. It was stressed that organisations were effective mechanisms for working with difficult public problems, rather than relying only on the option of market forces. This reflected the underlying conflict and debate concerning the role of the state and the market.

Others argued that while flexibility allows greater freedom to respond effectively to a changing situation, it could be misused for personal/ bureaucratic/ dominant local interests (Jordan and Richardson 1987). While findings from bottom-up perspectives are descriptive of what happens, it was questioned whether it should be the norm for the policy process (Sabatier 1993)

More recent implementation studies suggest that 'demonstrating the complexity of implementation processes is an antidote to predetermined problem analysis and standardised solutions which short circuit situational learning and adaptability' (Brinkerhoff 1997b;229). Several of these insights are relevant to public health programmes.

To sum up, analysis of policy processes could be described as falling into two categories: top-down, and integrative with a bottom-up perspective. Their characteristics and underlying differences are highlighted in Table 5. The approach taken affects the way implementation is understood, with important consequences for the effectiveness of programmes such as the NTP. Policies evolved by experts, think-tanks, planning bodies tend to be top-down. The field of medicine/public health is particularly prescriptive, with specialised knowledge controlled largely by medical professionals providing a source of power. Following in this tradition policy formulation and analyses of TB programmes so far

have been top down, and as described later result in certain conclusions. Policy implementation is however dependent on a large proportion of other professionals/groups and on the participation of patients, supported by their families. Indicative of the imbalance of power these crucially important groups receive little consideration in policy processes other than being expected to comply/adhere with what they are told. This study values and incorporates the views/participation of patients and front-line implementors by utilising a bottom-up, integrative approach.

Table 2.1 Top Down and Integrative Approaches & Their Influence on Implementation

Approach	Policy Process Characteristics	Implementation Characteristics
Top-down approach	rational, linear, stagist, problem-solving, analytical, content and decision focused.	hierarchical, policy driven, technical, managerial, with objectives, measurable outputs, administrative lines of control and command, compliance, people as target groups/ objects.
Bottom-up/ integrative approach	incremental, process oriented, recognises the political, iterative, interactive, evolutionary.	builds on motivation/ capacity/ strategies of implementers at front-line and different levels, interorganisational interaction, people as participants/ key actors/subjects.

2.4.1 Explanatory Factors for Implementation Gaps

Analysts working on implementation identified factors responsible for implementation failures and gaps. Others framed conditions considered necessary for success. Pressman and Wildavsky, 1973 (cited in Cleaves 1980), suggest that if complexity of technical features, complicated methodologies and new untried technologies characterise a policy, chances of good implementation are reduced. Administrative complexity requiring new organisational forms, extensive co-ordination, multiplicity of actors, long duration's, multiple goals, and dependence on resources make implementation difficult and require greater power for it to be carried out (Cleaves 1980). Others too explained implementation failure of policies

processed through large bureaucracies as a managerial problem resulting from inadequate co-ordination, control and compliance (Jordan and Richardson 1987).

Several analyses construct health policies instrumentally as mechanistic interventions, emphasising surface level cause effect relationships in technical terms. A process of reductionism converts social problems into narrower technical entities. Increasing levels of specificity, measurable objectives and time frames are deemed desirable. Requirements for management, organisation and administration of policies on large scales and for compliance follow logically. Experience over four decades of international and national health policies (family planning, malaria, TB) reveals the complexity of problems and systems, both deeply embedded in society.

While metaphors, models and theories create insight or ways of seeing, they are also ways of not seeing (Parsons 1995). Perspectives and ideologies of authors/researchers influence findings and inferences inspite of attempts at objectivity and neutrality. Obtaining multiple perspectives and reflecting dialectically on the assumptions, world views and values of theories/methodologies may deepen understanding and suggest additional explanations (Ganapathy 1985).

The complexity of health problems has latterly received greater recognition. So have underlying issues of power and conflict inherent in problems intricately linked to iniquitous social relations and their influence on policy processes. Public policies were to level social inequity, but policy making and implementation structures being part of society have internalised its social relations. Hence social sector policies may perpetuate the existing social order.

2.4.2 Conditions for Successful Implementation

Conditions identified as necessary for successful implementation are the other side of factors responsible for perceived implementation gaps. Ideal models of how things should be were developed from the 1970's. Hood in 1976 suggested five conditions for perfect implementation (Parsons 1995): clear lines of authority; definitive objectives and

enforceable norms; compliance/obedience; perfect communication in and between units of organisation; and no time constraint. In this approach policies apparently valid and for the greater, common good, were conceived as separate entities stripped of socio-political context and social reality. Imbued with authority and power at the top, they appear like military operations, dependant on good management and compliance for success.

Sabatier and Mazmanian in 1979 & 1980 synthesised variables into six sufficient and necessary conditions for effective implementation of legal objectives (Sabatier 1993). These were: clear consistent objectives; good causal theory; implementation process legally structured to enhance compliance by implementing officials and target groups; committed and skilful implementing officials; support of interest groups and sovereigns; changes in socio-economic conditions not substantially undermining political support or causal theory. Thus concepts expanded with recognition of political factors and realities such as causality, legality, context, importance of interest groups and implementors. Interestingly the studies identified implementing agency support as the most critical point.

The 'perfect implementation' model of Hogwood and Gunn (1984) developed ten 'ideal' conditions for successful implementation, namely: availability of adequate time and sufficient resources, availability of the right combination of resources at each stage, minimal dependency relationships, policy based on a valid theory of cause and effect, direct relationship between cause and effect, agreement on objectives, fully specified tasks conducted in the correct sequence, perfect co-ordination, perfect compliance and that external circumstances do not impose severe constraints. Implementors facing uncertainties on most conditions and powerless to alter them are not necessarily helped in moving policies forward. Its rationalistic assumptions do not consider more complex political processes. The health sector with concepts and interventions developed within a scientific paradigm fit logically with the rational approach.

Cleaves' (1980) more realistic approach discussing political power as a condition for successful implementation is outlined below. The scope, ability and political acumen of actors to mobilise sufficient power and political resources influences policy

implementation. So does the strength and power of other actors with other agendas in the policy environment. Power that is widely distributed or fragmented in a policy arena with a multiplicity of actors may lead to smaller chances of significant change occurring. In open democratic political systems, with political organisation (parties), governmental agencies and interest groups, formation of alliances can tilt the content and implementation of policies. Through elected representation, previously powerless groups and their preferences are incorporated into the policy and decision making system. State-society relations condition the power underlying implementation and implementors need to have a general idea of power distribution in society. Greater power is required for more problematic policy areas. Public apathy may manifest as non-opposition to a policy, which may reduce participation and possibility of success. Hence demands, pressures and questioning are a positive sign of interest and support.

Implementation is now widely considered an intrinsic, continuous part of policy process, interactively linked with other elements (Grindle and Thomas 1991, Walt 1994, Brinkerhoff 1996). Complex processes of interdependency, adaptation and potential learning are recognised (Jordan and Richardson 1987). This study views implementation as integral to policy process that maybe as dependent on political processes as on techno-managerial elements.

2.4.3 Additional Policy Characteristics Influencing Implementation

Specific policy characteristics affecting implementation, identified by policy studies since the 1980's, are discussed below. However one is cautioned against the assumption that policy makers control the organisational, political and technological processes that affect implementation (Elmore 1982).

Political characteristics: Within organisations the use of discretion at point of service delivery, the point where 'big decisions become operating policy' (Elmore 1982), the formation of local bargaining coalitions particularly involving those affected by the policy, and non-hierarchical 'reciprocity of relationships between superiors and subordinates in organisations' have been observed to alter policies. Inter and intra-

organisational conflict is common with differences between different sections and levels of government (Howlett and Ramesh 1995). The ability of policy leadership to mobilise political forces in support of policy and to counteract those likely to pose significant threats is important, as are mechanisms for public involvement and participation, systems of information sharing and accountability, enhanced autonomy and empowerment of people/patients and positive public reaction or apathy (Grindle and Thomas 1991, Cleaves 1980).

Interest groups/stakeholders in society support and oppose change (Brinkerhoff 1997b). Their relative strength is determined by location (dispersed or urban), organisation (internal communication systems, leadership structures, mobilisation) and socio-economic structures (capacity to get information and wield influence) (Grindle and Thomas 1991). Elite consensus and possible conflict between groups are determining factors. Policies of private groups can affect public policies (Cleaves 1980).

In long-term policies, during the prolonged period required for implementation, actors may alter goals, leadership may change, new actors enter with different goals and unintended consequences may take place. Ownership of policy change and of capacity building effort, with development of 'indigenous policy champions'(Brinkerhoff 1996). Ownership is clearly important, but it could be created to serve various interests. Policy legitimisation, constituency building, resource accumulation, strategic and contingency planning, adaptation, managing external relationships and linkages (*ibid*). For political leaders the public visibility of programmes, difficulties with coerciveness, chances of failure and the nature of support and opposition may influence choice (Howlett and Ramesh 1995).

Financial Aspects: Several types of resources are required for sustainable policy implementation (Crosby 1996). Finances are not real resources, but can purchase infrastructure, equipment, skills etc. which take time and effort to develop, especially human resources with competencies. There is need to focus resources on organisational units with greatest likelihood of affecting delivery level performance. Skills required are

financial management, ability to utilise resources effectively, generate funds from alternate sources, shift unspent resources, use special accounts/ external aid and to function within financial constraints.

Managerial Characteristics: Besides control of budgets, personnel appointments and promotion, support services from transport to purchasing, these include institutional development (Grindle and Thomas 1991), human relation skills, conflict resolution, team work, developing mechanisms for supportive supervision and continuing education, problem solving, interacting with other departments, ministries and politicians. Skills are required to 'shepherd policies through a complex and shifting geography on the political, socio-economic and bureaucratic landscape'(Brinkerhoff 1996;1396). Leadership qualities and skills at different levels are crucial as are continuity of administrative resources and infrastructure. Corruption in association with weak organisational capacity is a particularly difficult institutional challenge (Brinkerhoff 1997b).

Technical Aspects: At the national level capacities for technical analysis, economic analysis, forecasting, and sector specific competencies are required (Grindle and Thomas 1991). The role of research in evolving policy content, and in monitoring/assessing its implementation is important.

New scientific and technological developments influence policy change (Howlett and Ramesh 1995). Issues concerning social control and accountability, social relevance and their effects on social relationships are crucial. Implementation depends on capacity and problem solving skills of front line staff.

2.4.4 Studying Implementation

First generation implementation studies were case-studies, while the second wave included more analytical comparative studies (Sabatier 1993). Both used 'top-down' approaches discussed earlier, starting with policy decisions, studying extents to which objectives were achieved, and reasons why they were not achieved, with the methodology itself biasing findings towards identifying failure.

Other than 'forward mapping', the top-down view of implementation, alternative approaches to implementation studies are 'backward mapping' an analytical approach centring at the point of service delivery (Williams 1982, Elmore 1982). It starts with perspectives of those delivering and receiving services and works sequentially through levels of organisational actors till the traditional top is reached. It concentrates on resources available and those needed for the policy from the perspective of those delivering and receiving services. This is similar to the bottom-up approach where implementors are seen as important players/participants in a process that could inform policy upwards (Walt 1994). Policy goals are often incomplete, vague and even contradictory, with new ones being added on to existing ones. Methodologically, studying implementation from the bottom may help make sense of the new additions/inputs (Hill 1993). A third integrative approach combines the two (Lazin 1995)

As a framework to study implementation an interactive, dynamic model has been suggested, with several participants at different levels and with 'formulation and implementation in a continuous loop and both as political as the other' (Walt 1994;157). Factors such as commitment of central government to policy, centre-state relations especially where states/ local authorities are dominated by opposition parties, source/adequacy of funds, communication networks, availability of information, values of accountability, social justice, equity, and organisational loyalty all play a role in process and implementation of policy.

In-depth case studies utilising historical approaches/longitudinal designs permit clearer understandings of public policies and implementation, though they may not be representative (Williams 1982, Ganapathy 1985, Lazin 1995). They can illustrate or test theories concerning important aspects of the policy process (Sabatier 1991a).

In studying implementation, it was found that relying on official reports and secondary sources of information give partial and often incorrect understandings of what takes place in the field (at points of interaction between provider and patient in health) i.e. of local

implementation of policies and programmes (Williams 1982). This approach was also unhelpful in arriving at explanations for gaps between policy intent and implementation.

Alternative concepts and approaches in studying implementation include (Williams 1982): a) capacity, commitment and behaviour at point of service delivery, with individual persons actually providing services forming the central focus of an implementation perspective; b) organisational structure and process within which interaction between provider and patient takes place, highlighting resources available and supports and barriers at that level of service delivery organisation. This thesis has incorporated these perspectives as part of its bottom-up integrative approach.

Early literature and conceptualisation regarding policy process and implementation arose from case-studies of sectoral policies within industrialised countries where the State played a dominant role. The context in different parts of the world with differing politico-economic and socio-cultural realities and policy processes requires greater study. A body of work in the past 15 years derives from studying the implementation of 'reform' driven by the economic imperative, with a shift from statist to neo-liberal market oriented policies. Implementation problems in 'developing' country reform policies, concerning rural electrification, nutrition and housing, have been studied by donor agency consultants with a view to improve performance (Grindle and Thomas 1991, Brinkerhoff 1996 &1997, Crosby 1996). Valuable insights have been gained, but the perspective is external and relates to and is driven by a particular agenda. This study has an Indian perspective, building on the policy work of Banerji and Ganapathy and the research work connected with the NTP in the Indian context.

2.5 Conceptual Framework

This study analyses explanatory factors for the implementation gap of the NTP in India by focusing on context, process, actor and content (Walt 1994, Walt and Gilson 1994). It uses a

historical approach, starting from the mid-1940's when the policy originated, centring on the:

a) social, economic, political context within which the NTP functions;

b) definitions/construction of the problem (TB) i.e. its policy relevant societal, epidemiological and technical dimensions;

c) evolving technical content and assumptions of the programme; and particularly on

d) policy processes and implementation factors (Table 2.2) including the role of actors and interest groups.

There is a paucity of implementation studies using a policy analysis approach particularly in the health field, posing a methodological challenge. Hence a framework of implementation factors (Table 2.2), based on the literature cited in this chapter, has been developed as a conceptual approach to understand implementation of the NTP at national, state and district/local levels. The factors are not mutually exclusive, but are inter-related with several influencing all three levels.

Table 2.2 Framework of Implementation Factors at District, State & National Level

Implemen-tation Factors	District Level	State Level	National Level
Political Process	Public participation or apathy; interpretation and use of discretion by delivery staff; adaptation to local circumstances; accommodation between personal goals, interests, values vs. program goals; informal networks within formal structures.	Adequacy of power; centre-state relations; functioning of local govt.; interest groups; negotiation, bargaining, alliance formation, compromise (all levels), accommodation of interests.	Factors/ forces resulting in evolution & change of policy; power, commitment, capacity of central unit; sense of policy ownership; leadership of policy, ability to mobilise power & resources, advocacy, developing multisectoral linkages; mix of state and market mechanisms - their interaction; strength & power of other actors with other agendas, conflict; role/involvement of private and voluntary sector & international actors
Technical	Praxis of tasks related to objectives; capacity, problem solving skills of staff; sufficient uninterrupted supplies.	Technical support to implementors; availability, use & sharing of information.	Cause effect relationship; new technological developments; technological complexity; strength & regulation of medical profession; unintended consequences.
Managerial	Organisational structures/ processes that support/act as barriers to health service delivery	Administrative complexity; multiple actors; support and powers to district level.	Clarity of objectives, norms, lines of authority, single/multiple actors, communication, duration.
Resources	Availability of infrastructure, staff, equipment.	Source and adequacy of funds, drugs.	Adequacy and source; use as policy leverage; competing interests.
Values	Social justice, equity, accountability, participation (at all levels).		

CHAPTER THREE

STUDY DESIGN AND METHODS

3.1 Research Questions

The key questions were:

a) What explanatory factors underlie the perceived implementation gap of the National Tuberculosis Programme in India?

b) Can these be analysed in terms of policy content, contextual factors, policy process and actors?

c) What are the implications for policy from this analysis that can strengthen the NTP?

3.2 Hypotheses

Using an iterative method, tentative hypotheses (given below) were developed regarding reasons for the perceived implementation gap. They derived from an initial analysis of documents, interviews and a brief historical review. They provided direction to subsequent search and were not designed to be tested or proved/ disproved. Issues identified were focused on more analytically and in greater depth during data collection and analysis.

3.2.1 Private For Profit Sector

Governments' implicit support for the private sector undermined the NTP and public sector.

- While the NTP concerned itself almost exclusively with the public sector, separate Government steps simultaneously promoted and supported growth of private sector health care, from the 1950s onwards. The private sector grew without regulation and without cognisance of the principles of the NTP. The number of allopathic doctors working in the private sector increased from 60.4% in 1963-64 to 73.4% in 1986-87 (FRCH 1990). Physicians of Indian and other systems of medicine are almost all in the private sector.

- Utilisation of public sector resources (staff time, drugs, infrastructure) for private practice, including charging for free services, partially reduces access to public services or causes irregular treatment among the poorest.

- Economic interests of the pharmaceutical industry, of medical professionals and of those concerned with drug purchasing for the public sector play an important role in these developments. Economic constraints of government due to external and internal factors are related.

3.2.2 Public Sector Dynamics

Weak States and peripheral institutions, inadequate resources and urban rural disparities in health care provision suggest low Government commitment to the NTP.

- The State level is crucial to implementation of the NTP (and other health programmes) in India's federal system. State Governments however depend on Central Government financially and technically, and provide inadequate direction, support and motivation to their employees implementing the programme.

- Resources (financial, personnel, drugs and equipment) required to achieve the objectives of the NTP were inadequate, especially at sub-district level, from the start of the programme.

- Peripheral Health Institutions (PHI's) at sub-district level, the point of contact between patients and providers for the majority rural population, are the weakest in the NTP in terms of capacity to handle this complex programme. Negative staff attitudes to poor patients and to TB play a role.

- The historic and growing disparity between medical and public health services for organised sector employees (large public and private sector industry/services) and urban areas, as against those for the rural poor and unorganised workers, affects the NTP.

- Economic and class interests probably underlie developments mentioned above with social relations being reproduced in this sector.

3.2.3 Competing Interests

Health programmes backed by stronger interests adversely affected the NTP.

- From the 1950s vertical programmes (malaria, smallpox, family planning/welfare and immunisation) dominated public health, adversely affecting general health services at primary care level and the NTP, which was integrated with this. Vertical programmes had support of the bureaucracy, political leadership (for a major part of the period), national elite and international agencies.

3.2.4 Political Will

Political support to the NTP was inconsistent and counterproductive when coercive.

- After an early phase of central government commitment from 1947-1960s, TB was neglected. Renewed political attention in 1982, included it in the Twenty Point Programme, but with insufficient resources. Introducing targets for sputum examination at this time resulted in negative consequences.

3.2.5 The Voluntary/ NGO and Peoples' Sector

Marginalising voluntary sector participation in policy limits the balancing influence of civic society.

- The TB Association of India (TAI) helped place TB on the agenda in the 1940s, a time when government was responsive to voluntary sector initiative. NGO's subsequent attempts to raise issues concerning inadequate and irrational tuberculosis care were unsuccessful in influencing policy change. Since establishing the NTP, NGO role in policy process has been partly marginalised by Government policy makers.

Health issues, particularly specific disease problems like TB, are peripheral to peoples' social movements. There is thus little countervailing power to the strong interests mentioned earlier.

3.3 Aim

To understand underlying explanations for the perceived implementation gap in the National Tuberculosis Programme of India by undertaking:

a) A historical, analytical study of policy process and implementation at the national level since the 1940s, and

b) A case-study of policy implementation in one State, at District and *Taluk* level.

3.4 Objectives

A. National Level Policy Formulation and Development

3.4.1 To contextualise the NTP to economic, political and social factors influencing policy formulation and development.

3.4.2 To review briefly changes in policy content namely problem definition, epidemiological methods used to determine its size and nature, basis of intervention strategies and their modifications over time.

3.4.3 To study implementation processes (Table 6), including creation of infrastructure (TB specific and general health services), resource flows and to identify roles of key actors/interest groups and levels of power in implementing the NTP.

B. Implementation at State, District and *Taluk* level

3.4.4 To identify how actors/interest groups influenced implementation.

3.4.5 To study the availability and distribution of resources for the NTP at State, district and peripheral levels. These include trained staff, training institutions, physical infrastructure, TB diagnostics and drugs.

3.4.6 To study organisational mechanisms and inter-relationships of the NTP at different levels.

3.4.7 To compare implementation processes at *taluk* level between the public sector and an NGO which has taken responsibility from Government for the NTP in one *taluk*. In the two *taluks* to study:

a) Staff perceptions regarding the NTP;

c) Perceptions of TB patients regarding their experience of the NTP functioning;

d) Perceptions of elected representatives and informal leaders regarding functioning of the general health services with which the NTP is integrated.

3.5 Research Methods

3.5.1 General Approach

An *empirical, historical/longitudinal, in-depth case study* of the NTP was undertaken, using a mix between a bottom-up and top-down framework to study policy process and implementation. The inductive component studied the functioning of the NTP to understand explanatory factors for the perceived implementation gap. In this approach to theory building, explanations of events are developed through a detailed analysis of those events (Edwards and Talbot 1994).

An *iterative* process of policy analysis (Hogwood and Gunn 1984) was used, with progressive focusing of issues around the framework of context, process, actor and content, leading to newer directions of search. To structure the understanding of policy process, a framework of implementation factors was developed from the literature, providing a two-tiered framework of analysis.

Multiple sources of information/ methods of data collection used were:

a) semi-structured/ in-depth interviews (with checklists);

b) review of internal documents, records, published reports, media reports;

c) observations of implementing agencies at local, district and state level.

Interviews were unstructured, open-ended, with respondents picked not by statistical methods but because of their knowledge/ status (Yin 1982).

A *multi-level sample* was drawn from the following administrative and political units: local/ village, subdistrict or *taluk,* district, state, national and international. Respondents

comprised TB patients, elected representatives, private practitioners, government personnel including peripheral health workers, PHC medical officers, DTC staff, state and national programme managers, and personnel representing international agencies.

Validation of findings was done through *triangulation* (use of more than one source of information /method for data collection). Triangulation, used in inductive research, involves taking multiple, often three perspectives on a phenomenon/ event (Edwards and Talbot 1994). Different types of data (qualitative and quantitative) and data collection methods can reveal different aspects of reality. Additionally triangulation can use different investigators, study the problem over a period of time, and/or use different theories/ perspectives to interpret a single set of data (WHO Mental Health Div. 1994). Most commonly mixed triangulation is used. It is also used as a method of checking reliability in qualitative research. Because of the complexity revealed by the process one major data collection method is primarily used, while others provide supplementary evidence. In this study, the main method for the district and sub-district levels was interviews, while for the historical, national level it was review of documents.

A Research Assistant, a sociologist, with experience of survey research (in medical and developmental/social topics) was trained to conduct semi-structured, in-depth interviews with patients, elected representatives and peripheral health workers. He belonged to the area, was familiar with the local dialect and established a good rapport with respondents. The checklist of questions was double translated into Kannada (the local language). Pilot testing of interviews with PHC Medical Officers, Health Assistants, TB patients and elected representatives was done. Patients were interviewed at their homes and health personnel at the health centre. A 10% sample of patients were re-interviewed 4-6 months later to check reliability. About half of the interviews with TB patients were tape recorded, as testing showed non-interference with flow and quality of interviews, with patients essentially telling their story and nothing to lose or gain. Regular debriefing sessions with the research assistant were held. Many related valuable observations and perceptions picked up during the extensive fieldwork were shared. At other levels (e.g. some governmental personnel) it was found that sometimes even making notes during the interview caused respondents to

hesitate. To achieve maximum recall in these interviews (two-thirds of the total) notes were written as soon after the interview as possible, and on the same day. This necessitated time scheduling as writing up took a little longer than the interview.

There was a need to release emotional tension that accumulated during intense encounters with suffering. Sharing, meetings, writing (the research assistant is a poet) helped, but a deep imprint remains.

3.5.2 Sample

Sampling commenced with listing:

- key policy makers involved in the NTP over time at national and state level;
- representatives of interest groups; and
- key actors at local level (patients, doctors, health workers and elected representatives).

A non-probabilistic sampling approach was used. Snowball or chain sampling (Edwards and Talbot 1994) helped select additional respondents. The initial sample provided names of many knowledgeable about/involved in the NTP. These were prioritised and numbers limited due to time constraints and logistics.

Selection of state, district and taluks were as follows:

1. *State*: Karnataka, one of 25 States in India, with a population of 44.8 million (1991 census) was selected. With reference to national standards, indicators show that it has average levels of socio-economic development and that the NTP performs moderately (ICORCI 1988). The researcher was based in the capital city Bangalore, in the Community Health Cell, an NGO resource centre which provided the study infrastructural support. The National Tuberculosis Institute in the city provided much information.

2. *District*: Mysore district, one of twenty districts in Karnataka state, with a population of 3.1 million (1991 census) was selected. It has an average index of development and moderately developed health services. It is larger than the average district. It was chosen because NTP services for an entire *Taluk* had been taken over by an NGO and this could provide a point of comparison for identification of implementation factors. Positive

experiences would demonstrate that in spite of contextual constraints, implementation was attainable within a socio-cultural situation.

3. *Taluk* (sub-district administrative unit): Implementation was studied in 2 of 11 t*aluks* in Mysore district: a) Heggade Devana Kote *taluk* (210,000 population), an average *taluk* with a mix of public, private and voluntary sector services and the countrywide pattern of the NTP being run by the government. This was socio-economically the poorest *taluk* in the district.

b) Yelandur *taluk* (population 70,000) had the same mix of services, but a voluntary organisation had taken responsibility for provision of TB services for the *taluk* from the state government since 1991. Reasons for this, processes of implementation and outcome of NGO intervention were studied.

Patient Sample: Lists of TB patients were obtained from the District TB Centre, *Taluk* General Hospital, voluntary organisations and Primary Health Centres. Selection criteria were:

- equal numbers of men and women, though prevalence of disease is 2/3rd in men and 1/3rd in women - to identify gender discrimination, if any, in programme functioning;
- geographical spread of patients in villages throughout the *taluk* i.e. remote and near the headquarters town; rural urban mix;
- economically and socially disadvantaged patients;
- drop-outs from treatment;
- a few children and patients with extra-pulmonary TB;
- patients from above backgrounds treated by public and voluntary sector.

A mix of the most powerless were consciously chosen. There was no statistical analysis as this is a policy process study, focusing particularly on political dimensions.

A sample of elected representatives from local government at *Gram Panchayat* (village level) and *Zilla Parishad* (district level), for their perceptions regarding the functioning of the public health services with which the NTP is integrated. Public health comes under their

purview of responsibilities. Members from socially disadvantaged groups and women were chosen

3.5.3 Specific Research Methods for Different Levels of Study

a) National Level

- Documents for the historical review included administrative and research reports, evaluations, journal articles and books. It involved gaining access, reading and re-reading, identifying themes regarding context, content, actors and processes followed by a process of analysis by sub-themes, synthesis and interpretation (sources in Annexe 2 and bibliography).
- Semi-structured interviews with 62 policy makers and senior researchers involved historically and currently with the NTP/RNTP and 23 respondents from international organisations (list in Annexe 2). Repeat interviews were necessary and useful. Attending national level meetings provided insights and opportunities for discussions with a wide range of people with different views and perspectives (list of meetings attended in Annexe 2).

b) State, District and Taluk Level

- Interviews with key actors and interest groups (lists in Annexe 2, checklists of questions in Annexe 3):
  - 90 TB patients;
  - 22 elected local government representatives and 8 staff members from the *Zilla Panchayat* office;
  - 70 implementors from the front-line upwards (health assistants, doctors, voluntary organisation staff, district level staff); and
  - 11 private practitioners and visits to pharmacies in the two *taluks*.
- Answers to relevant questions raised in the State Legislative Assembly;
- Media coverage- TB and health service coverage in a local language (Kannada) district newspaper were reviewed.
- Records from the National TB Institute concerning the District;

- Records from the State Directorate of Health Services and TB Control section; and
- Records from the District TB Centre and the voluntary organisation.

3.6 Limitations Of The Study

The researcher fell ill towards the end of the fieldwork resulting in some curtailment of State level and organised sector data collection. In retrospect, the Erythema Nodosum that developed were early signs of TB. Later supraclavicular lymph node enlargement led to a biopsy, diagnosis and six month therapy with rifampicin, pyrazinamide and isoniazid during the writing up phase. Cardiac shadow enlargement during treatment and growth of lymph nodes at the end of treatment added anxieties. Hence analysis was supplemented by a personal experience of the disease under study, adding an unintended emic perspective.

Efforts were made to reduce possible 'researcher bias', reported in policy studies as researchers becoming co-opted by the unit of observation as advocates or critics (Williams 1982). Awareness of researcher subjectivity in data collection and interpretation influenced by personal values, professional background and experience was maintained in order to limit it.

Selection and recall bias among respondents is a well known factor. In this study repeat interviews and validating interviews helped reduce this. The inherent complexity of the problem and adoption of a wide ranging approach necessary for policy analysis resulted in certain issues not being followed up.

Efforts were made to minimise limitations by using multiple methods, divergent sources of information, pilot testing check lists and practising interviewing.

Though the private sector is an important actor in TB care in India, issues concerning it were minimally addressed as the study focused on the policy process and implementation of public policy. It therefore provides a partial picture. This is an area for further policy analysis.

3.7 Ethical Dimensions of the Study

Permission of the concerned authorities was obtained before conduct of the study. Similarly consent of people was taken prior to interviews and confidentiality was assured to respondents for their protection. This was maintained through confidentiality in reporting, thus names of interviewees are not mentioned in the body of the text. Even designations are not mentioned e.g. district health officer or WHO official as this would make it possible to identify respondents. Finally, study findings will be discussed with authorities and groups involved.

CHAPTER FOUR

HISTORICAL CONTEXTUAL DEVELOPMENT OF THE NATIONAL TUBERCULOSIS PROGRAMME

This chapter reviews the evolution of the TB programme at national level over fifty years (1947-97), with a brief background from 1900. Time periods covered correspond to major phases of policy development and change. Processes and actors are highlighted within a contextual background.

4.1 Evolution of the Tuberculosis Policy in India

4.1.1 1900-1940: Emergence and Recognition of the Problem

India was under British colonial rule during this period. Organised medical and public health services primarily served the interests of the army, civil service and local elite (Ramasubban 1984). The nationalist movement for independence had formal roots from 1885, with the formation of the Indian National Congress. Negotiations resulted in Legislative Acts in 1919 and 1935 through which certain powers and responsibilities were transferred to elected Provincial governments (Spear 1978). This included medical care, public health, sanitation and statistics. Being relatively unimportant 'low politics' issues (Walt 1994), imperial interests were not affected by the transfer (Jeffery 1988). The shift was opposed by the medical profession (*ibid*). Hospitals and dispensaries were started by provincial and local bodies, possibly more responsive to needs of the electorate. Interestingly rising public sector health expenditures are reported after 1919 (*ibid*). With increasing numbers of graduates from new Indian medical schools, private practice grew, especially in urban areas. In 1947, output from 22 medical schools were inadequate for a population of 340 million, with doctor population ratios below required norms. Shortages of nurses and allied health professionals were greater. Voluntary medical work was initiated by philanthropists and missionary groups. Practitioners of Indian and other systems of medicine functioned primarily as individual private practitioners. Indian systems of medicine lacking state support and recognition, languished consequently (Banerji 1985). While all sectors treated patients with tuberculosis, the private sector dominated medical care.

Two world wars and the great depression of the 1920's and 1930's worsened the economic situation, adversely affecting people and health services, besides absorbing the attention of government. The intensified struggle for independence after 1928, was the most important agenda for the nation. Anticipating freedom, the Congress set up a National Planning Committee, with the Sokhey Subcommittee on Health, in 1938 (Banerji 1985). Recommendations included a state organised free health system, health as an individual right, universal population coverage with medical/public health services especially under-served rural areas, integration of systems of medicine, large scale training of village level health workers and para-medical staff (*ibid*, Chatterjee 1988).

This was an experimental period in technology development for TB (diagnostic, therapeutic and preventive). Koch's established causal relationship between *Mycobacterium tuberculosis* and the disease in 1895, strengthened a powerful medical paradigm, the germ theory. Treatment was non-specific and relatively ineffective. Isolation in sanatoria, with dry climates, good food, rest and graded exercise, developed in the West (Davies 1994), were available to only a few in India with ability to pay (Nagpaul 1989). During the 1930's, various therapies (Annexe 1) were unsuccessfully tried. Essentially, the natural history of the disease ran its course. New technological developments were introduced in India fairly soon after their discovery (including cuti-reaction/tuberculin testing and BCG) by medical professionals in the private/voluntary sector. TB therapies of Indian systems of medicine were not considered, investigated or encouraged.

TB care/treatment continued almost exclusively to be the domain of private actors. Voluntary, not-for-profit efforts were isolated not linked (CHEB 1961, GOI 1961) and inadequate for the magnitude of the problem. In 1947 there were 120 TB specialists in the country, while 15,000 were required for the population (Dubos and Dubos 1952). Families were the main carers, in the absence of state or institutional services. Some provincial governments/ municipalities offered limited services (CHEB 1961).

The King George V Thanksgiving (Anti Tuberculosis) Fund in 1929, and the King Emperor's Anti-Tuberculosis Fund in 1934, were first efforts at a larger level, started by the voluntary sector with official patronage (TAI 1956). Anti-TB leagues, the TB

Association of Bengal established in 1929 (CHEB 1977) and the first TB survey by the Government of Bengal were precursors of an anti-TB movement (MSTA 1971). The first BCG vaccinations were given by Ukil who had worked with Calmette and Guerin (*ibid*). The Tuberculosis Association of India (TAI) formed in 1939 (GOI/Mudaliar 1961) provided intellectual and organisational impetus to addressing the problem nationally with a scientific basis and a community health approach (ICMR 1975). It undertook training and research. A membership organisation primarily of medical professionals, it received patronage from the colonial government, with the Vicerine as president (TAI 1956). Funds for these associations were raised from the public in India (*ibid*). These developments resulted from '*public opinion gathering strength demanding action to deal with the increasing menace of tuberculosis*' (CHEB 1977;7).

The state was conspicuous by its absence in the policy arena for TB control during this period. Reasons cited are that, concrete steps were not taken, because of preoccupation with diseases like cholera, plague and smallpox and *'because of the staggering magnitude of the problem and a lack of clear conception as to what should and could be done to combat it'* (CHEB 1961;9). Initial research was undertaken by the Indian Research Fund Association, a quasi-governmental body in Calcutta, to understand the extent of the problem. The state transferred responsibility for care of army personnel with TB to the voluntary sector in 1944 (CHEB 1961).

In summary, voluntary and private for profit actors were major players and as seen later, continued to influence policy during subsequent phases. This and other evidence suggests that existing, older policies, especially if serving dominant interests, are resilient, exercising continuing presence. With patients and families the main sufferers and carers, public demand for action is reported. Non-decisions and inaction, by the state in this instance, were components of the policy process.

4.1.2 1941-1950: Getting Onto the Political Policy Agenda

This was a period of dramatic political change. The second world war caused shortages and privation in India. A severe Bengal famine, largely man made, claimed thousands of lives in the early Forties. There was intense political activity, uncertainty and repression of the freedom struggle. Finally India attained Independence in August 1947. Partition

of the country resulted in much violence, death and disruption, a war with Pakistan in 1948, displacement of people on both sides of the new border, and an influx of 10-15 million refugees into India (Joshi and Little 1994). Economically 80% of the population were below the poverty line. All these societal factors could be expected to worsen the TB epidemic, with consequences lasting at least a generation.

Partition and its aftermath exacerbated the TB problem (GOI 1961) and consumed national energies. Refugees with TB received governmental financial assistance while awaiting hospitalisation or on home treatment and hospital beds were earmarked for them (MOH/GOI 1959-60, Planning Commission 1956)[1]. Prevalence of tuberculosis in the general population was high (Chapter 1). However quantitative information was inadequate for national planning. Of about 2.5 million TB patients, less than an estimated 5% (mainly urban), received treatment in 1947 (Ete & Khrime 1995) through the 85 TB clinics and 6,500 TB hospital beds (CHEB 1961).

The key post-Independence change was the Indian Government's acceptance of responsibility for the health of all its citizens. The denominator for Government health services expanded to cover the entire population. This was necessarily an 'ideal' with scarce finances, trained personnel, physical infrastructure, equipment and drugs. Following this political decision, the state began equipping itself and emerged a stronger player. The Indian Medical Service, linked to the colonial administration and army, was abolished in 1947 (CBHI 1985)[2]. Integrated posts of Director Generals of Health Services were established in Central and State Ministries of Health to advise Governments on medical and public health matters (Park 1994). Indicative of a sense of priority and urgency, a new Tuberculosis Unit was created in 1948 in the Directorate of Health Services at the Centre, with an Advisor in Tuberculosis to the GOI (CHEB 1961). The incumbent with over 20 years experience in TB work as physician/ researcher in the voluntary sector and as technical advisor to the TB Association of India (TAI 1956) had direct access to the political leadership (Nair*1996). The health minister became president of the TAI continuing traditional formal linkages. Expertise and policy

[1] Increased TB morbidity, mortality and transmission are recorded in populations affected by war (Barr and Menzies 1994) and among refugees/displaced people (Annexe 1).
[2] A decline in public health capacity ensued as this was not replaced by a national alternative (Banerji 1990).

advice from voluntary/professional groups were used by government to develop its services. It was widely believed that the state would uphold the interests of all its citizens. The alliance was fruitful in terms of research, development of policy content and implementation.

Political change, strong central leadership, and technical breakthroughs in TB treatment, offered a unique historical moment or window of opportunity (Walt 1994) that was seized, to initiate a national policy for tuberculosis control.

The decade saw expanding knowledge and technology in TB therapy globally. Streptomycin the first TB drug was discovered in the USA in 1944 and isoniazid in 1952. In 1948 the Government of India commissioned research, using voluntary sector (TB Association of India) expertise to study local application of technology at community level. These included studies of safety and efficacy of BCG under Indian conditions and effectiveness of community based control programmes (Frimodt-Moller 1960). The Bhore Committee recognising difficulties of increasing TB beds for isolation (the internationally recommended treatment), from an existing 6000 to the required 1-1.5 million using western norms, gave priority to organised home treatment through TB clinics (GOI 1946), used/studied from 1940 by Sikand at the New Delhi TB Centre (TAI 1977). It recommended thirty three 200 bedded TB hospitals (1/10 million), 33 main clinics for training, and 183 TB clinics (1/district), district mobile units with X-rays/drugs, 'intensive educational propaganda' (p165), expanded training for 13,000 TB specialists, research to understand the extent and nature of the problem and encouragement of non-official efforts (GOI 1946). Despite making local modifications, it was strongly influenced by Western methods (CHEB 1977). However it located specific anti-TB measures in the context of socio-economic development (Chapter 1). Its membership comprising many professionals part of or influenced by the freedom movement stated, *'Governments cannot absolve themselves of their responsibility'* for care, after-care and welfare services for infectious TB patients (GOI 1946;166). Addressing health service development they considered district health boards, village health committees and informed public opinion necessary to improve national health (GOI 1946).

The Technical Committee of the TAI, a powerful think-tank for government functioning since 1948, helped place TB on the political agenda and recommended a national BCG Campaign. It continued the Bhore Committee tradition with a small group of professionals dominating policy making. TAI was a member of the International Union Against TB[3] and maintained contacts with the newly established WHO and UNICEF (TAI 1956), forming an international policy network influencing global TB policy.

The International Tuberculosis Campaign (experienced from post-war BCG campaigns in Europe in 1945) helped the Indian BCG pilot project and campaign from 1948-51 (CHEB 1961), supported by WHO and UNICEF from 1951 (UNICEF 1980's). The international agencies provided funds, equipment and technical staff. The GOI established a BCG Vaccine Plant in Guindy, Madras in 1948, with WHO and Danish support, producing tuberculin, vaccine, and diluent to supply the Indian programme, Afganistan, Ceylon, Burma, Pakistan and Malaya (MOH/GOI 1959-60). The WHO set up its Field TB Research Unit, with the GOI in Madanapalle in 1949. Assuming greater susceptibility of children and urban workers and the protective efficacy of BCG, the vaccination programme expanded to organised groups such as school children and factory workers, developing into a school BCG programme in 1949-51 in all States (*ibid*). This was despite high profile controversies in the media and Parliament about the safety of BCG (interviews). Public resistance in some regions required mass publicity campaigns to increase its acceptability (UNICEF 1980s). The BCG campaign could be described as policy borrowing (Leichter 1979) or global policy dissemination which became increasingly common in international public health.

The government started building dispersed institutional capacity/expertise with three TB training and demonstration centres started in Delhi, Patna and Trivandrum, with WHO and UNICEF support (CHEB 1961).

The small circle of political and technical actors at the top with Prime Minister Nehru[4], Health Minister RajKumari Amrit Kaur[5], TB Advisor Dr. V Benjamin, and Dr. KCKE

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[3] TAI members occupied executive positions in the IUAT. The annual meeting of the IUAT was organised in New Delhi at which research findings were discussed. TAI helped set up the Eastern Regional Unit of the IUAT (TAI 1956).

[4] His wife Kamala Nehru also active in the freedom struggle, suffered from TB for 18 years and died in 1939 in a sanatorium in Switzerland. Her daughter Indira, future Prime Minister of India, was with her

Raja Director of Health Services, member of the Bhore Committee (UNICEF 1980s), were powerful, with strong personal commitments and supportive of each other. Several TB/chest specialists, members of the TB Association, advised State governments on TB control. The Indian Medical Association representing medical professionals' interests supported the programme, with Dr. BC Roy's[6] nationalistic, political leadership. A consultative approach between key actors was used when making content related decisions regarding TB control during this period. There were no institutional actors other than the TAI then. The States were relatively weak actors and the centre grew stronger in the policy process of national health programmes.

4.1.3 1951-1962: Early Policy Cycles

Formulation, Implementation & Reformulation

The context during this period has been characterised as one of hope, planning, and creative activity with internal stability, single party (Congress) rule in all States and international goodwill (Spear 1978, Mukarji 1993). A key political process factor was the enactment of the Constitution by Parliament in 1950. Important Constitutional features included strong powers for Central government, division of subjects between Central and State governments, with health being largely a State subject (as were agriculture, power and irrigation) and division of revenues and finances between Centre and States (Joshi and Little 1994). Concerning health, Article 47 under the Directive Principles of State Policy reads, '*The Constitution of India ... aims at the elimination of poverty, ignorance and ill-health and directs the State to regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties, securing the health and strength of workers, men and women, especially ensuring that children are given opportunities and facilities to develop in a healthy manner'* (Park 1994). Article 246 enumerates health subjects in the Seventh Schedule under Union, Concurrent and State lists. The State list includes provision of medical care and preventive health services, giving State governments

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till she passed away. Thus TB had directly influenced 3 Prime Ministers of the country Pandit Nehru, Indira Gandhi and Rajiv Gandhi (Ali 1991).

[5] A committed Gandhian social worker, was a friend of the TB Advisor to the GOI, took a personal interest in TB.

[6] Dr BC Roy, President of the Indian Medical Association (IMA), was active politically in the freedom movement. The profession was influenced through the Journal of the IMA. He became the first Chief Minister of West Bengal after Independance.

authority over all health services operating in its jurisdiction (Park 1994). The centre however ensured dominance in health policy by monopolising linkages with international agencies, through grants to State governments for preferred programmes, and through national health programmes (Banerji 1990).

The Planning Commission a new central policy advisory body established in 1950, played a lead role in economic and social policies through analysis and control of Plan finances (NIHFW 1992). In the health sector it covers national programmes including TB, medical education and pharmaceuticals. Other institutional mechanisms were ministerial bodies, the National Development Council and Central Council of Health and Family Welfare, discussing and ratifying Planning Commission proposals, providing avenues for democratic participation (*ibid*).

The economic situation, though poor, improved during the First Plan (1951-56), followed by a balance of payments crisis during the Second Plan (1956-61) and emerging political problems (Spear 1978). Integration of princely states into the Indian republic, reorganisation of States, and formation of new States were the high politics issues of the time, overshadowing health, though politico-administrative changes had consequences for it.

For tuberculosis, the first Plan[7] expanded organised home treatment through increased TB clinics, before the well-known study on domiciliary treatment. It was soon realised that expansion of TB clinics for home treatment according to norms (1/10,000 population i.e. 3,400 were required) and Bhore Committee recommendations for beds were impossible requiring investments of over Rs.5000 million (CHEB 1977;16). Priority was therefore given to preventive measure through BCG, considered low cost, quick and of relatively proven value internationally (*ibid*). Despite stated priority the first Plan TB budget was just Rs.46.3 million over 5 years, of which Rs.38 million was in the State sector (*ibid*). Resource constraints, epidemiological findings of equal rural prevalence of TB, against the urban concentration of services promoted earlier, and technological developments of chemotherapy, led to an intensified search after 1955 for

[7] After Independance the government of India adopted a model of planned development. Five year plans were initiated in 1950.

TB control measures/ a policy strategy for the disease under Indian conditions with a sound scientific basis (Nagpaul 1989).

Policy alterations during implementation, non-implementation and problems occurring in the first two Plans, further indicated it was not high priority. TB clinics, including the 55 newly established, were poorly run with inadequate diagnostic facilities and staff for effective domiciliary services (CHEB 1961). Despite Plans, no TB Training and Demonstration Centres or rehabilitation centres were established in the first plan, and of 5000 new TB beds, not all were with the TB programme or used for infectious cases (*ibid*).

With tuberculin tests revealing large proportions of infections occurring after school leaving age, and not all children attending school, the BCG Campaign intensified into a mass campaign[8] in 1951, implemented nationally by central government. It aimed to cover an estimated 170 million susceptible, unprotected young population, and new births in 10-12 years before integration with health services for ongoing newborn coverage (CHEB 1961, Barua 1971).

By 1958, 120 million persons were tuberculin tested, of whom 42 million were vaccinated with BCG (ICMR 1960). By 1960, 167 million persons were tuberculin tested and about 57 million vaccinated by 170 teams working in various States (CHEB 1961, GOI 1961). Administrative reports highlighted achievements such as being one of the largest public health campaigns carried out in any country. By 1962, 178 million were tuberculin tested but the proportion unvaccinated was large (Barua 1971). Coverage was incomplete and slow with organisational and other difficulties faced by mobile teams. Difficulties in storage, transportation and cold chain maintenance, resulted in shifting to freeze dried vaccine (CHEB 1961). The proportion of ineffective immunisations due to poor cold chains and ineffective vaccines remains unknown. Varying vaccine trial results and the high prevalence of atypical mycobacteria generated debate and doubts concerning protective efficacy of BCG, leading to the setting up of the world's largest prospective BCG vaccine trial in the 1960s.

[8] During village to village visits Tuberculin skin tests (Mantoux) were done, read after 72 hours, with those negative given liquid BCG vaccine by special mobile teams.

The relevance methods used in Europe such as diagnostic mass miniature radiography and hospitalisation, was increasingly questioned. While lack of resources and infrastructure made these impractical for widespread use, their scientific basis was also weak. Studies suggested low specificity of X-rays and that good cure rates were possible with domiciliary treatment. Costs of diagnosing a patient with infectious TB by mass radiography was about Rs.500 (TAI 1970;5). With 1.5 million estimated infectious patients (ICMR 1959) minimum costs were Rs.750 million. Commercial interests and the medical profession promoted these approaches (interviews). It was estimated that hospitalisation of all infectious patients would cost Rs.3,600 million, in addition to capital required for construction and staffing (TAI 1970). Some foreign experts even suggested that since TB infection was so widespread, isoniazid should be introduced into the water supply system (Nagpaul*1996).

Consequently research was given high priority in evolving the content and conduct of the programme. A political mandate to policy makers, and new research institutions to develop socially relevant, nationally applicable policies provided the impetus for new approaches to be experimented with. From this process new ideas emerged that shaped the National TB Programme. Most elements of policy changes were introduced after operational research. Findings became part of a public health approach to TB, but were continuously contested or not internalised by the medical profession.

Vertical, disease/problem specific programmes established by central government for family planning in 1952 and malaria in 1953 (Park 1994) were much better resourced, paying for infrastructure and staff in peripheral services, became strong competing interests to the TB programme. Vertical approaches were considered necessary as peripheral health services were still undeveloped and it was held that these problems could be conquered/eradicated with concerted efforts, with international public health lobbies behind them.

The process of developing a countrywide health service infrastructure and of setting up training institutions for doctors, nurses, auxiliary nurse midwives and allied health personnel was initiated in the 1950s. The Community Development Programme launched in October 1952 for comprehensive rural development included health as an

integral component. The first Primary Health Centres (PHC's) were started in 1952 (Park 1994, Banerji 1985).

Establishment of TB clinics for diagnosis and home treatment of patients was planned as a practical approach that could be introduced fairly quickly for the management of TB with hospitalisation only of seriously ill patients and those with complications (GOI/Mudaliar 1961).

Bhore Committee recommendations for hospitals and sanatoria were no longer considered feasible or necessary. An important reason for this change was the discovery and increasing market availability of effective anti-bacterial TB drugs.

Rapid increase of State run medical colleges in the 1950-1960s made medical education available at very subsidised costs, with reservations of seats for socially disadvantaged groups. Most graduates (60-70%) subsequently worked in the private sector (FRCH 1990). This public policy decision increased numbers of medical practitioners, provision of medical services, and generated employment in the medical and related sectors. However the private medical sector grew with little regulation. Incentives given to doctors for rural practice did not overcome strong urban predilections, resulting in continued urban rural disparities. The private for profit health care service sector was not formally involved in the national TB control effort though there was referral in TB and informal interaction. Notification of TB was not made mandatory hence the proportion of TB patients treated by the private sector is unknown. There was state collaboration with the voluntary health sector from national to district level through District TB associations (TAI Annual Reports/Conference Proceedings), though varying in type and quality of work. The public sector became the dominant sector in policy planning.

The circle of actors from the earlier phase continued up to the mid-1950's. Two important institutions were started viz. the TB Chemotherapy Centre (TCC), Madras in 1956 and the National TB Institute (NTI), Bangalore in 1959 (Gupta 1985)[9].

[9] The role of the Indian Medical Association, the Medical Council of India and the medical profession requires further study.

During the period radical conceptual shifts occurred from individualised treatment, isolation and specialist care available to a few, to a community based, public health approach which included protecting vulnerable populations with BCG, early case detection, converting infectious to non-infectious patients with domiciliary chemotherapy in the shortest possible time, by generalist doctors and health teams in an attempt to reduce transmission and control TB in the population (GOI 1961).

Policy processes during this period are summarised in Table 4.1.

Table 4.1 Tuberculosis Control Policy Process in India: August 1947-1962

CONTEXT	CONTENT	ACTORS	PROCESSES
Political Independence Partition, violence 10-15 million refugees 1948 war with Pakistan Integration of Princely states/ kingdoms Reorganisation of States	Tuberculin testing, BCG as preventive, introduction of antibiotics, isoniazid and streptomycin, research commissioned, regimens developed - domiciliary & intermittent, NTP strategy developed.	GOI- Union and States, TAI, UNICEF, UNRAA, International BCG campaign, WHO	1947 IMS disbanded, Ministries of health at Union and State levels with Directorates of Health Services. 1948 TB Advisor to Union Government appointed, 1950 Constitution - State responsibility for health, Health a State subject, communicable diseases on central list as well, 1950 Planning Commission - allots Plan funds for TB/ health, 1952 Central Council for Health formed, 1948 BCG Vaccine Production Unit set up, 1954 Antibiotic Production Unit set up, 1948 onwards research studies commissioned to understand the problem in Indian context [*], 1956 TB Chemotherapy Centre established, 1959 National Tuberculosis Institute established, Gradual increase in TB clinics, TB beds, build up of State and District TB Centres, primary health centres, hospitals, training of staff.

* vaccine efficacy, community based control, domiciliary chemotherapy, appropriate diagnostic technology, sociological and epidemiological studies, operations research, evolution of a National Tuberculosis Programme.

4.1.4 1963-1980: Implementation with Changing Priorities & Competing Interests

The NTP, articulated in 1962, with the District Tuberculosis Programme (DTP) as functional unit (NTI 1994d), was research based, rationalistic, managerial, with logical goals, objectives, strategies, definitions and measurable elements. For instance, the NTP is '*an organised effort which aims to bring under control the problem of tuberculosis in the community through defined objectives, activities and resources. It comprises of well known anti-TB measures knit into a comprehensive, practical, acceptable and economically feasible programme'* (Sivaraman 1982;82).

Its aim is to reduce suffering, disability and death due to tuberculosis, and long term goal `*to reduce the problem of TB in the community sufficiently quickly, to the level where it ceases to be a public health problem'* (Sivaraman 1982;82, Uke 1994;1). This would occur when: a) One case infects less than one new person annually; b) The prevalence of infection in the age group 14 years is brought down to less than 1% against about 30% at present (Gupta 1985).

With general objectives '*to break the chain of transmission by active detection and treatment of infectious cases'*, short term, operational objectives included: BCG vaccination of majority of eligibles (possibly more than 70%); detection of the maximum number of symptomatic TB patients among outpatients attending health institutions, with adequate treatment and priority to sputum positives; to function all institutions as an integral part of the general health services in the country (Sivaraman 1982;82, Gupta 1985). Services designed to meet people's felt needs, were to be free, within easy reach, with local government (*panchayat*) and Community Development department participation (NTI 1994d, Piot 1962). States held responsibility for implementation and evaluation (Nagpaul 1989).

Principles included: passive case finding, reliance on sputum microscopy for diagnosis (low cost, appropriate, effective technology), domiciliary treatment, integration at point of first interaction between patient and provider (NTI 1994d). This was a radical departure from its own vertical BCG campaign and other national programmes for malaria, leprosy and smallpox (Park 1994). The programme was two-tiered, integrated

at service delivery in peripheral health institutions, but specialised above District level. The District TB Centre, the nodal point for referral, management, training, supervision, and flow of reporting, had a five member managerial team with a Medical Officer (the District Tuberculosis Officer), Treatment Organiser, Laboratory Technician, X-ray Technician and Statistical Assistant (NTI 1994d). Two MO's were recommended for simultaneous clinical and programme work. Together these elements comprised the District TB Programme, the functional/organisational unit of the NTP (*ibid*).

Though apparently receiving political recognition, financial allocations were meagre in comparison to recommendations and need (Chapter 5). There were pressures to select the least expensive strategies for public programmes. Despite knowledge that combined treatment achieved better cure with lower risks of drug resistance, monotherapy with isoniazid (costing Rs.8/patient or Rs. 35,000/district) was chosen instead of isoniazid + PAS, which increased costs (Rs.80/patient for entire treatment or Rs.235,000/district) (Piot 1962). Those with ability to pay accessed private sector treatment reflecting societal stratification. The organised public sector from the 1950's and earlier developed health systems (NIHFW 1988) with better quality care, paid partly by contributions but largely by the public exchequer (Chatterjee 1988), creating disparities within public sector health care.

Specialised programme training by the NTI since 1962, evolved new concepts of team training for DTC teams, who were to provide in-service training/supervision to peripheral health institutions in the District (NTI 1994d). DTC's provided referral, additional diagnostic (X-ray) and inpatient facilities for seriously ill patients and those with complications (Nagpaul 1989). NTI published manuals in 1962 (revised in 1969, 1978 & 1994) with detailed descriptions of methods, activities and tasks for each member of the DTC team and for peripheral health institutions (NTI 1994a).

By 1974, 301 District TB Centres were established, increasing to 329 by 1979 (NTI 1994d). These were largely TB Clinics that were upgraded. The NTP a centrally sponsored scheme, supplies TB drugs and equipment to DTC's, financed on a 50-50 shared basis between Centre and State. States bear 100% of operational costs (Chapter

5). For Union Territories and TB clinics run by voluntary bodies, drugs and equipment are supplied as a 100% centrally sponsored scheme (TAI 1987).

Based on the National Sample Survey, planners estimated average districts with 1.5 million people to have 20,000 radiologically active cases, of which 5000 were infectious (Piot 1962). Four thousand new radiologically active cases, including 1000 sputum positives, were estimated to occur annually assuming an incidence 1/5th prevalence (*ibid*) Eighty percent of patients were rural, spread over 2000 villages/district. Operational studies found 3.5% of new outpatients at peripheral institutions aged 10 years and above were chest symptomatics (cough for more than two weeks), of whom 11% were new cases of pulmonary TB detected by sputum microscopy at peripheral institutions (Baily *et al* 1967). Findings were used to develop potentials/expectations and later targets for sputum examinations and positivity. DTP's were found capable of diagnosing 45% of the estimated prevalence of infectious cases in a district in a year (*ibid*). The workload for TB case-finding at peripheral institutions involved 1-2 sputum examinations per working day, requiring no extra staff (*ibid*). All chest symptomatics were referred to the DTC for X-rays, but 66% agreed to go, while only 16% actually went (*ibid*). Thus referrals were envisaged a minor role, with most case finding ideally close to patients' homes. Sputum microscopy at PHI's was often by paramedical personnel with short training, not by qualified laboratory technicians. Assessments in the 1960's found standards fairly good, but compared to culture results under-diagnosis of 38.2% and over-diagnosis of 2.6% occurred (Rao *et al* 1971). Again, financial considerations decided the choice, with cost ratios between microscopy and culture of 1:6.6 (*ibid*).

The Eighth Expert Committee of WHO (1964) standardised and promoted the NTP model among member countries[10] (WHO 1974, Rao 1984). Thus Indian research/experience contributed to international TB policy (Nagpaul 1989).

Direct BCG vaccination without prior tuberculin testing was introduced in 1965 on a house to house basis (Park 1994). Problems of the BCG campaign became further

[10] The Ninth WHO Expert Committee opined that decline in TB was not proportionate to resources spent, attributing this to inadequate national planning, coordination and evaluation, and failure to change from traditional approaches to current knowledge (WHO 1974).

manifest in the mid-1960's, with estimated coverage's of just 16.5% of the 0-14 year age group in 1968 (Barua 1971).

Awareness regarding implementation difficulties in the NTP gradually grew. Studies by the TB Association found apathy, lack of implementation/expansion of the NTP at PHC/subcentre level, lack of supervision by DTC's, staff indiscipline, political interference and low salary scales (Bordia 1971, Deshmukh 1971). They predicted drug resistance and chronic invalidism due to irregular drug taking and ineffective chemotherapy (*ibid)*. None of the 'non-technical' issues, that appear crucial to implementation had been considered during formulation. TB workers across the country reported unsatisfactory functioning of the NTP (TAI 1968-78). Remedies suggested to Government were to give priority to TB as the foremost 'public health enemy', undertake large scale expansion of organisation and clinics, ensure adequate numbers of trained personnel, ensure availability of sufficient quantities of TB drugs, and evolve methods for drugs to be taken regularly by patients (TAI 1970). Largely techno-managerial, these did not address basic problems being encountered. Though no longer as influential/powerful in policy making as in the past, the TB Association was a respected body and in touch with the field particularly with District TB Officer's, through annual conferences held from 1946 and its publication (Indian Journal of Tuberculosis). Following internal discussions the Association raised its concerns directly with the Union Health Minister Karan Singh suggesting an evaluation, which was accepted and conducted by the Indian Council of Medical Research (ICMR 1975). Thus the voluntary sector again played an important policy watch-dog role. Consequently, in 1978 a monitoring system was introduced, with monthly reports from PHI's to DTC's, and quarterly reports from DTC's to the NTI.

Demographic growth and changes in districts affected the administrative functioning of the NTP. India's population was approximately 400 million in the 1950's. There were about 340 districts[11] each with an average of 50 peripheral health institutions (Nagpaul 1989). Though DTC's started functioning in 1962, coverage of all districts was never achieved, with time lags before DTC's could be created in new districts. Intra-district coverage of PHI's by the NTP was also incomplete.

[11] Numbers changed with new administrative districts carved out of larger ones.

The NTP was launched during a turbulent period, with two wars (aggressions by China 1962, and Pakistan 1965) and political instability (Joshi and Little 1994). Foreign aid was suspended in 1965 (NIHFW 1992). The ruling Congress party declined in popularity in the third general elections in 1962 (Frankel 1984). Prime Minister Nehru died in 1964 and his successor Lal Bahadur Shastri in 1965. Severe droughts from 1965-1967 worsened the economic situation and the rupee was devalued in 1966 (NIHFW 1992). In the 1967 general elections the Congress lost 8 of 16 major States, with its majority declining in the Centre as well (Spear 1978).

India's population growth was perceived as a major impediment to development by national and international elites, with the mid-1960's population approaching 500 million. Family Planning began to dominate the health agenda of the country (Banerji 1982). Advised by Ford Foundation and the UN, the Family Planning Programme was reorganised in 1963, adopting intensive programmes for sterilisation's, condoms and the loop (Intra-Uterine Contraceptive Device) for large scale implementation in 1965 (Rao 1994). India's food and economic crisis made it vulnerable and dependant on US food aid, tied with pressures to increase private investment and retreat from its social goals (Frankel 1984). Active pursuance of the family planning programme was promoted as part of this and supported by the World Bank, UNFPA and SIDA, with budget increases inspite of the economic crisis (Rao 1994).

The Congress split in 1969 with the Indira Gandhi led group coming to power (Frankel 1984). Policy measures like bank nationalisation, cessation of privy purses to erstwhile princes, substantial increase in the Fourth Plan budget, among other factors, led the Congress to win a massive majority in the 1971 elections under the slogan *Garibi Hatao* (remove poverty) (*ibid*).

Very soon afterwards with unrest in East Pakistan against West Pakistan nearly 10 million refugees came into India (Spear 1978). Following military action by Pakistan and build up of US presence in the Indian Ocean, India intervened and the Republic of Bangladesh was created in 1971. Crop failures and the international oil crisis in 1973-74, price rises and scarcities of essential commodities in 1974-75 created hardship and unrest (Frankel 1984). In June 1975, the Indira Gandhi government, declared a state of

'Emergency', during which civil rights were severely curtailed and authoritarian tendencies reigned supreme. This lasted till 1977. In 1976 the Prime Minister's Twenty Point Programme was initiated and on 16/4/76 a new Population Policy enunciated (Banerji 1982). The focus of the entire health system was forcefully turned to family planning with targets and a '*host of harsh incentives and disincentives*' (Rao 1994;65), with 13.2 million sterilisation operations were conducted between 1974 and 1978 (Jobert 1985 quoting Minhas). Credibility of the Government health system with people declined, particularly with the poor at whom the family planning programme was directed (Banerji 1982).

A student and political movement spearheaded by Gandhian socialist JP Narayan and escalating political events led to the 1977 election, in which a coalition of opposition groups forming the Janata Party, defeated Congress. Analysts attribute the fall of government partly to family planning excesses (Rao 1994, Brass 1994).

Thus during the critical initial period when the NTP was developing, the contextual policy environment was unsupportive and increasingly complex. When an issue becomes low profile politically, other more parochial interests within institutions and bureaucracies gain importance. The quality of political and policy leadership at Centre and States declined (Banerji 1990). Though rural health services did not grow adequately in quantity or quality (ICSSR/ICMR 1981), special schemes for the organised sector such as the Central Government Health Scheme, Employees State Insurance Scheme expanded (Park 1994). Services such as the defence, railways, post and telegraphs, police, public sector industries organised their own health services with higher per capita outlays (Chatterjee 1988). The private sector grew and was available to those with ability to pay, resulting in growing disparities in access to health care. Analysts also refer to an increasing awareness of a larger crisis in India's health system since the end of the 1960's (Banerji 1982, Jobert 1985).

A summary of the policy processes during this phase is in Table 4.2.

Table 4.2 Tuberculosis Control Policy Process in India 1963-1980

CONTEXT	CONTENT	ACTORS	PROCESS
Two wars (1962 and 1965); Political instability; Death of two Prime Minister's 1964 and 1965; Suspension of foreign aid; Severe drought 1965-67; Economic crisis; Rupee devaluation 1967; Refugees from East Pakistan 1971; Military action, Bangladesh formed Oil crisis 1973-4, crop failures, price rises, popular unrest; Emergency declared 1975 -77; Family planning excesses; Janata government 1977-80, political factions and infighting.	The NTP comprises: Passive case detection, with sputum microscopy, domiciliary multidrug chemotherapy, free treatment, through peripheral health institutions, Dist. TB Centre referral/ supervision, Dist. TB Programme functional unit, District team training, complications hospitalised, cases estimated per district based on epidemiological studies, BCG vaccination integrated with general health services.	Multiple Actors a) Central & State ministries, Centre DDG/central unit DTO's/ team, PHC MO's, diffuse. Special central schemes: ESI, CGHS, defence, railways, post and telegraphs, police etc. b) Private sector; c) Voluntary sector: TAI nationally, service NGO's in the field; c) International agencies WHO, SIDA.	Starting District and State TB Centres; Drug supply systems; District team training at NTI; Communication: NTI Newsletters; Inadequate resources; Competing interests - FP, EPI, malaria; Health services credibility poor due to FP excesses and other factors; Poor implementation leads to evaluation; Organised sector, urban bias; Fall in mortality especially in higher income groups; Decreased international interest; NTP on back burner.

4.1.5 The 1980's: New Solutions, Persisting Problems

In 1982 it was estimated that 47% of the country was not covered by the TB programme (Sivaraman 1982). Incremental changes continued in policy content and strategy driven by varying forces. TB was mentioned in central government's New Twenty Point Programme in 1982[12] (GOI 1982), though without supportive discussion/strategies, that other selected issues relating to the economy received in the document. The National Health Policy of 1982 mentioned the NTP as priority, outlining targets (GOI 1985). Central expenditure increased from Rs.204 million for the entire Sixth Plan (1980-85) to Rs.111 million in 1985-86 and Rs.141 million in 1987-88 (NIHFW 1988). SIDA assistance to the NTP from 1979 (*ibid*)[13] accounted for part of the increase. The number of District TB Programmes increased from 320 in 1980 to 375 in 1989 (NTI 1994d). Some argued that following adverse public reaction to Family Planning, government needed to appear to demonstrate commitment to programmes concerning the poor, hence the special attention (interview 1995).

Top-down strategies were soon adopted, with targets set centrally in 1983 for numbers of sputum examination to be conducted at peripheral institutions and District TB Centres, and in 1984 for case detection, which increased every year (NIHFW 1988). Multi-purpose workers at sub-centres and PHC's were involved (Nagpaul 1989) in a policy shift to active case finding, with monthly targets, collecting sputum samples from chest symptomatics during home visits[14]. However potentially positive health worker involvement, proven by operations research in 1981 (ICORCI 1988), used with coercive targets had unintended effects. While numbers of sputum examinations increased, particularly at peripheral institutions, sputum positivity rates among chest symptomatics declined from 13% to 5% (ICORCI 1988). Over-diagnosis and treatment of X-ray suspects in the public sector of an estimated 5-600,000 patients annually, caused unnecessary iatrogenic suffering/anxiety, and cost Rs.80-90 million (*ibid*). This accounted for a large proportion of the increased case detection from 700,000 new cases in 1981 to 1.4 million in 1988 (NIHFW 1988). Sputum positivity declined from 25% in

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[12] To *'substantially augment universal primary health care facilities and control of leprosy, TB and blindness'* (GOI 1982, Point 14).

[13] The rupee value was shown in the NTP budget statement (interview 1996).

[14] 600 new sputum examinations annually was the target for Primary Health Centres (NIHFW 1988).

1980 to 20-21% in the late 1980's (Nagpaul 1989, Datta 1994). Contradictions such as low achievements of sputum examinations but high case detection in some States suggest poor quality work (NTI 1994d). Damage done included wasted resources on sputum examinations, lowered morale and credibility, and a masking of the real situation. Though there were some gains, political action in this case was counterproductive. The Ministry of Planning and Programme Implementation centrally monitored 119 items under the Twenty Point Programmes 1986 (GOI 1995a). The NTI continued monitoring the NTP, with inadequate response to their repeated feedback regarding corrective action (NTI 1996 & Bulletins). In 1994 acknowledging the futility of the approach, targets were dropped (Datta*VHAI 1994).

From 1978 responsibility for BCG moved from the NTP to the Expanded Programme of Immunisation[15]. In 1985 this was converted by the GOI to the Universal Immunisation Programme (UIP) in India, as a living memorial to the late Prime Minister Indira Gandhi[16]. Senior experts were sceptical about quality of BCG technique used (Baily*1995, Ramesh*1995). Following budgetary constraints to the BCG Laboratory, India moved from self-sufficiency to importing part of its BCG vaccine requirements.

Family planning/welfare continued to dominate health services. Its budget of Rs.34.5 billion in the 7th Plan (1985-90) compared to Rs.33.9 billion for all other health programmes, reflecting the interests of the political, bureaucratic and professional leadership (Banerji 1990). The negative impact on the NTP was highlighted by national assessments (ICORCI 1988). Malaria, the other competing programme, received a budget of Rs.970 million in 1992-93 compared to Rs.290 million for TB (NTI 1994d).

Persisting Problems: By 1988, only 25% of the 371 DTC's had fully trained teams, 30% did not have trained DTO's, supervision was poor, only 60% of DTP's had vehicles, budgets were inadequate and drug supplies irregular (ICORCI 1988, Nagpaul 1989). An evaluation team stressed the need for greater devolution of responsibilities, powers and budgeting for integration to really play its role (ICORCI 1988). Disparities

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[15] A global time bound programme by UNICEF and WHO for 6 immunisable diseases to cease to be public health problems.

[16] A national review of the UIP in 1989 and studies in West Bengal reported problems with supplies, cold chain, vacancies, poor work culture, and poor performance by multi-purpose health workers, such that most vulnerable segments were inadequately covered (Banerji 1990).

in access to NTP services continued, with 37% of the rural population lacking access in 1988, while semi-urban/more populated rural areas were better served (Nagpaul 1989). The coverage of 63% was incomplete (*ibid*). If quality of care and functional efficacy are considered, the proportion lacking access increases.

Treatment completion with standard regimens was 27% around 1981, against a potential of 45% (Nagpaul 1989), when tuberculosis was included in the Twenty Point Programme. Partly concerned about this low rate, Short Course Chemotherapy (SCC) was introduced in 1983-84 on a pilot basis in 18 selected districts of the country (MOH&FW 1983-84) monitored by the Tuberculosis Research Centre, Madras. While monitoring results were still awaited, SCC was introduced to 26 districts in 1986-87 (Jhunjhunwala 1994). With low treatment completion rates of 52% (though higher than the Standard Regimen), potential dangers of drug resistance developing to second line drugs, were anticipated with SCC introduction in a programme functioning through weak health services, with insufficient managerial capacity (Banerji*VHAI 1994). Despite these arguments and with insufficient attention to training field staff particularly at peripheral level, or to developing infrastructure and streamlining supply lines, SCC coverage of districts increased rapidly during the Seventh Plan, from 26 districts in 1986, to 75 in 1987, and 194 in 1989 (MOH Annual Reports). By 1991-92, 253 districts (65%) were reportedly covered (Datta 1994). SIDA grants supported introduction and expansion of SCC (MOH Annual Reports, 1979-80 to 1990-91). Coverage never extended to entire districts, and drug shortages occurred increasing likelihood of later drug resistance (interviews 1996). There was no public report till 1995 from the TRC from its monitoring of SCC. In 248 districts monitored by NTI, only 35% of peripheral institutions were covered by SCC, drug collection of 75% or more was 45% in streptomycin containing regimens and 53% in those with ethambutol (Suryanarayana *et al* 1994). Smear examinations were done only for 33% of patients put on treatment, with 90 and 96% sputum conversion among them (*ibid*). Only 33.2% in a district using unsupervised SCC collected 75% or more of their drugs, though 72-77% became smear negative irrespective of adherence (only 48% with drug resistant strains) (Chaudhuri *et* al 1993). Implementation gaps occurred even with the best technology, with potentially more serious consequences. While expanding SCC coverage in this manner, the

Ministry continued referring to it as a pilot study phase up to 1992-93 in its annual reports (Jhunjhunwala 1994, MOH 1984-85 to 1992-93). Political reasons (to be seen to provide for their constituencies), economic forces (pharmaceutical industry including multinationals gaining greater profits from SCC) and personal gains for various people involved fuelled rapid extension of SCC (interviews 1996). BCG coverage in 1993-94 was 8.4 million, only 68% of its target and 8.2% less than the performance in the previous year[17] (GOI 1996).

Stratified TB services continued with better quality treatment for the better resourced and organised public sector. By 1984, the Employees State Insurance Scheme (ESIS) covered over 7 million industrial workers and 21 million dependants and the railway health service covered 7.6 million employees and dependants (Jeffery 1986). The Central Government Health Scheme covering 4.5 million central government employees (current and retired) incurred an annual expenditure of Rs.888.7 million (Rs.222/person) in 1992-93 (GOI 1996;62). The private sector was estimated to treat an equal proportion of patients as the public sector, i.e. about 1.5 million new cases per year (Nagpaul*1995).

Changes in national context sharpened in this decade with increased privatisation and liberalisation[18] (Duggal 1997). Following the assassination of Prime Minister Mrs. Gandhi in 1984, the new Prime Minister and others accelerated processes of globalization (Patel 1995). Over 30 years while slipping in the world economy[19] economists observed growing inequalities in ownership of productive assets[20], while '*the balance of social power ...in villages and cities...moved in favour of the upper 10%* (Patel 1995;ix). Government spent more than its revenue collections, non-development expenditures rose faster than for development and domestic and external debt increased with rising burdens of debt servicing (*ibid*). These social forces, and diminishing state intervention in public services and development have negative impacts on TB as

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[17] There seems to be a discrepancy in numbers. Another table in the report mentions 21.6 million BCG immunisations in 1991-92 and provisionally in 1992-93 (GOI 1996).

[18] 'A rolling back of the State from the sphere of production and productive investment, and a significant curtailment in the level of social expenditure' (Patnaik 1994).

[19] India's share in world trade reduced from 4% in the early 1950's to 0.5% in the mid-1980's (Patel 1995).

[20] Assets of the top 20 business houses were 3 times higher than all the possessions of 100 million Indians (Patel 1995). The top 10% held 56% of total land under cultivation (*ibid*).

discussed elsewhere (Chapter 1, Annexe 1). The policies had specific effects on the health sector. Stagnant public expenditure on health over the decades and in the 1980s, allowed growth of the private sector (Jesani and Ananthraman 1993, Baru 1994), with National Sample Survey data from 1986-87 showing over 70% of people utilising private practitioner outpatient services (Baru 1994).

A summary of processes during the 1980s is given in Table 4.3 and policy changes in the 1990's are discussed in Chapter 6.

Table 4.3 Tuberculosis Control Policy Process in India 1981-early 1990s

CONTEXT	POLICY CONTENT	ACTORS	PROCESS
Congress Govt. back in power; Central tendency strong; Revised 20 Point Programme; Economic liberalisation and privatisation from mid-1980s; Internal political instability; terrorism, separatism; fundamentalism; Prime Minister Mrs. Gandhi assassinated 1984, and ex-PM Rajiv Gandhi in 1991; Frequent change of government; Structural Adjustment Programme since 1991.	Active sputum testing and case finding through MPW's; 1985 BCG part of UIP; BCG study results question its protective efficacy against adult pulmonary TB; 1983-84 18 distict study of SCC; 1986 -87 SCC extended to 246 districts; 1988 In-depth study of the NTP; 1992 GOI/WHO/SIDA programme review; 1993 pilot phase of Revised NTP with DOTS.	Central and State governments, Private sector growth in the 1980s, SIDA donor to central govt. WHO & WB active from the 1990s promoting global policy, Voluntary sector advocacy,	routinisation of NTP processes; increased infrastructure - PHC's, subcentres, DTC's; corruption, irregular, inadequate drug supplies; New voluntary sector actors raise critical issues regarding TB care -MFC, AIDAN, FRCH, VHAI shift from service provision to advocacy and research; World Bank a major new actor- provision of loan from social security net for TB, linked conditionally to introduction of policy package. Recognition of private sector presence.

Summary: The historical overview of the development of the TB programme gives a number of clues that begin to explain why implementation was never as strong as envisioned.

- Old policies especially serving dominant interests exercised considerable influence. Government inaction, a strong private sector, clinical approaches, urban biases, and central control over policy are examples.

- With hindsight we know that BCG, the chosen strategy for a nation-wide campaign at great cost was of limited value. Thus the basic cause effect relationship underlying the policy was flawed. This experience and others factors such as geographic distribution, role of Mass Miniature Radiography highlight gaps in knowledge, cautioning against dogmatism and policy borrowing, common in international public health.

- The new NTP was a research based model that worked under special conditions. Gaps between performance and expectations raise questions regarding original expectations. Exclusive focus on epidemiological/technical dimensions of policy content, though developed within a context of social relevance overshadowed societal dimensions.

- The dynamic, political nature of policy processes with covert/overt conflicts of interest, stratification of TB services, competing programmes, changing roles between public, voluntary and private for profit sectors, complex contextual environments and the influence of these factors on implementation are evident. Given this, the inattention to policy process factors was a major weakness.

4.2 IMPLEMENTATION OF THE NTP: AN OVERVIEW

4.2.1 Incremental Policy Change

References to the NTP suggest that a specific policy package was implemented in 1962. This review reveals that the TB policy developed and was implemented incrementally over time (Table 4.4).

Table 4.4 Incremental Changes in TB Policy in India

Year	TB Policy	Comment
1946	Bhore Committee recommendations on TB. No specific national policy by government.	Not implemented. Private and voluntary sectors main actors, provincial govt.'s emerging actors, families primary carers.
1947	TB Advisor to new GOI appointed.	Health services restructured.
1948	BCG campaign started, with school children and factory workers.	BCG vaccine plant established.
1951	Mass BCG Campaign started-tuberculin testing and liquid BCG, increase in TB beds, establishment of State TB Demonstration & Training Centres and District TB Clinics using home treatment.	Bhore Committee recommendations began to be implemented, found to progress slowly, established centres not always functionally effective. BCG campaign used a vertical approach.
1962	NTP/DTP articulated with passive case finding, domiciliary chemotherapy, free treatment, recording/reporting system, DTC team as nodal point. BCG campaign shifted to house to house vaccination, integration of BCG teams with DTP started.	Shift to integration with health services. Central government sponsorship 100% for development of DTC, training of DTC team, drugs and equipment. State responsibility for staff salaries and implementation.
1965	BCG approach shifts to direct vaccination for 0-20 year age group, and freeze dried vaccine.	Shift of production technology from liquid to freeze dried vaccine.
1969	Refocus on school coverage with BCG.	
1973	Involvement of Multi-Purpose Workers (1/5000 population) in identification of chest symptomatics, sputum collection, smear preparation, motivation, community education, BCG vaccination.	Shift from a doctor dominated programme to greater peripheral health worker involvement. Continued.....

1977	BCG merged with Expanded Programme of Immunisation (EPI). Community Health Volunteer Scheme started, involved with identification, motivation, follow-up, defaulter retrieval.	BCG given by MPW's, no longer under administrative control of NTP.
1978	Monitoring of NTP by NTI.	No feedback mechanisms to districts/PHI's
1982	NTP put on New Twenty Point Programme.	
1982 -83	National Health Policy sets targets for NTP. Annual targets introduced for sputum examinations at Peripheral Health Institution's.	Shift to active case detection during home visits by MPW's.
1983 -84	Annual targets for case detection at PHI's. Introduction of Short Course Chemotherapy.	Targets were dropped in 1994.
1986 -87 on	Expanded coverage of districts with Short Course Chemotherapy.	253 districts (65%) covered by 1991-92.
1990	Case detection by multi-purpose workers withdrawn from the NTP.	
1992	Programme review. Negotiations initiated with WHO/WB regarding Revised NTP.	TB control gains the attention of international bodies from the late 1980's.
1993 1997	Pilot phase of Revised NTP. Agreement signed with WHO and WB.	Covers 23 million out of 950 million by 1996. Increased coverage planned over 3 years.

Source: Chapter 1 and 4

Politico-economic need was often the reason for change, with research used to provide the justification e.g. domiciliary chemotherapy, use of targets, introduction of SCC. The incremental nature of the policy process can be explained by the following factors: leadership, power relations, inequality and infrastructural development.

4.2.2 Leadership

The importance of individuals with personal/social skills, vision, capability, dynamism and commitment to take leadership was raised frequently during interviews. Political leaders in 1947 selected leadership for the new TB programme not from government cadres, but from the voluntary sector of a person experienced in TB work. He in turn energetically selected professionals with multi-disciplinary backgrounds from different parts of the country, for the BCG campaign and to build the NTI/other national institutions. This laid the foundations for second generation leadership with long term benefits. Personalities of leaders played an important role in

the policy process. Autonomous policy leadership arising from and supported by advocacy networks, characterised by *'passionate commitment to make a difference by advancing a particular policy quest'* has been discussed in the policy literature (Wallis and Dollery 1997;1).

While leadership can reinforce top-down approaches, it can also create an environment in which bottom-up perspectives get space to influence policy. Mechanisms used in the 1950's included regular contact with front-line workers, familiarity with and concern for field problems and national consultative meetings to discuss problems. Interviews for this study pointed out that early leadership promoted the programme proactively, developed national and international alliances, and generated resources. Successful leaders do not always lead, but often play catalytic roles depending on their networks for policy advice and support (Wallis and Dollery 1997). This happened with young researchers at the NTI questioning basic tenets, suggesting alternative approaches. This included learning from people, changing their own vertical approaches, questioning the protective efficacy of BCG, in which they believed and invested heavily, among others.

Evolution and implementation of the NTP was best when political leadership sought and supported good national policy leadership, which promoted leadership at other organisational levels. When this changed, state and district leadership still being developed, weakened with reduced power and personal involvement in the programme. There was an interdependent domino effect of political and policy leadership at national, regional and institutional levels. A sense of policy ownership by implementors is important for any programme/policy to be carried through (Brinkerhoff 1997). Team leadership for the NTP at peripheral health institutions, particularly PHC's, never developed and continues to be a major weakness.

Table 4.5 National Leadership in the NTP

Period	Leadership Qualities	Evidence
1947-62	a) Dynamic, responsive to new developments and understandings, created mechanisms for generating new knowledge, research oriented, analytic, critical, questioning given theories and its own policies based on implementation experience, accepting /learning from problems/mistakes and changing policies. b) Created political space, had negotiating skills, developed and sustained international linkages, built institutions with clear political mandate. c) Energy invested in selection and development of staff- younger researchers, administrators and practitioners. d) Commitment to cause, experienced in TB/research/ voluntary sector, risk taking. e) Used a collective approach.	a) Conducted mass BCG campaign- largest in the world. b) Started TB Chemotherapy Centre and National TB Institute whose research influenced global TB control. c) Initiated building of State TB & Demonstration Centres & District TB centres. d) Stability in leadership-15 years. e) Influenced WHO, sustained international links.
1962-92	Committed, experienced in TB, honest, less dynamic, increase in bureaucratic styles, faced a more difficult policy and political environment.	Operationalisation of NTP, about 400 DTC's started, research, training, newsletter, incremental policy changes.
1993 onwards	Frequent change, not always experienced in TB/NTP, greater political interference, absence of open debate influencing policy, lowered morale of other staff, confusion.	Four incumbents in 4 years, 1 charge sheeted for possessing wealth beyond source of income, corruption in TB drug purchase.

Source: NTP documents; interviews; Banerji 1993

Leadership during the second phase was less effective in generating resources and influencing state governments. It was also less pro-active, accepted constraints more easily, was dependant on political masters and 'higher ups' (preoccupied with other interests), unwilling to challenge status quo, appearing relatively uninterested and apathetic. The cutting edge was blunted as the policy environment became more complex. Unconstructive internal conflicts and routine became more manifest. Programme managers lacked assertiveness. Weak leadership became one of the factors adversely affecting policy implementation. It could be argued that lower

priority in later phases reflected structural factors, the lower socio-economic-political power of patients dependant on effective public policy.

For a chronic problem like TB, to consciously nurture and plan for leadership at different levels is important.

4.2.3 Power Relations in the NTP

A thinly spread intervention strategy functioning through general health services for a problem diffusely spread across a large population theoretically requires stronger power for success (Cleaves 1980). However power in the NTP is weak and fragmented and demand for effective services ineffective.

Around 1947, with 80% of the population below the poverty line, the socially powerful were vulnerable to TB (exemplified by the death from TB of Kamala Nehru). Political pressure for effective public policy for TB was greater, expressed as 'public demand' (4.1). Later with economic development, TB declined among the privileged classes, who were well served by policies promoting the private sector, and had no further need to exert political pressure to improve the NTP. Patients without access to effective services, the poor and powerless though large in number, were dispersed, lacking organisation to promote their interests. Hence little countervailing power or pressure existed for effective policy implementation.

Central policy leadership in the 1990's is small and fragmented for the task. The Central TB Unit in the Directorate General of Health Services (DGHS) has 4-6 technical staff for the entire country, drawn from the Central Health Services, usually with a public health training but not necessarily a background in TB or the NTP. Preoccupied with routine administration (such as processing drug supplies to DTC's), inadequately in touch with the states (ICORCI 1988), transferable between units/programmes, they function in a relatively politicised environment (interviews and observation 1995 & 1996). Personal commitment to the programme, vital to sustain the same at state and district levels, is variable.

Underlying conflicts currently exist between the central unit, and the NTI with a total staff of 200. Technical staff here are experts in TB/the NTP, more conversant with field problems, but lacking administrative powers, are primarily advisory unable to

take action (interviews 1995). Policy analysts suggest that institutional assets like the NTI with specific mandates are currently being consciously denigrated, allowing space for new policy initiatives. The NTI is criticised for passive participation/absenteeism from national meetings concerning the Revised NTP (interviews 1996). It is suggested that bureaucratisation and relative apathy set in before the RNTP process[21]. The NTI is also criticised for centralising training and being rigid and resistant to change (Uplekar and Rangan 1996). Though promoting integration, it has been disease and programme oriented not applying itself to strengthening general health services in policy or practical terms.

The third national organisation is the TB Research Centre under the Indian Council of Medical Research, with internationally accepted research contributions Consultative mechanisms between the national institutions exist, but their vitality depends upon the personalities involved. There is a tendency for each to promote its own institutional interests, partly at the expense of energy that could be invested in improving the NTP.

With the RNTP (Chapter 5) newer institutional power centres are being created (e.g. the LRS Institute in Delhi), required for a country the size of India, but there seems to be a whispering campaign against older institutions (observations and interviews). Whether this process will strengthen or fragment power depends on perceptions and strategies of those involved.

Power at state level is weak and at implementation level extremely diffuse in the 21800 Primary Health Centres in rural India and 4432 public sector hospitals through which it functions (CBHI 1991). Inadequate administrative power and resources (also disempowering) of District TB Centres, the fulcrum of the NTP, is a key factor explaining poor implementation. They are reduced to being curative centres, at the cost of their primary function of direction and management of the DTP. This generates frustration, apathy and poor quality services at PHC's.

Inadequate power given to the NTP at various levels provides an important explanation for poor implementation. Without power and a sense of direction the state

[21]Apathy, a political statement of disinterest, can greatly harm a policy.

apparatus seems caught up in its own interests and internal competitions. The review also suggests that power is not just given, but needs to be created, mobilised and demanded. This is more necessary when the problem (TB) is related to conditions of poverty, insecurity and social injustice disproportionately affecting the powerless in society. In the absence of effective public services the private sector filled the gaps with questionable treatment practices and no systems of accountability or regulation.

4.2.4 Inequities in Health Care Services

Commitments to equity in health and health care have been repeatedly made nationally and internationally (Table 4.6). However implementing such commitments lagged behind and by 1997 global inequities reportedly increased (WHO 1997c).

Table 4.6 Equity in Health and Health Care

Report	Recommendations
Bhore Committee 1943-46	Universal access to health care irrespective of ability to pay. TB had special mention.
Several Government schemes/ initiatives, 1947 onwards	Build up of rural health infrastructure, national health programmes (TB control was among the earliest since 1947), reorientation of medical education, training of paramedical staff, community health worker scheme.
WHO, Alma Ata Declaration 1978	Health for All by 2000 with Primary Health Care as strategy.
GOI & GOK, Eighth Plan Document, 1992	Health for the Underprivileged.
WHO, 1997	Renewal of Health for All in the Twentieth Century.

Source: GOI 1946, 1992; WHO 1978; WHO 1997c

In India urban rural differences in health status continue with substantially higher rural mortality (CBHI 1991). Urban preferences in provision of health care services are seen in the implementation of the NTP (Nagpaul 1989), despite 74% of the population being rural (1991 census).

Table 4.7 Urban and Rural Health Care Infrastructure-1991

Health Facility	Total Number	Urban	Rural
Hospitals	11,254	7,286	3,968
Hospital beds	6,19,433	5,24,118	95,315
Dispensaries	27,994	15,710	12,284
Dispensary beds	22,184	9,270	12,912

Source: CBHI 1991

Of the increase in hospital beds since 1951, numbers in urban areas are greatly disproportionate to those in rural areas (WB 1992). The population per bed in rural areas is three times that in urban areas (*ibid*). Rural PHC's/dispensaries have low functional capacity providing low quality of care. For serious illnesses including TB, patients often have to go to urban centres. From a gender perspective women underutilise health services or have lower access. Shortages of women doctors and nurses in rural areas accentuates this situation (Chatterjee 1988, Rangan *et al* 1997). Disparities between and within States and between districts in health and health care have been increasingly discussed and studied during the past decade (WB 1992) but have not been taken into account by the NTP.

While the NTP shifted policy towards majority rural needs, no special efforts were made to reach poorer sections of the population or to provide greater inputs to districts with weaker infrastructures. By not explicitly responding to disparities and differing levels of power in society, the uniform policy of the NTP could mask and/or reproduce social realities.

4.2.5 Infrastructural Development

Training and infrastructural development are critical to TB programmes providing mechanisms for their functioning. Acute shortages of all categories of health personnel existed in 1947. Health care services were inadequate, urban based, curative in focus, providing preferential access to the army, expatriates and local elites (Ramasubban 1984). Changes relevant to TB during the subsequent five decades are discussed briefly below.

Production of Medical Graduates/ Growth in Medical Education:

TB treatment is doctor dominated, though the training/role of laboratory technicians, radiographers, nurses, treatment organisers, and multi-purpose workers is equally if not more important. The central government, responsible constitutionally for medical education, made policy decisions increasing the production of medical graduates through increasing state sponsored, subsidised medical education (GOI Plan documents). Increased annual outputs of medical graduates (Table 4.8) after 1947 changed a doctor deficit situation to one of saturation.

Table 4.8 Growth in Medical Colleges & Annual Output of Medical Graduates

Year	No. of Medical Colleges	Annual Admissions	Annual Output
1947	22	1,983	959
1957	52	4,083	2,743 in 1955-56*
1966	87	10,620	5,387*
1977	106	11,176	11,962
1987	125	11,622	12,280
1993	145	16,200	approx. 13000

Source: SCHARA 1995, *Banerji 1985

Doctor-population ratios were 1/6,300 in 1937 (Ete & Khrime 1995). With 1,90,838 medical graduates (allopaths) by 1974 and over 3,94,068 in 1991, the ratio became 1:2159, over the prescribed norm of 1:3500, despite the population tripling. Including graduates from Indian and other systems of medicine, the ratio is 1:1000 (SCHARA 1995). Thus the number of service providers trained to treat TB increased substantially since 1947. The NTP in 1962 by removing TB treatment from the domain of specialists to general practitioners multiplied the spread effect (Banerji 1993). Problems of urban rural distribution of doctors exist particularly for specialists, but market forces and sheer numbers now push practitioners to the countryside (interview). Treatment of TB and NTP concepts were introduced into the undergraduate curriculum (Park 1994). The NTI organised orientation workshops for teachers from medical colleges and participated in student training (NTI annual reports).

Private ownership of medical colleges grew from less than 5% in 1947 to 30% in 1993-94 with the largest increase occurring after 1988 during the phase of privatisation (SCHARA 1995). The New Education Policy from the mid-1980's promotes private sponsorship of higher education including medicine, while the State focuses on primary and secondary education (*ibid*). Government colleges (70%) provide highly subsidised education to students. A majority of graduates (75%) subsequently practice in the private sector whose growth is thus supported/promoted by the public sector (FRCH 1990). State run medical and health services and infrastructure increased after 1947 providing job opportunities for about 30% of graduates (*ibid*). Questions concerning quality, social relevance and community orientation of medical education and role of other health workers have been raised (GOI-Srivastava Report 1975, MFC 1991, Narayan *et al* 1993) with several initiatives and experiments over the years. However despite over production of doctors, vacancies exist in Primary Health Centres adversely affecting the NTP. In 1994, 40% of PHC doctors posts were vacant in Uttar Pradesh, India's largest state. Maharashtra one of the richest states had 25% vacancies (SCHARA 1995 citing Bajaj 1994). Government promoted/subsidised medical education, producing graduates for the private sector. The public sector particularly in rural areas is still understaffed.

Development of General Health Services: Central government policies since the 1950's, developed a health care infrastructure (Table 4.9) through which national health programmes function (Banerji 1985).

Table 4.9 Government Health Care Infrastructure

Health Centre	Health Centre Characteristics	Comments
Sub-Centre (rural)	Covers a population of 5000 (3000 in hilly terrain's), based on 1987 population, staffed by 1 male & female Junior Health Assistant (HA).	Vacancies exist, buildings inadequate, salaries of female HA's come from Family Welfare budget and for male HA's from National Malaria Eradication Programme. Work in NTP is minimal.
Primary Health Centre-PHC (rural)	Developed since 1952 as nodal point for national health programmes, covers 30,000 people (20,000 in hilly areas), has 4-6 inpatient beds, staffed by 1 MO, 7 paramedics, 7support staff, 6 subcentres administered by each PHC.	Vacancies/understaffing, staff commute, often unavailable; drug shortages; illegal private practice; excessive focus on family planning & immunisation; people lack confidence in them.
Community Health Centre-CHC (rural)	Introduced in the 1980's, 1 CHC covers 4 PHC's, it is the first level of referral, has 30 inpatient beds, 4 specialist doctors, 11 paramedics, population covered 60-120,000.	Complete country-wide coverage not yet attained, regional differences, vacancies esp. of doctors, NTP has not specified any particular role to them other than being a peripheral health institution.
Taluk Hospital (urban)	50 bedded with specialist staff, population covered 100-200,000, provides medical care, run by State Govt.'s.	Based in *taluk* headquarter town, vacancies particularly of doctors, seen by NTP only as a PHI.
District Hospital (urban)	Bed strength varies from 400 upwards, if it is a medical college hospital it could provide tertiary care.	Regional variations, economically backward districts with poorer populations and greater health needs are underserved i.e. there are internal inequities at district level, though for PHC/CHC's population norms ensure greater equity
Teaching and Specialist Hospitals (urban)	Attached to medical colleges and post graduate teaching centres. Some tertiary care and autonomous research centres.	Located in State capitals and larger cities. Graduate & post graduate centres treat TB. TB sanatoria have become TB & Chest Disease Hospitals

Source: GOI 1995d; Park 1994

The NTP's rural focus seemed a distant dream. With 80% of India's 439 million population (1961 census-CBHI 1991) being rural, spread over 5,80,000 villages, and medical services then largely urban, the problem was immense. Rural health services were then just being developed from 1952 (Table 4.10 below). From a negligible rural

service in 1947, the creation of a nation-wide rural health infrastructure and the training of an army of allied health workers is widely recognised as an achievement by government (Banerji 1985, Chatterjee 1988, Jeffery 1988, GOI/WHO/SIDA 1992, WB 1992). For an integrated programme like the NTP this potentially provided a multiplier effect. The shift in balance of power that this entailed was not fully recognised and rural services remain relatively underfunded.

Table 4.10 Development of Public Sector Rural Health Care Infrastructure

Period	Sub-Centres	Primary Health Centres	Community Health Centres
1st Five Year Plan till 1955	NA	725	-*
2nd Plan-till 1960	NA	2,565 (when the NTP was articulated)	-
3rd Plan-till 1965	NA	4,631	-
Annual Plans-till 1969	22,826	4,919	-
4th Plan-till 1974	33,509	5,283	-
5th Plan-till 1980	47,112	5,484	-
6th Plan-till 1985	84,590	7,284	759
7th Plan-till 1991	130,960	21,641	1855
8th Plan-till 1995	132,285	21,802	2401

Source: CBHI 1991, GOI 1995d, *Community Health Centres were introduced in the 1980s.

Time lags for centres to become functional, and shortfalls in achievements adversely affected the NTP. Earmarked funds under the Minimum Needs Programme for creating primary health care infrastructure were not fully utilised, especially by poorly performing states with weak infrastructures (MOH/GOI 1994-95). Politicisation of health institutions, corruption, profit motives of doctors, subservience of authorities to political bosses in government health services adversely affect quality of care (Subrahmanyam 1997).

TB services through DTC's increased after 1962, though population growth required continual expansion of services (Table 4.11).

Table 4.11 Growth in Population and NTP Infrastructure

Period	Population	No. of Districts	Average pop./district	No. of DTC's	No. of PHI's/district	No. & % PHI's implemented
1950's	400 million	300	1.5 million	-	50	-
1988	800 million	437	1.8 million	371	60	14,000 (63%)
1992	920 million	438	-	390	-	16,363

Source: Nagpaul 1989, NTI 1994d

Utilisation of public sector infrastructure for private interests by government health care personnel and pharmaceuticals is documented (Kamat 1995, Subrahmanyam 1997, Chapter 7). Experience of voluntary agencies in the field (VHAI, MFC) suggest its occurrence for decades. These aspects are not considered by the NTP in its strategies. Official evaluations and reports on the NTP record low performance, staff vacancies, old equipment unused because of repairs, idle equipment not installed, loss due to expiry of life of medicines (ICMR 1975, CAG 1988, ICORCI 1988).

The *private medical service sector*, comprising private clinics, nursing homes, pharmacies and diagnostic services, has grown considerably even in rural areas, since the 1980's (Jesani and Anantharam 1989). 74.6 % of qualified allopathic doctors practised in the private sector (*ibid*). Utilisation of private sector services by all sections of society is about 75%, inspite of cost of services and quality of care issues (Duggal and Amin 1989). There are concerns about inadequate mechanisms for regulation of the private health care sector (Bhat 1993, Srinivasan*1996). In TB, private practitioners diagnose and prescribe irrationally and over-prescribe (Uplekar and Shepard 1991, Uplekar *et al* 1996). No strategies have evolved in the NTP regarding the role of the private sector though the issue has been recognised for long (Sivaraman 1982) and the TB Association evolved training modules for general practitioners since 1984 (TAI 1991). Due to a lack of a system of notification and few macro studies concerning the private sector and TB, the contribution ofprivate practitioners to TB control cannot be accurately assessed. It is assumed that nationally that the proportion of patients seen by them equals those by the NTP (Napaul*1995). The basis of the estimates is fragile and probably does not account for regional and social class differences. Also it appears from indirect evidence that the increase in the number of medical graduates and practitioners has not altered the TB situation.

Conclusions:

Implementation of the NTP was incremental and failed to achieve its goals for a number of reasons including resilience of older policies, non-decisions favouring existing biases, conflictual political factors and a difficult policy environment. When reviewed against characteristics that enhance or reduce the 'problematique' of a policy, the NTP simplified and standardised technical components and developed/disseminated clear goals and objectives. However more problematic aspects were that the policy is inherently of long duration, involving multiple actors in a federal constitution, and perhaps more importantly implied a fairly radical shift from existing practices and policies.

Table 4.12 Policy Characteristics of the NTP

Less/more Problematique Policy Characteristics	NTP Characteristics
Simplicity/ complexity of technical features	Simplified, demystified technical features, but older more complex features still function.
Marginal/ comprehensive change from status quo	Radical change proposed from urban to rural focus, from a vertical to an integrated approach, from specialists to generalists.
Single/ multi actor target	Multiple actors spread across a vast area
Single/ multi goal objective	Reduction of suffering and transmission, however it was dependant on several factors viz. health services, commitment of states in a federal system.
Clearly stated/ ambiguous goals	Clearly stated- but time scale, social disparities & political processes need greater attention.
Short/ long term duration	Long term, needs sustained interest and resources

Source: Developed around framework by Cleaves (1980)

Implementation Gains of the TB Programme

Despite the focus on implementation gaps/problems, several strengths of the government TB programme are discernible (Table 4.12). These include creation of institutional frameworks for research, adoption of a multidisciplinary approach, radical evidence based policy changes, conceptual links to national development in the early phase, newsletters/bulletins, team approach, training manuals, orientation of state policy managers and medical college teachers, interaction with NGO's etc. As

evident in the literature, the period was characterised by zeal and commitment of several individuals that has provided motivation/inspiration to others. The development of a country-wide infrastructure, self-reliance in trained staff and pharmaceutical production have long-term benefits.

Table 4.13 Implementation Gains of the NTP

Gains	Effect
1. Development of knowledge base.	Altered TB control policy content in India and globally. Shifted away from: hospitalisation, reliance on X-rays for diagnosis, reliance on BCG as preventive against adult pulmonary TB and for epidemiological gains, vertical approaches, active case finding. Developed scientifically sound, cost effective methods in conjunction with other global research. Of value to individuals and the state. Older approaches more expensive for patients and public providers and profitable to private providers.
2. Development of institutional mechanisms.	State institutions for research and graduate /post-graduate education. TB Units at national and state directorates of health services. 17 State TB & Demonstration Centres. 391 District TB Centres/496 districts
3. Development & staffing of health care infrastructure.	Creation of countrywide network of Primary Health Centres, CHC's, *Taluk* & District Hospitals, Specialist and Teaching Hospitals. Creation of a large & adequate number of teaching & training institutions.
4. Patient coverage.	Estimated that 50% of TB patients are detected/treated by the public sector. Others benefit by related policies. 1.5 million TB patients diagnosed annually- in contrast to 5% receiving treatment from all sectors in 1947. This has been in the context of limited resources within which NTP functions. Public policy has stimulated and supported the growth of the private sector which treats a substantial proportion of patients.
5. Pharmaceutical Policy.	Self reliance in production of TB drugs. Maintenance of drug prices at a reasonable level.

Sources: NTI 1993-94, NTI 1994d

Considering the financial constraints and political pressures under which it functioned, these gains of government TB policy, though tempered and diluted by struggles, are substantial and form the foundation of future policy development and implementation.

CHAPTER FIVE

COMMITMENT TO THE NTP: FINANCIAL AND PHARMACEUTICAL

5.1 Financial Commitments:

Insufficient financial resources for the NTP has been identified as an important explanatory factor for the NTP not performing to expectations (Gupta 1986, ICORCI 1988, GOI/WHO/SIDA 1992, Singh *et al* 1994). Chronic underfinancing of a programme concerning a preventable and treatable disease with high mortality and morbidity, under-utilisation of financial and other resources at Central and State levels, and dynamics of current policy initiatives, raise issues concerning political economy.

5.1.1 Central Government Health Expenditures

Health received small and declining shares of public expenditure through Central Government Plan allocations over the decades (Table 5.1), indicating low political priority in terms of state investment.

Table 5.1 Central Government Expenditure for Health & Family Welfare[1]

Five Year Plans	Health Actuals in Rs. & as % of Total Plan Outlay	Family Welfare
First Plan 1951-56	652mill. 3.3%	1mill.
Second Plan 1956-61	1408mill. 3.0%	50mill. 0.1%
Third Plan 1961-66	2259mill. 2.6%	249mill. 0.3%
Fourth Plan 1969-74	3355mill. 2.1%	2780mill. 1.8%
Fifth Plan 1974-79	7608mill. 1.9%	4918mill. 1.2%
Sixth Plan 1980-85	20252mill. 1.8%	13870mill. 1.3%
Seventh Plan 1985-90	36886mill. 1.7%	31208mill. 1.4%
Eighth Plan 1992-97	75822mill. 1.7%	65000mill. 1.5%

Source: CBHI 1993

[1] Sixty Rupees = £1 (1998)

Low allocations by the political leadership, the Planning Commission and Finance Ministry, were despite recommendations by other governmental bodies. The Bhore Committee recommended 15% of government budgets to health (GOI 1946), the Central Council of Health in the 1950's suggested 10% (CBHI 1985), while the Mudaliar Committee observed that allocations during the first two Plans were too meagre (GOI 1961). During the 1980's the NTP budget comprising an average 1.7% of the central health and family welfare budget (CBHI 1994), with a per capita expenditure of Rs.0.15 (Krishnamurthy 1993), was very inadequate. In India indirect taxes (e.g. sales tax on common commodities) from the majority population, form the major source of revenue for public services including health, rather than direct income tax from richer segments of society (Patel 1995). Meagre funding for a major public health problem suggests little accountability to tax payers.

The development of strong competing interests, particularly family planning[2] from the mid-1960's, is evident from expenditure patterns in Table 5.1. Among centrally sponsored programmes (excluding family welfare) in 1992-93, TB received 11% of the central health budget, compared to 35% for malaria and 22% for AIDS (Verma *et al* 1994). Financial support for primary health care infrastructure and staff salaries come from vertical programmes (ICORCI 1988). The family welfare budget covers development of subcentres, training and salaries of female multipurpose workers and training and honoraria of community health workers. Training and salaries of male multipurpose workers and of microscopists/laboratory technicians is from the malaria budget. These workers potentially play an important role in the NTP. Health workers focus primarily on programmes paying their salaries, at the expense of integrated programmes like the NTP (ICORCI 1988). Recommendations for a common salary pool (*ibid*) have not been accepted.

Declining real expenditure in the 1970s and 1980s did not keep pace with population growth (WB 1992). Infrastructural expansion in the mid-1980s[3] resulted in reduced

[2] Renamed Family Welfare after widespread protest to state excesses in the Family Planning Programme during the 1970's.

[3] There was an increase in establishment of primary health centres and sub-centres, though not necessarily of functional efficacy.

spending on non-salary inputs, with public health and communicable disease programmes most affected (*ibid*).

Plan allocations cover capital expenses and new schemes. Non-Plan funds particularly from State governments, covering salaries and maintenance, account for approximately 65-75% of annual health expenditure (Chopra*1995, Chatterjee 1988). This is spent mainly on *Taluk*, district and other hospitals, where a large proportion of patient care, even for TB, takes place (Chapter 8), making State governments major funders and providers of TB care.

5.1.2 Government Expenditures on the NTP

It is difficult to correctly estimate public expenditure on TB/the NTP because of contributions made by central, state and local governments and varying patterns of assistance from Plan to Plan (Gupta 1986). The programme being horizontal at peripheral level, makes it difficult to work out the proportion of expenditure on health services for salaries and infrastructure utilised for the programme (*ibid*). Additionally there are inter- and intra-state variations in government health spending over time. States often reportedly do not contribute their agreed 50% share towards purchase of drugs, materials and equipment (interviews 1996), while central government funds for the NTP get diverted for other purposes (CAG Report 1988). Funding of health services for present/retired employees and their dependants of the organised public sector[4], providing more expensive TB care, with more investigations, Short Course Chemotherapy and hospitalisation in the defence services (TAI 1996), is not included in NTP budgets. Total annual public expenditure on the TB programme was estimated at Rs.950-1050 million (Rs1.50 per capita) in the mid-1980s (Gupta 1986, Table 5.2).

[4] Railways, Defence, Post and Telegraphs, Police, Labour Welfare, Employees State Insurance Scheme (ESI), Central Government Health Services, and large public sector undertakings.

Table 5.2 Estimated Total Government Expenditure on the NTP in the 1980s

Items of Expenditure	Annual Expenditure
Cost of hospitalisation in 46,000 TB beds; domiciliary services through 600 TB clinics, including 365 DTC's	Rs.600-650 million
Central assistance for drugs & equipment; maintenance of NTI and TRC; State government funds- Plan & NonPlan; other public sector services and schemes	Rs.350-400 million

Source: Gupta 1986

This is an under-estimate as manufacturing, distribution and supply costs of freeze dried BCG, diluent and PPD, and service provision through the Universal Immunisation Programme are not included in the table or in financial analyses. The Central government manages and pays for public sector drug companies producing about 30% of TB drugs required. Their investment, maintenance and manufacturing costs, along with distribution systems through Medical Stores Depots, contribute to TB control efforts but are not computed in analyses. Similarly budgets for institutions/special projects such as the NTI, the TB Research Centre, the TB Prevention Trial are not included. In 1994-95 the budget for the NTI was Rs.11 million, for the BCG Vaccine Laboratory Rs.19.5 million, for the LRS Institute of TB and Allied Diseases Rs.47 million[5] (GOI 1996).

Central government allocations to the NTP in the 1980s and expenditures for some years are given in Table 5.3.

[5] This reveals an imbalance of resources between organisations, with the first two covering the entire country and receiving one-fourth the budget of a capital city institution.

Table 5.3 Central Government Allocation and Expenditure on the NTP

Rs. in millions

Year	Allocation	Expenditure		
		TB Drugs	Materials & Equipment	Total
1980-81	n.a.	7.4	11.5	18.9
1981-82	n.a.	10.7	9.6	20.4
1982-83	32	18.5	1.5	19.9
1983-84	60	34.3	12.6	46.9
1984-85	80	93.3	4.9	98.2
1985-86	110	96.9	13.2	110.2
1986-87	120	96.0	12.5	108.5
1987-88	135	123.3	12.1	135.5
1988-89	125	n.a.	n.a.	n.a.
1989-90	120	n.a.	n.a.	n.a.
1990-91	140	n.a.	n.a.	117.5
1991-92	152	n.a.	n.a.	68.8
1992-93	270	n.a.	n.a.	259.5
1993-94	350	n.a.	n.a.	143.0
1994-95	420	n.a.	n.a.	n.a.

Source: Verma *et al* 1994, ICORCI 1988, DGHS 1995 (Greater spending is by the States, as seen in the differences in expenditures in the 1980's when comparing this to Table 5.2.)

In 1988-90 general budget cuts in health were reflected in the NTP budget which decreased from Rs.135 to 120 million(Table 5.3). In 1991-92, a substantial reduction in expenditure occurred, followed by a sustained increase. In 1993-94, only 143 million was spent from the enhanced NTP budget of Rs.350 million indicating poor performance, capacity or commitment (interview*1996).

In 1995 TB drug costs (SCC) for 1 million new sputum positive cases/year at Rs.1,500/patient (estimates by Health Secretary) would cost Rs.1500 million annually. Increased budgets (assuming equal contribution by States) under the Revised NTP are inadequate for these needs, without even considering the 50-66% sputum negative patients or costs of diagnostics and infrastructure.

The budget was inadequate to cover drug costs for the estimated 10 million patients in 1981, with Rs.1.30 available per patient, or Rs.2.60 assuming equal State

contributions. Budgets below critical levels, with most expenditure on salaries/maintenance rather than on effective services, can be counterproductive (WB 1992). Additionally in TB, drug resistance consequent to low funding and poor/irregular drug supplies is harmful and costly.

For the budget, external assistance given in kind, is expressed in monetary terms. Increases in the 1980's partly reflect SIDA assistance (X-ray machines, vehicles, film rolls, drugs for Short Course Chemotherapy) (MOH/GOI Annual Reports 1980-1990).

5.1.3 Cost Sharing of the NTP Between Central and State Governments

The pattern of funding has been changing. Central government provided 100% assistance from 1947-1974 for the BCG vaccine plant; the BCG campaign; establishment of TB clinics; State TB Demonstration and Treatment Centres; new TB beds; the National TB Institute; the TB Research Centre in part; after the NTP the establishment of District TB Centres, training of DTC teams, TB drugs for domiciliary chemotherapy (MOH Annual Reports, Verma 1994). It helped create an infrastructural and institutional base, but also used funding for policy leverage. Its contributions came partly from international agencies (UNICEF, WHO and later SIDA) which provided supplies often from international markets (MOH Annual Reports, interviews). Its control of linkages with international agencies gave it power (Banerji 1990). State Governments met maintenance and salary costs, a substantial proportion.

From 1975 (5th Plan) a further shift of financial responsibility to the States occurred, with costs for establishing DTC's and TB beds borne by State governments, while continuing 100% assistance for drugs. This coincided with the period that UNICEF discontinued funding the NTP. From 1980 (6th Plan) moving from a Centrally Assisted Programme to a Centrally Sponsored Scheme, the centre provided X-ray machines from SIDA[6] and only 50% of drug costs (Verma *et al* 1994). As the shift occurred, State governments did not match central government contributions over

[6] SIDA shifted its funding from the discredited Family Planning programme in 1979, following debate in the Swedish media and parliament, to the TB programme as it met the needs of the poor (interviews).

long periods, showing low commitment to the NTP and the people affected (Table 5.4).

Table 5.4 State Utilisation of Central Assistance to the NTP (Rupees in millions)

State	Year	Central Assistance (in kind)	Expenditure by States (in cash)
Andhra Pradesh	1980-81	0.62	0.1
	1981-82	0.75	0.27
	1982-83	0.8	0.34
	1983-84	1.0	0.89
	1984-85	5.0	4.1
Kerala	1980-81	0.47	Nil
	1981-82	0.52	Nil
	1982-83	0.84	Nil
	1983-84	1.65	0.01
	1984-85	3.1	0.7
	1985-86	3.0	0.87
	1986-87	3.1	0.94

Source: CAG 1988

The Comptroller and Auditor General found States X-ray machines unutilised due to staff shortages or waiting for minor repairs and large numbers of patients lost to follow-up resulting in a wastage of resources (CAG 1988;42).

States with a better development index such as Maharashtra and Gujarat get larger allocations (based on NTP performance, not on population norms) while Rajasthan, Madhya Pradesh and Bihar, in greater need, receive and utilise less (Table 5.5). While better developed and administered states like Gujarat, Tamil Nadu and Punjab underutilise NTP funds, others (Maharashtra, Karnataka) over-spend. Large variations from year to year lead to chaos in the field. Disparities occur with the capital city Delhi (population 10 million) receiving a disproportionate share of the budget as compared to Bihar (population 90 million). Delhi also has public sector hospitals under the Central Government Health Scheme, for defence personnel etc. whose budgets are not included here. Since 1993 pilot projects of the Revised NTP are also sited in Delhi. Plan allocations also 'get quietly diverted to non-Plan areas and to large

urban hospitals' (interview 1996) accounting for differences between NTP allocations and expenditures.

Table 5.5 Central Government Allocations and Expenditures on the NTP at State Level in the 1990's

(Rupees in millions)

Year	Karnataka	Gujarat	Maharashtra	Rajasthan	Bihar	Delhi	India*
1990-91							
Allocation	4.0	9.5	16.0	5.0	10.0	6.1	128.0
Expenditure	6.4	6.8	18.7	4.2	6.4	6.0	117.4
1991-92							
Allocation	4.5	10.8	15.5	5.3	9.7	7.3	133.7
Expenditure	2.8	4.4	9.6	3.6	1.8	2.3	68.8
1992-93							
Allocation	8.9	22.8	30.8	11.8	14.3	6.6	270.0
Expenditure	17.0	15.8	38.6	8.5	6.8	9.2	259.5
1993-94							
Allocation	11.7	27.6	36.6	16.6	20.6	8.6	351.3
Prov.Exp.	10.2	11.1	16.1	3.6	1.0	11.0	143.2
1994-95							
Allocation	15.4	28.2	41.3	18.7	20.7	29.0	404.0

Source: DGHS 1995, * small discrepancies are seen in allocations in Table 5.3 due to different sources.

Deficient knowledge, information and interest in the budget was observed among senior NTP programme managers at State level (ICORCI 1988), indicating low involvement and power in the process.

Operating costs and salaries/wages are calculated at 20% each of expenditure on the RNTP, with 60% on drugs (Jhunjhunwala 1994). In the NTP currently States cover salaries and wages and operating costs of DTC's, TB beds, TB clinics and PHI's through which the NTP works. They also cover 50% of the cost of drugs (for domiciliary treatment), film rolls and chemicals. Thus extrapolating the RNTP break-up to the NTP, the States bear approximately 70-75% of the costs of TB care in the public sector. This is probably an underestimate as cost of treatment in sanatoria, and secondary care hospitals (which a substantial proportion of patients in this study used,

Chapter 7) is borne by the States. Though some states do not contribute their 50% share, towards matching grants for the NTP their overall contribution is still higher than the Centre. However their policy role, particularly in policy making for national health programmes is weak, despite health being a State subject. The Central Plan budget forms less than 6% of public expenditure on health overall but exerts a disproportionate leverage over the States (WB 1992).

5.1.4 Political Economy Factors

It is useful to estimate total costs (private and public) for TB care. Studies of health care utilisation suggest that the public sector accounts for approximately 20% of service provision and the private/voluntary sector for 80%[7]. Assuming a similar scale of expenditure for TB as the public sector, private sector expenditure would be about Rs.4,000 million annually making an estimated total expenditure of Rs.5000 million annually, an underestimate since private expenditure is usually higher. Estimates are 10 years old and diagnostic/drug costs have increased. With population increase (160 million in a decade) and increased life expectancy, the absolute number of TB patients have increased during the decade. Thus total national spending on TB is considerable.

Gains accrue to the diagnostics and drug industries (see 5.2) and to medical professionals, whose macro interests differ from those of patients and of public health. Irrational prescribing practices in TB by private practitioners (Uplekar and Shepard 1991), overdiagnosis of X-ray positive suspects in the public sector (ICORCI 1988) and overmedication (Uplekar*1994), benefits industry and providers. The doctor-drug producer axis as an exploitative force has been recognised by the Indian Council of Social Science Research and the Indian Council of Medical Research (ICSSR&ICMR 1981). For BCG, though the government Vaccine Laboratory has production technology and capacity, because of budgetary constraints a high dependency on imports has developed. In 1992-93, of a total of 47 million doses 30 million were imported at considerable cost in foreign exchange (GOI 1996).

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[7] The 42nd round of the National Sample Survey in 1986-87 found 75% of all health care in the private sector and 25% in the public sector (WB 1992). A district study found utilisation of government facilities in 13% of illness episodes (Duggal and Amin 1989). Hence an approximation of 20% is used.

Financial resources are not real resources but can purchase resources such as trained staff, buildings, equipment and supplies. Increased budgets/drug supplies have not ensured better NTP performance at Primary Health Centres and with weak organisational structure and poor leadership at every level may increase leakages and drug resistance (Jhunjhunwala 1994, VHAI 1994).

Economic costs from TB have been estimated at Rs.20,000 million a year through person hours of work lost (Ram Kumar 1993). Indirect costs of treatment to affected families are high, including transport, food, costs of accompanying person, loss of economic productivity of the patient and at least one other member of the family, and are larger than direct costs of diagnosis and treatment[8]. Levels of indebtedness and pauperisation resulting from TB are distressingly high (Chapter 8). Economic loss to patients, families and the nation is significant (Singh *et al* 1994) while suffering is a price paid that is immeasurable.

Government resource constraints were accepted unquestioningly by NTP programme managers, unable or uninterested in increasing allocations to it from different sources. Resource inadequacies over 40 years make it almost a placebo policy, raising questions regarding the commitment of central and State governments. The nature of the problem requires long term sustained resource commitments.

In summary,

- Government financial resources for the NTP though underestimated are inadequate. TB policy leadership is unable to mobilise sufficient funds for the programme;
- Funding is used for policy leverage between various levels;
- State government's spend more than the centre on TB;
- Underutilisation of financial resources, particularly by some states, suggest low commitment tothe programme;
- Competing programmes funded vertically receive disproportionate funding;
- There is low accountability to the major source of funding which is from the general public through indirect taxation;

[8] Costs to patients/households of Rs.4-5,000 are reported from Malshiras village, Pune by an FRCH team (interview citing FRCH 1988).

- Total public and private expenditure on TB nationally is substantial, benefiting pharmaceuticals, diagnostics and the medical profession, while the price is paid by patients.
- Inter-State disparities occur favouring better developed States.

5.2 DOMINO EFFECT OF DRUG POLICIES AND THE PHARMACEUTICAL INDUSTRY ON TB CONTROL

The pharmaceutical industry is an important actor in TB control linked in complex relationships with government. The latter provides a conducive environment for the industry's economic growth, in which both have a shared interest. Government simultaneously controls and regulates industry, attempting to make its products respond to national epidemiological and social need. The industry's economic profit making drive, while providing the engine for growth, is in conflict with these societal needs. The Indian government, mandated to uphold public interest, is a player in a more involved sense, having become a drug manufacturer itself. It is not neutral, nor unified in purpose or consistent over time. Ongoing negotiation and compromises, driven by these underlying interests, impact on prices and availability of TB drugs, affecting TB control.

Consumer and voluntary groups active in health/ drug issues are other players in this game. TB patients in India are powerless, unorganised and dependant on the medical profession, which is wooed by the pharmaceutical industry[9].

5.2.1 Pharmaceuticals and TB Control - A Double-Edged Relationship

Internationally and nationally, TB control strategies in the past 35 years rely on drugs, with chemotherapy as their mainstay (WHO 1964, 1997). This became more so from the 1980's, when the epidemiological impact of BCG in terms of reduced transmission of TB was accepted as being small (WHO 1982). The development of effective TB chemotherapy started in 1944 with the discovery of streptomycin[10].

Technological and chemotherapeutic developments led to increased economic growth and political clout of the chemical and pharmaceutical industries. It is an international industry dependant on scientific research which it sponsors or conducts. A relatively small number of Trans-national Companies (TNC's) dominate the global market for specific drugs. The formation of cartels gives them control over drug prices (interview

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[9] These elements, though important, are not considered here.

[10] Followed by: thiacetazone (1946), isoniazid (1952), pyrazinamide (1952), para-amino-salicylic acid, ethambutol (1961) and rifampicin (1967) (CDRI 1993).

1996). Governments had to legislate to restrain monopoly and to install pricing and production controls in the interests of consumers and citizens.

Eighty percent of the pharmaceutical market is in developed market economies (WHO 1988) whose needs and demands determine production patterns. TNC's are a dominant force with 70% of the market share (*ibid*). New TB drugs have not developed since 25 years, following a decline of the TB epidemic in these economies by the 1960's (WHO 1997). Research was initiated subsequent to resurgence of TB in the USA and Europe and development of Multi-Drug Resistant TB. Global estimates are that $300 million are spent annually on TB drugs. With markets likely to double, the pharmaceutical industry is showing renewed research activity (*ibid*).

Existing TB drugs have passed the patent period and market prices are relatively low. This makes TB one of the most cost effective infectious diseases to treat (WHO 1995). However inadequate production and distribution, low purchasing capacities of patients and programmes and high indirect costs make the issue less straightforward.

In India, in the 1940s and early 1950s imported drugs were expensive and in short supply, foreign exchange limited and there was no indigenous TB drug production. Those in need could not benefit from lifesaving drugs for TB and other diseases. The state therefore intervened.

5.2.2 Development of the Pharmaceutical Sector in India: A Brief History

Foundations for indigenous pharmaceutical manufacturing capability were laid by nationalist entrepreneurs in 1901, with the Bengal Chemicals and Pharmaceuticals Limited (ICSSR/ICMR 1981). Growth of the industry took place during the two world wars when imports were restricted (Narayana 1984). However at Independence (1947) the pharmaceutical sector with sales of Rs.100 million was almost entirely dominated by foreign owned companies (*ibid*). Drug prices were among the highest in the world (Sengupta 1996, citing Kefauver Senate Committee)[11]. The Indian

[11] The Kefauver Committee in the USA was the Senate Committee on Pharmaceutical Companies on 'Administered Prices in the Drug Industry-1959-1962'.

Parliament expressed concern that life saving drugs were not affordable to the common person (Ekbal 1988).

Development of Public Sector Policies and Institutions: The new government's industrial policy from 1947 encouraged growth of the Indian public and private sector as part of a planned, mixed economy approach to development. Foreign companies were encouraged. The 1948 Industry Policy Statement noted that participation of foreign capital, technology and knowledge was necessary for rapid industrialisation (Narayana 1984) acknowledging a dependency. Government, often responding to parliamentary debate or external events (as in health and TB), developed institutional and legal frameworks, within which the pharmaceutical industry grew. Table 5.6 indicates key state policy interventions.

Table 5.6 Government Interventions and the Pharmaceutical Industry

Year	Interventions/ Developments	Comment
1951	Pharmaceuticals included in 'core sector' of industry by parliament, under purview of Director General of Technical Development, through a Development Council with industry, trade and official representation. Pharmaceutical Enquiry Committee Report, 1954, outlined framework for growth of pharmaceuticals.	Stated priority to respond to vast unmet health need. Pragmatic policy support to public, private & foreign sector.
1954	First public sector drug manufacturing company, Hindustan Antibiotics Ltd (HAL), set up by central govt. with WHO and UNICEF assistance.	HAL produced Streptomycin from 1958.
1961	Second public sector company, Indian Drugs and Pharmaceuticals Ltd (IDPL), set up by central govt. with Soviet technology. It gradually developed 6 units in different cities. They undertook technology intensive, low profit bulk drug production.	Other TB drugs were among the earliest to be produced here by the public sector.
1962	Drug Price Control measures introduced during emergency at time of Chinese aggression under Essential Commodities Act.	Policy shift towards govt. regulation of industry.
1960's	Govt. supported Indian private sector development in two streams- small scale sector (SSS) and organised sector through financial incentives, gradual transfer of technology and provision of bulk drugs from public sector for formulation. State Trading Corporation (STC) established to pool imported and domestically produced raw materials and distribute them to drug manufacturers in the public and private sectors. Monopolies and Restrictive Trade Policies Act placed a ceiling on foreign share holdings of foreign owned companies.	Indigenous TB drug production increased with increased availability and reduced prices. Antibiotic prices fell by 60-70% with growth of public sector and related policy measures.
1970	Drug Price Control Order introduced on Tariff Commission Recommendations.	
1971	Indian Patent Act (Process Patents for 7 years) passed by Parliament. CSIR labs (council for scientific & industrial research) through indigenous R&D developed new processes for drug production for public and Indian private sectors.	Production of isoniazid, PAS, thiacetazone (easy to manufacture) shifted to SSS & private sector.
1974-75 1974	Parliament concern about ownership and role of drug industry. Hathi Committee Report advised priority be given to the public sector and to essential drugs. Drug Price Control Order covered 450 drugs.	TNC's produced and marketed more Category 3&4 drugs -relatively non essential, higher profits.

1978 1979	New Drug Policy-graded price and production controls, leadership to public sector, restriction of foreign owned companies, reserved markets for public and private sectors. Drug Price Control Order- categorised drugs on basis of essentiality with restricted profit mark-up for these. Price control coverage reduced to 347 drugs.	e.g. 45% mark-up allowed for TB drugs, 100% for non-essential drugs Industry claims this had a counter-productive effect with decreased production of essential drugs.
	6 Joint Sector companies set up between HAL & IDPL and state govt's. In 1972, 1978 and 1981, 3 other sick private sector companies taken over by central govt.	Role of public sector and Indian private sector expanded
1980	UNIDO classified Indian pharmaceutical industry in Category V i.e. capable of self sufficiency.	Organised Indian private sector & TNC's lobbied against price & production controls.
1984 1986 1987	Formation of NDPDC* to evolve drug policy-with drug industry representation, no consumer or health action groups involved. Drug Policy focused on growth of the industry with production and price decontrol, delicensing, import liberalisation i.e. greater shift to market mechanisms. Drug Price Control Order reduced coverage to 166 drugs.	 Drug prices increase. Shortages of essential drugs including TB drugs continue.
1991	New Economic Policy and New Industrial Policy promoting liberalisation, TNC's with foreign equity of 51% treated on par with wholly Indian companies.	Industry continues growth.
1994 1995	New Drug Policy- greater liberalisation, increased returns allowed on bulk drug manufacture. Drug Price Control Order reduced coverage to 73 drugs	Drug prices treble since 1980.

*NDPDC- National Drugs and Pharmaceuticals Development Committee

Source: GOI 1975a, Ekbal 1988, Narayana 1984, Sengupta 1996, Shiva 1996

The table shows that the pharmaceutical industry was on the political and policy agenda throughout this period, with a continuous conflict between economic and social needs sought to be mediated by political means. The public sector with varying political support became an important new player in an arena previously the monopoly of the private sector. International organisations like the UNICEF and WHO supported the establishment of the first public sector company and efforts towards self reliance in drug production. Several developing country governments similarly moved towards greater state intervention in a sector dominated by

multinationals. They developed national formularies (Chile and Sri Lanka in the 1950's), drug regulation (Sri Lanka) and introduced generics (Pakistan in 1972) (Chowdhury 1996). The Indian Patents Act in 1970 provided for Process Patents rather than Product Patents. Indigenous R&D helped develop local modifications of processes (interviews 1996). This encouraged competition rather than monopoly and reduced prices, gaining recognition and support from UNIDO (Keayla*1996). The Hathi Committee Report (GOI 1975a), an extensive study of the pharmaceutical situation in India, introduced the essential drugs concept and discussed the ownership and regulation of the pharmaceutical industry. The WHO in support published the first model list of Essential Drugs in 1977, initiated the WHO Action Programme on Essential Drugs in 1981 and developed 'Guidelines for Developing National Drug Policies' in 1988 (WHO 1988).

Not surprisingly, problems were encountered and the process was complex. Public Sector Pharmaceutical companies produced bulk drugs, reducing imports, thereby conserving foreign exchange. They became the 'mother company' providing bulk drugs for formulation and enhancing diffusion of technology and growth of the private (small scale and organised) Indian sector. TNC's too bought bulk drugs from the public sector reaping larger profits from formulation. Bulk drug production is technology intensive and has fewer profits. Isoniazid initially produced by the public sector was almost entirely taken over by the small scale sector by the 1980's. Streptomycin, with a more complex fermentation production process, is still largely manufactured by the public sector company, Hindustan Antibiotics Limited (interview 1996). Most basic raw materials (32/35) for production of isoniazid, PAS, streptomycin and thiacetazone were produced indigenously by public and private sector chemical and petrochemical units (GOI 1987). Thus while the public sector challenged the foreign and private sector, it also supported their growth and profits.

Profit margins of 45% were allowed for essential drugs including TB drugs, while a maximum of 100% profit was allowed for non-essential drugs. Prices in India now became among the lowest in the world. However, according to industry, price controls were disincentives to produce essential drugs in adequate amounts. Private companies,

particularly TNC's, opted for nonessential drug production with higher profit margins. Mandatory requirements to produce basic drugs were not enforced.

5.2.3 Policy Processes and Pharmaceuticals

Analysts argue that most recommendations of the Hathi Committee were not implemented under pressure of multinationals and the organised Indian sector represented by the Organisation of Pharmaceutical Producers of India (OPPI) (Shiva 1996, Sen Gupta 1996). The Indian Drug Manufacturers Association (IDMA) represents the Small Scale Sector. They compete, but form alliances to promote common interests such as opposing the price control policy. They are a powerful, well-resourced and organised lobby, with rapid means of communication and ability to mobilise the opinion of medical professionals in their favour. Most big companies have 'liaison offices and officers' based in Delhi comprising influential people with access to the Department of Chemicals and Petrochemicals (Ministry of Industry), the Ministry of Health and political decision makers. Government orders banning certain drugs are delayed or circumvented by obtaining stay orders from Court, employing the best lawyers. The lobbies influenced a revision of the drug policy in 1984 to their advantage at a time when political forces favoured privatisation. This was at the cost of weakening the public sector, reducing constraints on the product range and profits of the private sector and allowing growth of monopolies by TNC's.

Despite adequate indigenous technology and manufacturing capacity, shortfalls between production and requirements of TB drugs (see Table 5.7) were reported by prestigious government bodies (ICSSR/ICMR 1981). They documented that with half the world's TB patients, India only produced a third of its requirements of TB drugs. It is suggested that shortages of inexpensive first line drugs were created, through under-production, allowing costlier, imported drugs to enter the market (Majumdar 1984).

Table 5.7 TB Drug Requirements and Production (in metric tons)

Drug	1979-80 Requirement	1979-80 Production/Imports	1980-81 Requirement	1980-81 Production/Imports
Streptomycin	300	220-local/large co.'s 72.8-imports	330	227-local/large co.'s 44-imports
Isoniazid	200	112.5-local/large co.'s 41.8 -SSS 26.2-imports	240	129-local/large co.'s 150.5-SSS 6.8-imports
Ethambutol	60	23.6-local/large co.'s 0.7-SSS 96.1-imports	78	24.9-local/large co.'s 10.1-SSS 29.1-imports
Rifampicin	5.4	5.4-imports(no local	7.3	8.9-imports

Source: VHAI 1984 (citing Ministry of Chemicals and Fertilisers)

This was the period following the second oil shock of 1979, when average annual growth rates in drug imports in developing countries, which were 20.8% between 1970 and 1980, fell to -1.3% between 1980 and 1984 (WHO 1988). It probably stimulated development of the small scale sector.

TB drug shortages, noted by the voluntary sector from 1978 (VHAI 1984) inspired the formation of the All India Drug Action Network (AIDAN) in 1982 (Shiva*1996). Several state specific and local drug action groups (e.g. Drug Action Forum Karnataka, West Bengal Drug Action Forum, groups in Maharashtra, Gujarat, Tamilnadu) raised issues concerning drug policy and rational therapeutics for public debate through the media, publications, study groups, training programmes for professionals, and working with parliamentarians. Campaigns concerning specific drugs were conducted, TB drug issues studied and discussed at national meetings on 'TB and Society' (MFC 1984), and at various levels by the Voluntary Health Association of India.

One example is the banning of strepto-pencillin, a combination used as a broad spectrum antibiotic for general infections and likely to cause drug resistance with short term use, if patient have TB. The need for a ban was raised by the AIDAN since the early 1980's. Four groups (Drug Action Forum, Karnataka, AIDAN, National Campaign Committee for Drug Policy and LOCOST) subsequently filed a Public

Interest Litigation in the Supreme Court in 1993 to ban a range of harmful and bannable drugs, including strepto-penicillin. The case continues in Court. Delays and problems occurred in the setting up and functioning of a special technical advisory committee. Arguments and persuasion by drug companies regarding need to clear existing stocks prevailed over dangers faced by individuals and the community , so that striped-penicillin will finally be banned only from January 1998. These examples indicate the interests and power of the pharmaceutical lobby, and the mechanisms by which they work.

Production technology for newer drugs, ethambutol and pyrazinamide, were acquired and out of 10 basic raw materials required, 8 were produced indigenously in 1987 by the chemical industry. Efforts were made for several years by the public sector to produce rifampicin, requiring more complex fermentation processes. Technology acquired and experimented with by the IDPL proved inefficient and was abandoned. Rifampicin was produced by the private sector in the 1980's from imported intermediate stages. Recently in the past 3-4 years a private Indian company has started manufacturing from the basic stage. An Indian private company (Lupin) is a major global producer and exporter of ethambutol.

There are 60,000 formulations on the market, many of which are irrational, useless or harmful. Thus the industry has grown and the market flooded with drugs, but essential TB drugs are in short supply in the public health system and not within the purchasing power of impoverished patients. Manufacture of TB bulk drugs (isoniazid, thiacetazone, PAS, ethambutol, pyrazinamide and rifampicin) have been delicensed making it easier to start new units or expand capacity. In the past and present, licensed capacity is underutilised due to low mark-ups. Isoniazid, the sheet anchor in TB chemotherapy, is very inexpensive and simple to produce. However these features make it unattractive for production as profit margins are low. Newer TB drugs including rifampicin are placed in Category 2 allowing a higher 150% mark-up. This acts as an incentive for production, but removes the products from the purchasing power of the poor. As has been pointed out, market mechanisms are inadequate in the pharmaceutical sector (World Bank 1996a). They are also incompatible with India's

stated social goal of 'Health for All, Particularly the Impoverished' in the Eighth Plan (GOI 1992).

The involvement of TNC's in TB drug production is minimal. The few involved (Ciba-Geigy and Glaxo) lobby strongly to capture the substantial NTP/RNTP orders. A leading Indian company has discontinued dealing with the GOI recently alluding to an unacceptable level of underhand dealings (interview).

Drug policy analysts envisage that GATT (General Agreement of Trade and Tariffs) and TRIPS (Trade Related Intellectual Property Rights) will have a major impact on the pharmaceutical sector with greater monopoly by TNC's, rise in drug prices, drug production patterns responding to the needs and purchasing capacity of the middle and upper classes, closure or merger of Indian companies and gradual loss of technological capacity (Keayla 1996; Shiva*, Sengupta*1996).

Since liberalisation substantial price rises of several drugs have been documented (Shiva 1994, Sengupta 1996). However, price rises of TB drugs noted after the 1986 Drug Policy (Tribune 1994) and the 1994 drug policy (Rane 1995, Sengupta 1996a) are relatively small, as they are still protected by price controls. TB drug production in India responds to market demand. For a disease of poverty like TB, where poorer patients are unable to afford drugs for the entire course of treatment, the market is a partial and incorrect indicator of actual drug needs based on the burden of disease, estimated using epidemiological data. The NTP has been critiqued for not ensuring an adequate supply of TB drugs (Shiva 1994). Mechanisms of dialogue and negotiation between the NTP, the Department of Chemicals and Petrochemicals and the industry are lacking (interview).

Pharmaceutical companies and drug purchase/supply systems for the NTP: The NTP provides its contribution to States in kind, as drugs and equipment, through the Directorate General of Supplies and Distribution (DGS&D) which functions under the Directorate General of Health Services (DGHS). Drugs are procured centrally through a rate contract system wherein public sector companies receive a slight preference, but lowest tenders get the orders. Some companies lower costs by reducing concentrations of active ingredients. Mandatory quality assurance tests can be falsified (several

interviews*1996[12]. Respondents suggest that informal contacts and commissions paid at different levels play a role at the stage when the contract is made. Ultimately drug purchase orders are passed by the Health Minister, who may also benefit (interview 1996). It is reported that manufacturers are unreliable, sometimes delaying delivery of consignments, affecting supplies to districts. Similar processes occur during drug purchases by States for their 50% share. The consequences are irregular drug supplies to DTC's and PHI's (frequently reported by NGO's and the media).

Production and growth of the combined Indian pharmaceutical sector is considerable (Table 5.8).

Table 5.8 Indian Pharmaceutical Production Trends (Rs. in millions)

Year	Estimated value of formulations	Estimated value of bulk drugs	Total
1947	100	NA	100
1952	350	NA	350
1962	1,000	150	1,150
1972	3,500	600	4,100
1982	14,300	2,890	17,190
1993-94	69,000	13,200	82,200
1996	n.a.	n.a.	90,000

Source: Narayana 1984, Sengupta 1996

Structural changes occurred in the industry as a result of policy instruments used by government. The industry was dominated by foreign owned companies in 1947. In 1979-80, 33% of aggregate investment was in the public sector, 24% in the Indian private sector and 43% in the foreign sector (Narayana 1984). An analysis in 1994 of the top 200 brands found that the share of TNC's was 17.8% i.e. predominant production is in the Indian sector (Sengupta 1996 citing Retail Survey by the Operations Research Group). Before introduction of the Patent Act (1971) TNC's provided 80% of drugs, whereas in 1992, 75% were from the Indian sector (Bannerjee 1996). Rapid economic growth in the industry took place after liberalisation of the

[12] Concrete evidence was difficult to gather, though one case was reported where rifampicin sent for testing contained less than the required amount of active ingredient.

policy (1986&1994). However TB drug shortages continue in the NTP (GOI/WHO/SIDA 1992, VHAI 1994).

In India, the Rs.2050 million TB drug market in 1996 comprised a small part, approximately 3.2%, of the pharmaceutical market (Srivastava 1996). The TB drug market has about 30 main players (top eleven in Table 5.9). They have reportedly benefited from the RNTP as WHO's recommendation of combi-packs 'created a new marketing opportunity leading to a 18.9 crore (Rs.189 million) market' (*ibid*;17). Public sector companies are not mentioned in this market analysis. While Lupin an Indian company has the largest single share, several TNC's have recently entered and are trying to increase their market share.

Table 5.9 Major Players in the Indian TB Drug Market

Company	Rs. in millions	% of total market	TB products at stake within company (%)
Lupin	873	42.6	59
Ciba	239	11.7	23
Cadilla Pharma	106	5.2	11.4
PCI	95	4.6	45.6
Plethico	75	3.7	27
Themis Group	88	4.3	64
Glaxo	92	4.5	2.7
Concept	71	3.5	45.2
Tata Pharma	76	3.7	33.1
Unichem	68	3.3	9.6
Macleod	65	3.2	96

Source: Srivastava 1996

The quantum of drug production, from the viewpoints of industry and Ministries of Industry and Chemicals & Fertilizers, depend on market off-takes, demand and time trends and not on the public health dimensions of the problem (interview 1996). The latter is mediated through the Ministry of Health, a much weaker and often uninvolved player.

Assuming expenditures of about Rs.150 million by Central government on drugs (little over 1993-94 figures), an equal amount by States (the actual spending is always

less), and an equal amount in the organised public sector, the total spending of about Rs.450 million by the public sector is a small proportion of the market. Drug purchasing occurs more in the private sector, even if half the patients treated are in the public sector. This supports findings in Chapter 8 that physicians in the public sector give private prescriptions to their patients. Whether this is justified or ethical from the patients/citizens point of view, and whether small compromises lead to exploiting patients at a time when they are vulnerable and dependant, raise broader questions.

The pharmaceutical sector in India reveals strong conflicts of interest with major stakeholders being Central Government (with fluctuating and contradictory interests), the TNC's (who dominate), and the Indian private sector (subdivided into organised and small scale sector). The carefully documented experience of Bangladesh shows that TNC's use the mediation of international organisations like the WHO, of multilateral donors like the World Bank, and their own home country governments to support their trade interests (Chowdhury 1996). In India TNC's are represented in important Government policy making bodies such as the Drug Technical Advisory Board (Shiva 1996). They often delay implementation of regulations by obtaining stay orders in Court, through employing senior medical consultants as witnesses, and selective use of information (interviews 1996). The NTP by not actively advocating their case, provide tacit support to pro-private sector policies.

The private sector pharmaceutical industry has a close symbiotic relationship with the medical profession. Companies sponsor national and state TB conferences, providing hospitality, gifts, sightseeing trips, and even air-fares for influential participants (observations, interviews).

Pharmaceuticals, insecticides and equipment consume a major part (70-80%) of Central Government expenditure on national health programmes costing millions of rupees per year. Public sector production of TB drugs currently accounts for only 25-30% of the market (interview*1996). The conflict between government's economic policy and health policy is not being addressed adequately, though economic imperatives seem to predominate.

The pharmaceutical policy salience is in contrast to tuberculosis (with greater human social effects and equally strong but negative and less visible economic effect) which has at times been on the agenda symbolically, but not carried through in implementation.

In conclusion, the impact of the pharmaceutical policy on TB control is insufficiently recognised by Indian TB policy makers and programme managers. Govenment policy built indigenous capacity for TB drug production, reducing monopoly by TNC's, lowering drug prices and increasing availability. This has been an important contribution to TB care in the public and private sectors, by the central government (through the ministries of industry and petrochemicals). Market demands are being met, though there is an under-production in relation to estimated epidemiological need. Although it is recognised that market mechanisms do not work well in the pharmaceutical sector, the pharmaceutical industry is a strong political force, and conflicting interests have to be reconciled.

CHAPTER SIX

POLICY CHANGE IN THE NINETIES: THE REVISED NTP (RNTP)

Introduction:

Origins of the 1990's policy change processes, their complex and divergent underpinning forces, and varying perceptions and interests of different actors are discussed in this chapter[1]. Impetus for change in India had a strong international component. Hence TB control strategies of international organisations are discussed prior to the RNTP process at national/local level. Bottom-up patient and staff perspectives on implementation are highlighted briefly.

6.1 Changing Global Dynamics and Perceptions of TB

Although TB continued as a major public health problem for several decades in economically disadvantaged countries (WHO 1988, WHO-SEARO 1994), it became portrayed as a globally re-emerging crisis following its re-emergence in a few powerful countries from the late 1980's. Conceptualising and creating its 're-emergence' as a global/national health crisis, indicates the strength of perceived interests of major players and sections of global society in agenda setting and public health action, even if focusing on the problem in industrialised countries was a strategy to elicit attention, interest and funding for TB.

With 14% of the world's population, India accounts for an estimated 17-23% of new cases annually[2], with a prevalence of 14 million persons (all forms) and 500 thousand deaths annually (NTI 1994c). In comparison China had 1.3 million new cases annually in the 1990's (Dolin *et al* 1994), a prevalence of 5.7 million cases of active pulmonary

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[1] Much data for this chapter is obtained from interviews and observations. For ethical reasons, to protect respondents, especially as this is still a current issue, names/designations are not mentioned.

[2] 9 million new cases per year are currently estimated globally and 2.1 million in India (Dolin *et al* 1994). It was estimated that 1.6 million new cases occur annually in India (GOI/WHO/SIDA 1992).

disease in 1984-85 (Friedman 1994, citing China's national survey results) and 250,000 deaths annually (Dakui 1993). However, the disease reportedly lost salience on the international health policy agenda from the 1970's (WHO 1994), reappearing in the 1990's, when TB rates rose in established market economies/the West (Murray 1994;587).

Increased TB in the West from the mid-1980's was reported following three decades of decline. Reversal of a sustained 30 year 5.3% average annual decline in incidence of TB in the USA was observed in 1985 (Snider 1994), with a 20 % nation-wide increase between 1985-92 and a 30% increase in New York City between 1988-92 (Reichman 1996). CDC estimated 63,800 excess cases between 1985-93 or approximately 8000 cases annually (Raviglione 1995). While 71% of cases in 1992 occurred in racial and ethnic minorities especially Hispanics, Asians, Pacific Islanders and Africans (Snider *et al* 1994), 27-30% of all cases in 1992-93 occurred among foreign born persons (Raviglione *et al 1995*). In Europe cases rose by 27% in Italy from 1988-92, 21% in Norway from 1988-91 (WHO 1994) and 33% in Switzerland from 1986-90 (WHO 1993). Seven of 15 Western European countries reported increased cases, attributed largely to immigration, with HIV contributing only marginally to the excess (Raviglione 1993). An excess of 4000 cases occurred between 1988-1992 in England and Wales (1000/year), when earlier declines in notification rates were reversed (Mangtani 1995, The Independent 1993). Increased absolute numbers in the USA and Europe are small compared to the magnitude of TB in lower income countries. Outbreaks of Multi Drug Resistant (MDR) TB in the USA and co-infection with HIV/AIDS (Raviglione 1995) caused alarm in international public health circles (WHO 1993, 1995). However less than 5% of TB cases world-wide were estimated to be associated with HIV (Snider 1994) and a relatively small proportion have MDR-TB in community based as against hospital studies e.g. 4% were resistant to isoniazid and rifampicin in South India (Datta 1993).

The rise of TB in industrialised countries elicited a global response as articulated by WHO. For instance, '*TB long considered a disease of the past has re-emerged...*', and

'We cannot expect to contain TB in one region of the world. Ultimately control of TB in industrialised nations will depend on its being sharply reduced as a public health threat in the developing world' (WHO 1993;inside front cover). *'WHO is warning that TB cannot be completely controlled in the industrialised world until it is sharply reduced as a health threat in developing nations...'*(*ibid*;press release WHO/31). Similar views were repeatedly expressed (World Health Forum 1993;3, Raviglione 1993;297, WHO 1994;2). This was fuelled by fears of further spread in an interdependent, globalised world, with increased travel, migration (WHO 1993) and movement of labour.

The inaccurate image created, that TB had been controlled globally and recently re-emerged, was reinforced by the media[3]. One story suggested, *'As tuberculosis infection rates plummeted world-wide in the past decades, health authorities relaxed their guard'* (Newsweek, May 17, 1993). Another that, *'TB is Back with a Bang! To many of us, TB is a disease of the past, or at least of the poor'* (The Pioneer, October 3, 1992).

6.1.1 The State: Its Health Services, Funding and TB Programmes

Besides HIV co-infection, reasons cited for the re-emergence of TB, included chronic neglect and under-funding of state TB control programmes (WHO 1993). In the USA targeted federal government TB grants from 1959 resulted in sustained declines of TB in the 1960's (Reichman 1996). In 1970 replacement of targeted funds by general block grants to states for public health services adversely affected TB services and was one of the factors for the resurgence of TB (*ibid*). This was exemplified in New York City where TB control budgets decreased from $40 million in 1968 to $4 million in 1988, followed by substantial increases in TB (WHO 1995). TB funding patterns in the USA were reversed in 1991, but it was feared that block grants would be reintroduced due to declining TB rates from 1994 and local political pressures (*ibid,* Hopewell 1995). European countries on the other hand adopted *'direct government responsibility'* for diagnosis, treatment and prevention as a basic strategy to counteract increased TB cases (Raviglione 1993;304).

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[3] Newsclippings from major English language papers were reviewed. The revised strategy had wide press coverage. This was possibly due to use of the media and press releases by WHO.

In India, NTP budgets increased over time but were inadequate (5.1). Following policy change and international attention the NTP received higher though still inadequate funding, with certain contradictions. The World Bank, which increased its health sector lending to India in the 1990's, advised that infectious disease control programmes should come under purview of the public sector, while general medical care, particularly secondary and tertiary care, should be left to the private sector (World Bank 1993, Duggal 1997). This dichotomy does not hold for TB where it is established that early diagnosis and cure integrated with primary health care is the best control/preventive measure (WHO 1988). As discussed in Chapter Four general medical/health services are crucial to TB control, and reduced budgets to public sector medical care systems, as part of minimising the state, adversely affect general health and consequently TB care. Thus declining trends in GOI central health sector expenditures and declining State expenditures on national disease control programmes (Duggal 1997) counteract increased NTP/RNTP budgets.

Government initiated and run NTP's are termed failures, as being poorly conceived and contributing to rising drug resistance through poor organisation (WHO 1993-96). These statements ignore the fact that basic concepts concerning TB control integral to the RNTP were made by State institutions in developing countries with international collaboration and more importantly that NTP's and basic infrastructure have been laid by the State (Chapter 1&4). They do not explore why funding and organisation are inadequate. While expectations have not been fully realised, gains and the inherent complexities of TB are inadequately acknowledged. In the absence of such analysis and action not suprisingly implementation problems recognised in the NTP have emerged in the RNTP (6.7).

6.1.2 Social Roots and Technical Frames

The situation analysis concerning the re-emergence of TB continues to de-emphasise the social roots of tuberculosis and underestimates the complex conditions under which the NTP's function. Having established the failure of government run TB control programmes, and potential threats of global spread of a disease that '*cannot be controlled by political boundaries*' (WHO 1993;11), the scene was set for international intervention.

'The global community must act quickly to control TB and the growing health threat it presents' (*ibid*;12). The international public health community have not played a significant role in drawing attention to relationships between underlying structural causes of poverty and the continued presence of TB as a global problem. Political economy factors including unfair terms of international/national trade and finance, cause millions to live in poverty, with overcrowded housing, poor nutrition, hard labour, stress, long working hours, in polluted environs, or unemployed. These conditions comprise the basic causal factors for TB to develop and spread (Table 1.3). This '*social suffering*' which has merited little public health action, requires '*health care systems to extend their gaze towards the social construction of disease and suffering*' (Benatar 1997;1635). In relation to TB this social perspective, acknowledged by Dubos and Dubos 1952, GOI 1946, GOI 1961 and described more sharply and politically as a by-product of 'structural violence' (Farmer 1997) has few proponents in the RNTP debate. Health professionals working as NGO's, academics and researchers attempting to place TB and its control in the context of a global societal analysis during the current policy discourse (VHAI 1994, Quadeer 1994, Banerji 1996) are considered unrealistic and marginalised from policy discussions, or 'managed', being invited to meetings to share views, which are subsequently ignored (interviews 1996).

The role of purely technical interventions in achieving sustained success for a socially rooted disease, especially for populations living in continuing poverty, can be debated[4]. Sri Lanka in earlier decades (interviews 1995) and Cuba achieved success despite poor economic circumstances because TB programmes were part of wider national health and development efforts (Gonzalez 1994). Incidence rates of TB in Cuba declined from 11.6/100,000 in 1979 to 6.2 in 1987 and 4.7 in 1991, the mortality rate in 1991 was 0.2/100,000 while primary drug resistance declined from 6% in 1982 to 2.4% in 1991, MDR strains are not identified and no reversal of the declining trend has occurred (*ibid*;192-193). However it is rarely mentioned in the current discourse.

[4] IUATLD programmes discussed in 5.2.1.

The revised strategy continues in the dominant bio-medical frame re-emphasising techno-managerial interventions. It narrowed this further by not recognising adequately the importance of good quality general health services within which the RNTP must function. Very prescriptive planning could reduce the space for implementors to evolve area and situation specific, flexible, humane, community based, alternatives for action and discourse. Strategies neglect the need for social support and rehabilitation, for community participation, ownership, empowerment, and for building alliances with movements for development and social justice[5]. TB patients become objects in this frame, in which the TB programme is projected as being more interested in their welfare than they are themselves. Directly observed therapy promoted to overcome treatment non-adherence/non-compliance/default ignores the life circumstance/social class barriers to regular, complete treatment, in which inadequate health services for the poor pose additional obstacles. Though described as a supportive partnership with patients (interview 1997) the medical profession or WHO does not use DOTS for diseases not perceived as threats[6].

6.2 International Actors and Policy Change

6.2.1 The International Union Against TB and Lung Diseases (IUATLD)

The IUATLD, a non-governmental, professional association, headquartered in France, active internationally in TB control since 1920, contributed to global TB control through mutual assistance, educational and public policy programmes, helping TB control programmes in developing countries from the late 1970's (Snider 1994, Enarson 1995, Reichman 1996). It was the main internationally active group at this time. Programmes developed in Tanzania, Malawi, Mozambique and Nicaragua achieved cure rates of 70-80% at a cost of about US$47 per case detected (WHO 1994, 1995, Enarson 1995). In Tanzania 'the average cost for curing one patient, including staff costs, transportation and other infrastructure costs, was under $200' (WHO 1995;6). TB programmes in these countries depend on external assistance for 40% of their funding (Enarson 1995). Adverse

[5] This applies to the NTP as well.
[6] It is used for leprosy and Sexually Transmitted Disease's (Porter and Ogden 1997).

impacts of vertical programmes on general health services in Tanzania, with other health problems not getting the attention they need, question the sustainability of the programme (Nagpaul*1995). A controversy arose about the International Union's use and recommendations for hospitalisation during the intensive phase of chemotherapy to ensure supervised therapy/compliance, with final consensus for domiciliary supervision (Editorial, IndJTub. 1987). Hospitalisation was not necessary (TCC 1959) or feasible/sustainable in many circumstances and WHO guidelines recommended that 'it has no value per se in the management of TB patients' (WHO 1993b;19). Successful features of the IUATLD approach included: use of 8 month SCC (2 months intensive phase of daily isoniazid, rifampicin, pyrazinamide and streptomycin under strict supervision including hospitalisation); uninterrupted supply of good quality drugs/other materials; network of microscopy centres; recording and reporting cases and treatment outcomes; staff training and supervision; and political commitment of government (Snider 1994). The model, assessed by the Health Sectors Priority Review of the World Bank in 1989, was adopted for developing countries by WHO and used in China (Enarson 1995). Dr. Styblo of the IUATLD visited several countries, including India, as technical advisor (Chopra*1995). The New York City epidemic using similar principles reported considerable success in cure rates, with a 21% decrease in reported cases from 1992-94 (Frieden 1995). However costs were high, approximately US$20,000 per patient in New York City (*ibid*;232), which increased its annual spending on TB to more than $40 million annually by 1993 for a population of 18 million (WHO 1995). Transport costs, food vouchers and other incentives were given to patients (*ibid*). Direct and indirect costs of the TB epidemic in the USA are estimated to be over 2 billion by 2000 AD (WHO 1994;10). This scale is inconceivable in India and appears not to fit with the cost-effectiveness claims for TB control. The approach, adopted in the World Bank supported project in 1991 in China (WHO 1995), is reported to considerably exceed the projections of cost per death directly averted made by the WDR 1993 (Bogg and Diwan 1996).

6.2.2 Past and Present TB Control Policies of the WHO

During the 1950's WHO supported Training and Demonstration Centres, epidemiological surveys, mass BCG campaigns (WHO 1965), and Isoniazid monotherapy as part of chemotherapy till the problem of drug resistance was realised. It then promoted NTP's in the 1960's-70's (WHO 1964, 1974). Some principles of the NTP were precursors of Primary Health Care (Mahler 1985). These include giving primacy to people, using a need based socio-epidemiological approach, developing appropriate technologies/systems and integrated health systems (Banerji 1990b). After the Alma Ata Conference in 1978 TB dropped from the international health agenda as a specific disease programme.

Though a single officer looked after TB at WHO from the 1970's-1989, it was integrated into primary health care and statements regarding basic causative factors were explicitly articulated (WHO 1982, 1988). For instance, inter-relationships between socio-economic conditions, dually with TB and efficiency of TB programme implementation, were specifically recognised by a WHO/IUAT study group which concluded, '*economic development based upon basic egalitarian principles is paramount for the final control of TB*' (WHO 1982;26). '*Fundamental changes in the world economic structures are called for and are basic for the long-term solution of health problems.... emphasising bilateral and multilateral transfers of resources*' (*ibid*;21). It was observed that disease specific programmes were established '*often with external urging and assistance*', '*strongly influenced by external donors and indigenous doctors with specialised interests*' (WHO 1988;7). Since vertical programmes '*competed with each other for ...scarce resources*' and were '*wasteful and relatively unproductive*', TB control was integrated into Primary Health Care (*ibid;*7). However the broader based approach met with early resistance and was soon verticalised (Banerji 1993) reducing the potential it had to provide a strong base for TB/other programmes.

During this period WHO played a facilitatory role, channelling assistance, (e.g. from SIDA to the Indian NTP) and supporting training of personnel from developing countries at various centres e.g. the NTI (a WHO Collaborating Centre), India and the TB Research

Institute, Tokyo, Japan (interviews 1996). WHO drew on national consultants for TB related work in member countries, with Indian consultants going to the Philippines, North Korea and other countries (Nagpaul*1995). Since TB had declined as a problem in Europe the number of experienced European TB consultants also declined (Tiroler*1995).

Dr. Kochi headed the WHO TB Unit from 1990, facing a worsening global TB situation. To have a positive impact on TB control, targets of curing 85% of detected sputum smear positive cases and detecting 70% of existing cases by 2000 AD were set by the WHO World Health Assembly in 1991 (WHO-SEARO 1994). A small team developed into the Global TB Programme assessing the global situation, undertaking country reviews, and initiating a new package of action (WHO 1993-97). This team in WHO placed TB on the international health agenda, for example by getting TB declared a Global Health Emergency on 23 April 1993 (WHO 1994). It publicised the TB epidemic by hiring an international public relations firm (Reichman 1997). WHO worked with national governments to give TB higher priority, with bilateral donor agencies to increase external funding for TB programmes in countries with the largest problem, with the pharmaceutical industry to revive research towards new TB drugs (which had declined in the 1970's after TB was controlled in the West), used the media and professional advocacy to promote the cause, promoted operations research to refine the programme and worked towards evolving methods for patient education (WHO 1993-97). Some argue that the WHO does not cooperate adequately with national and international NGO's including the IUATLD underutilising their resources (Reichman 1997). They refer to 'political minefields and internal competition between segments of WHO and its TB programme' (*ibid*;9).

The rationale for WHO's renewed interest in TB was that it was the largest adult killer among infectious diseases, with cost effective interventions, but low priority since 1975 and likely to become unmanageable if no action was undertaken. The worsening TB situation was due to demographic growth, HIV co-infection, population movement,

deteriorating social environments and emergencies, and inadequate control efforts (Kochi 1995). In Southeast Asia lack of leadership, diagnostic facilities, trained personnel and technical expertise for TB control were identified as problems, in addition to adoption of a centralised approach to control activities and low awareness concerning the problem (WHO-SEARO 1994).

TB was linked to social justice at the 1993 World Health Assembly, '*TB is closely associated with conditions of poverty, and those social justice groups and non-governmental organisations interested in assisting communities to deal with the root causes of poverty should make TB control an element of their strategies'*(WHO 1993, WHA/14). Justice dimensions were again stressed (WHO 1994;1), appealing to the humane element, '*Who would refuse to spend $30- the cost of TB medicines in many countries to save this human life?*'. An understanding of the implications of these statements with a clear social perspective are not evident in the strategies that have evolved, which continue to be time bound and within a rational, scientific frame. Political processes and struggles involved in social justice issues appear taken for granted.

The WHO TB Programme assumed global leadership in 1993, stating its '*regional and country level structure and contacts within individual ministries of health...make it uniquely suited to lead the fight against the TB crisis'* (WHO 1993). Its objectives to reduce TB deaths by half by 2000 AD and cut transmission and infection rates by identifying and treating smear positive patients till complete cure was endorsed by the World Health Assembly in 1993 (WHO-SEARO 1994). The strategy included (*ibid*) a) passive case finding[7] with direct microscopy for smear positive cases, b) standardised SCC for all smear positive and seriously ill sputum negative patients, with proper case management incorporating supervision/direct observation for the first two months. Four drugs during the initial phase (2-3 months) were recommended to avoid emergence of drug resistance, and a full course of treatment ensured to avoid relapse. c) drug procurement, uninterrupted supplies, timely delivery and adequate drug stocks. d)

[7] Case detection among symptomatic patients self reporting to health services (WHO, 1997, 5).

monitoring systems at district level with data on new cases, relapses and treatment outcomes.

The action plan was to: co-ordinate and target resources; use its experience and credibility with governments in the developing world to organise effective programmes; and co-ordinate control efforts and international research. Specifically, within two years it aimed: 1) to create political will; 2) disseminate WHO's treatment policies; 3) assist additional nations; 4) focus donor funds on priority TB projects; 5) improve drug supplies; 6) produce a simple and rapid test to improve TB diagnosis; 7) develop better methods to treat TB in countries with high rates of HIV infection (*ibid*). These were ambitious goals given the time frame and deeper societal factors operating and suggest that the complexity of processes was under-estimated.

In 1995 '*a battle plan for fighting TB*' was identified by WHO to '*prevent at least 12 million deaths from TB in the next 10 years*' (WHO 1995;24). Directly observed treatment, short-course (DOTS) where '*health workers must watch their patients swallow each dose of medicines. This supervision must continue everyday for the first two months and, ideally, for all six months of treatment*' (*ibid*;3). DOTS was identified as '*the key to curing the patient and controlling the TB epidemic*' (*ibid;*15). It made the point that TB control cannot succeed unless health care workers are highly involved in their patient's lives (WHO 1995). In 1995 the Co-ordination, Advisory and Review Group of WHO's Global TB Programme recommended strengthened monitoring of detection and treatment of sputum positive cases to document and report progress towards the programmes Year 2000's targets annually (WHO 1997b).

Seven countries, including India and China, all low to middle income, with large populations and major TB problems were targeted as high priority (WHO 1994) and interventions initiated. In India, a programme review of the existing NTP was the first step (GOI/WHO/SIDA 1992). In China (1991) and later in Bangladesh the policy was initiated directly with World Bank loans. Training modules for managing TB at district level were initiated. The South-East Asia Region emphasised that, '*besides the*

conventional approaches being adopted in most countries, there was a great need to formulate new practical strategies aimed at integrating control measures with Primary Health Care' (WHO-SEARO 1994;1).

The current TB control package for 'the success of its strategy' rests on 5 points :

i) government commitment to the NTP, ii) passive case finding, iii) short course chemotherapy for all smear positive PTB cases, under direct observation for at least the initial phase of treatment, iv) regular uninterrupted supply of all essential TB drugs, v) monitoring system for programme supervision and evaluation (Harries and Maher, 1996).

Four points were already components of the NTP in India. The fifth, namely SCC has been introduced gradually since 1982-83 covering 259 /506 districts, limitations for further rapid extension being budgetary. The additional element of direct observation is controversial. Principles underlying DOTS, of supervised and intermittent therapy, were reported first reported from Madras (TCC 1964), with several subsequent studies. Because of poor results under field conditions it is not widely used in the NTP. In Bangladesh directly observed therapy used from 1984 through an NGO programme with community health workers achieved 85% cure rates in the 1990's (Chowdhury 1997).

While the WHO strategy appears rational, logical and scientific, it has backtracked on the socio-political underpinnings of the 1970-80's and has not built on implementation lessons of the past. At the end of 1994, WHO estimates were that 10% of TB patients globally were under the new strategy. By 1995, 23% lived in regions where the strategy was available (not the same as coverage), 35% were sputum smear positive, with 76% treated successfully compared to 42% in regions not implementing the WHO strategy (Raviglione 1997). Thus, assuming the validity of routine data, progress was slower and achievements lower than anticipated, even in the early honeymoon phase of policy implementation.

6.2.3 The World Bank (WB)

The Bank, a more recent, important player in international public health (Buse 1994) made its presence felt in the TB arena in the 1990's, becoming the largest financier to TB

programmes in developing countries (WHO 1996). Promoting TB treatment as one of the most cost-effective public health interventions (World Bank 1993;63), they urged governments to adopt national TB control programmes. The WB utilised the leverage of lending capital to underfunded TB programmes and supported, often as a conditionality, WHO's specific, time bound, measurable global strategy. In India the WB moved into health development programmes in 1990, with priority to disease control (WHF 1995). Loans for leprosy, HIV/AIDS, blindness, strengthening secondary care hospitals were negotiated. In this context the propagation of western medicine on behalf of multinational drug and health care companies was questioned (Srinivasan 1995).

The WB offered 'soft loans' to targeted countries for TB control programmes, using WHO's technical consultants and conditional to countries adopting WHO's global strategy. Bilateral agencies provided supplementary support. The relatively united and coordinated approach by WHO, WB and bilateral donors narrowed the space for negotiation by national policy makers. The effect of other WB/IMF policies particularly Structural Adjustment has increased the burden on the poor and reduced their access to State health services (Loewenson 1995).

International actors, particularly a small group of individuals within these organisations, played a key role in promoting policy change through the RNTP. This analysis shows that the roles of international actors differed markedly in the 1960's and the 1990's. During the earlier period of close international collaboration and policy change in 1962 the NTP-DTP concept arose from within the country (in India), supported by the UNICEF and WHO, but not driven by them (Banerji 1993). Concepts were challenged and changed using an inductive approach with indigenous research, with mutual respect and shared beliefs of social relevance, self reliance and international solidarity. This received acknowledgement. IUAT/WHO '*emphasised the major role played by underprivileged countries in the development of modern chemotherapy, from which the affluent countries have been the major beneficiaries'* (WHO 1982;21). Similarly, '*in so many aspects of tuberculosis the western world owes a debt to developing countries and particularly to India where many excellent studies on TB have been done in the recent past'*

(Grzybowski 1983;preface). In the 1990's international actors are proposing a particular strategy rather inflexibly generating unconstructive conflict in the process and Indian partners are not engaging with the earlier spirit.

6.3 India's National Context in the Nineties

The political climate in India changed since the idealism of the post-Independence period during which the NTP was articulated. During the 1980's and 1990's there was a rise in sectarianism, parochialism, fundamentalism and criminalisation of politics (Parthasarathy 1997, Brass 1994). Political leadership appeared short-sighted and was criticised for developing a *'politics of patronage which extended the scope for the pursuit of self-interested power by privileged social groups both within and outside the State system. Without a will to implement the mandates, state intervention and development policy were highly politicised'*(Pannikar 1997;82). There was frequent change of government with four governments in quick succession, three without majorities, and the assassination of Rajiv Gandhi in 1991 (Patel 1995).

Many observers felt the most positive development has been the legal strengthening of the process of democratic decentralisation to *Panchayati Raj* institutions (local government at district, *Taluk* and village levels) by the 73rd Constitutional Amendment Act, 1992. Their role in ensuring better quality of care in health care services is widely recognised (World Bank 1992).

India had stayed out of the debt trap till the 1970's, but external debt grew to 20 billion dollars in the 1980's and nearly 80 billion dollars in 1991 (Patel 1995). Debt servicing rose from under 20% to over 30% of export earnings *(ibid)*. Compulsions to bring in foreign exchange to the country grew. The process of privatisation accelerated in the mid-1980's and India entered the Structural Adjustment Programme with the New Economic Policy in 1991 (Duggal 1997) reducing barriers to liberalisation and globalisation.

With 14% of the global population India currently has 28% of the world's poor. In absolute numbers the poor are about 360 million, the population of the entire country in

1951, (Reddy 1997). The importance of rapid economic growth for the elimination of poverty has long been recognised by the Planning Commission. While liberalisation increased GDP growth rate close to 7% during 1994-95 to 1996-97, there has been inadequate attention to distribution and equity issues and the development of the social sector *(ibid)*. Inequalities in income, wealth and economic power widened. The proportion of indirect taxes to direct taxes increased, with lower income groups contributing an increasing share of government's revenue and expenditure (Patel 1995).

During the 1990's growing numbers of corruption scandals in several Ministries, including health, increased public scepticism and cynicism about the government and its policies. Widely reported in the media, including details of judicial investigations, they include the HDW and Bofors Scam in 1987, Securities Scam in 1992, Sugar Scam 1994, Jain Hawala Racket in 1995, JMM case in 1995, Housing Scam and Telecom Scandal in 1996, to name a few (Outlook 1997). This added to widespread corruption of smaller magnitude at lower levels of government.

Thus the broader context within which the RNTP functions is more complex and difficult than that facing the NTP. The direction of the economy and the political economy of the pharmaceutical industry (Chapter 4) and of international aid are important forces shaping health and TB policy (Newstime 1994).

6.4 RNTP Policy Process in India

Real expenditures on disease control programmes were stagnant during 1985-91 (Index 1984-85=100), falling during the adjustment period (Index 92-93=83), when compression of government expenditure was required by the Structural Adjustment Programme (Tulasidhar 1993). In 1991-92 the MOH prepared an annual proposal for Rs.7000 million, double that of the previous year, later reducing it to Rs.5020 million. The Ministry of Finance cut it further to 90% of the previous years budget. This was restored to the level of the previous year by the Planning Commission. This included a new World Bank loan for Rs.580 million out of a health budget of Rs.3020 million that year, so that actual health sector allocation was Rs.2440 million (World Bank 1992). Thus in effect

there was a 20% reduction in the health budget including for the NTP. The malaria budget was reduced by 40% from Rs.830 million to Rs.500 million (*ibid*). This has a ripple effect since male Multi-Purpose Workers, involved in many communicable disease programmes including the NTP, were paid under this budget. There was also a 30% cut in rural water supply programmes and a 47% cut in the rural sanitation programme (*ibid*). Health budgets changed not in response to health needs but to financial and political economy imperatives.

On being advised by the World Bank that the NTP budget cut was too drastic, the GOI raised it in 1992-93 (VHAI*1994). This exemplifies how multilateral agencies such as the World Bank intervene in policy processes at least with regard to budget setting and how decision making moves out of the sphere of national policy managers.

The formal process of discussion/negotiation between the WHO, WB and GOI was initiated in 1990-91, resulting in the 1992 Joint Programme Review of the NTP (GOI/WHO/SIDA 1992). Though done apparently on request by the GOI, the real initiative appears to have come from international organisations (WHO 1994). It was also just 4 years after a nine month, research based 'In-depth Study of the NTP', commissioned by the GOI and supported financially by WHO (ICORCI 1988) whose findings were largely ignored (interview 1996). WHO's renewed and increasingly proactive interest in TB was made known through informal and formal channels along with the possibility of funding for TB programmes through the World Bank (interview 1995). Informal linkages, networks and communications were important in the initial phases and in decision making even at the national/international interface. Formal processes including studies/research took place later, playing a legitimising role.

Besides there being a need for foreign exchange, the TB programme was underfunded. The WHO, World Bank and international experts were therefore invited in. Unutilised money from SIDA assistance allocated for the NTP (for drugs, X-rays) was used for the Review (interview 1994). A senior official said this was 'a sad and scandalous story' because of the resulting countrywide shortages of TB drugs in the NTP (interview 1996,

reports by NGO's, Sudarshan* VHAI*1995). This was the year following introduction of SAP and the 20% NTP budget cut.

The Joint Programme Review team of 27 members with seven external consultants completed work in seventeen days (weekends included). Three subgroups visited 3 States (Gujarat, Tamil Nadu and Uttar Pradesh) interviewing state level officers and paying brief visits to PHC's and sub-centres. A report prepared earlier by the NTI was extensively used (interview 1996). A review team member said that certain inputs and comments by experienced Indian TB workers were excluded from the final report (interview 1995). Technical officers from the TB Association of India were met briefly at the end of the study, more as a courtesy call than for substantive discussion (interview 1995). There was little reference to the 1988 study. Recommendations included: strengthening central/apex policy making authority, establishing diagnostic criteria, ensuring quality of microscopy, using three smear examinations for diagnosis, short course chemotherapy, uninterrupted drug supply, cohort analysis of treatment outcome, decentralised treatment, treatment organisers and laboratory supervisors at subdistrict level (500,000 population), developing training materials, conducting operations research and pilot projects (GOI/WHO/SIDA 1992). Three sputum examinations and subdistrict staff were new, and observed therapy was not yet named DOTS. Given India's research history in the NTP/TB, the review could be said to have been used to internalise new strategies and create local ownership for policy change, which was projected as a GOI initiative. The GOI then applied to the World Bank for a loan to implement the Revised NTP (TB Division 1995b).

As a loan requirement, national financial commitment to the programme had to be forthcoming, hence the government increased the central budget for TB progressively from Rs.100 million in 1991 to Rs.500 million in 1995-96 from local resources (MOH Annual Reports). However in 1993-94 the TB Unit in the DGHS did not expend the enhanced budget allotted to it (Chopra*1995). The loan being negotiated was for US$150 million for a 3 year period and was conditional to the Revised NTP being introduced,

with the use of the WHO strategy which in 1995 (still within the prolonged negotiation period) had DOTS as its key component.

The Ministry of Finance and Department of Economic Affairs had informed the DGHS that it was necessary to secure this loan from the World Bank (interview*1996). Thus there were different interests within government and the key decision was already made. Whether seriously ill patients or health workers had to travel several kilometres for treatment thrice a week was immaterial.

An early approach paper for the Revised NTP (RNTP) focused on tribal populations/areas in five States, Bihar, Gujarat, Kerala, Himachal Pradesh, West Bengal (TB Division 1993). Selective attention to tribal populations was subsequently dropped from the proposal.

A draft proposal was revised following discussions with the World Bank Preparatory Mission in November 1993 and the WHO Technical Mission in April 1994. The proposal then envisaged implementing the RNTP in the same 5 states and 10 metropolitan cities (Bombay, Calcutta, Delhi, Madras, Bangalore, Hyderabad, Pune, Jaipur, Lucknow and Bhopal). 187 million people comprising one fifth of India's population were to be covered with an estimated budget of Rs.6340 million over 5 years (TB Division1995b). Reported figures regarding the total population to be covered and the size of the loan varied with time.

Later attempts to focus on urban TB control were justified by a 7.7% growth of the urban population from 17.9% in 1961 to 25.7 % in 1991. The then DDG-TB said, 'It is important to note that the infrastructure for TB was more organised and efficient in terms of domiciliary management in rural areas compared to urban areas' (Datta 1994). It is recalled that since TB was considered an urban problem till the 1960's, most TB infrastructure was urban. Even today, the 330 TB Clinics, 47,300 TB beds, general hospitals, medical college hospitals are urban. DTC's too are located in district headquarters towns. As discussed in Chapter 4 rural health services are still inadequate,

with lower funding, smaller number and poorer quality of services for rural areas comprising 74.7% of the population (ICMR 1975, Banerji 1985, Chatterjee 1988, ICORCI 1988). It is too early to halt NTP's attempts to reverse the imbalance.

In June 1994 the Pre-Appraisal Mission of the World Bank suggested, 'to have further experience and to identify the most suitable strategy the project may be implemented in a limited area of 10 cities and 5 districts of 5 states', financed by its Project Preparation Facility (TB Div.1995b;6). Pilot Phases were small. Phase I initiated in October 1993 covered 2.35 million people, in small pockets within four cities- Delhi (1 million), Bombay (350,000), Calcutta (300,000), Bangalore (250,000), and one rural area, namely 2 *taluks* of Mehsana district of Gujarat State (450,000) (TB Division1995b). This was supported by the PPF and unspent SIDA money for the NTP, with technical support by the WHO, till the end of December 1994 (*ibid*). Sputum conversion rates at 2-3 months were reported to be 90% (Banerji 1996). Phase II covered 15.83 million people with World Bank Assistance of 1.2 million US$ (TB Div.1995b). Assessments by the WHO Technical Mission found the pilot phases to provide good results and the revised strategy was accepted (*ibid*). The RNTP aimed to reduce ARI by 8-10% a year from the current 2-2.5%, increase case detection to 70%, increase cure rates to 85% and above, reduce relapse rates and chronic cases to less than 5%, and failure and case fatality rates to less than 2% (*ibid*). Its objectives were to emphasise cure of sputum positive and seriously ill sputum negative patients through supervised SCC and augmentation of case finding to 70% only after achieving desired cure rates (TB Div.1995b). Strategies included passive case finding with sputum microscopy, standardised treatment regimens; creation of sub-district supervisory units; regular uninterrupted drug supplies to the periphery; augmentation of organisational support at central and state levels for co-ordination; emphasising training, IEC, Operational Research, and NGO involvement; and increased budgetary outlays (*ibid*). The targets derived from IUATLD studies in small countries with substantial external assistance. It was unclear what the denominator for case finding was i.e. prevalence or incidence (Chakraborty* 1996) or how cure rates for non-sputum smear positive cases (50% of all cases) were to be determined. A senior Indian researcher,

appointed as technical consultant by WHO to write-up the RNTP proposal, left following disagreements regarding the concept of control, DOTS, and the lack of freedom, 'we have to accept everything' (interview 1996). This again points to the international locus of decision making and rigidities in policy change and to conflicts with the national level.

Bilateral Agencies: WHO worked with international donors, including bilateral agencies to increase funding for TB. The Health and Population Division of the British ODA (later DFID, Department for International Development) after a process of dialogue and consultation, identified 'specific disease problems that are predicted to increase (TB, Malaria and HIV)' as one of three priority areas for funding in mid-1993 (Grose*1995). Joint Pre-Appraisal Missions of the three international agencies (World Bank/WHO/ODA) took place in November 1994, February 1995, October 1995, February 1996. From January 1995, ODA supported Phase II of the RNTP for 18 months initially, in capacity building, training, research and service delivery (ODA 1995) by: a) strengthening the Central TB Division during the PPF period, till the larger World Bank project assistance was available (support for additional office space, equipment and salaries for continuation of extra staff); b) supporting the development/ adaptation of training modules to be used during Phase II and subsequent scaling up of the project. To design a mechanism to reorient clinical and laboratory education for newly qualifying health staff; c) covering 5.3 million people under the RNTP at 2 sites in Delhi (Nehrunagar and Motinagar) and in Medak District of Andhra Pradesh state as ODA was 'very interested in DOTS and to see if it is a workable solution'; and d) supporting operational research in these sites.

From mid-1994 ODA also supported the WHO TB Programme promoting TB research in India by building up a cadre of young Indian researchers, outside of the NTI and TRC, through supporting Operations Research. A grant of £486,000 was allotted for 2 years and a research co-ordinator appointed in 1996 in Delhi, based at the WHO-SEARO Office.

DANIDA, the other bilateral agency involved, planned to integrate TB services with its support to leprosy work in tribal regions of Orissa using a community based approach (informal discussion 1995). Japan Grant Funds supported workshops and training programmes.

Although international collaboration in the RNTP increased financial resources to TB control, and generated interest/debate among political leaders, the bureaucracy, academics, NGO's and the media (TAI 1995, 1996, newspaper reviews), it also caused considerable conflicts between groups. Select patients in the pilot sites benefited. However the process had problems with delays in staff selection, staff turnover, conflicts, suspicion, play of institutional and other interests and the development of bureaucracy (interviews 1995-97). As in the NTP, these impacted on implementation, even for the small populations covered. Attitudes of some international consultants were sometimes perceived to be patronising and unhelpful, as was the secrecy/lack of transparency of some national negotiators (interviews 1996-97). Negotiations regarding the loan between GOI, WB and WHO were protracted, taking over five years until 1997. The GOI wanted to cover the entire country with SCC (with more than half the country already covered over the past decade), while the WHO wanted it in stages. At one point the GOI said it would pull out of the negotiations and not take the loan. The WHO/WB too threatened to go to Parliament and expose a reported drug procurement scandal. Conflicts between and within donor/international agencies occurred, as they did within Indian groups (interviews and observations). Some wanted to demonstrate success quickly, pushing processes beyond their capacity, so that final negotiations and transactions were completed. The promotion of commercial interests through the well known aid and trade linkages were anticipated. Drug purchases accounting for 50% of the loan were to be based on international tender and preference to MNC's were possible, with the example from Bangladesh cited, where tenders were undercut below the 15% advantage given to national companies (Shiva 1994). The contracts for 1994 went to Ciba-Geigy (interview 1996).

NGO's and Academics: NGO's became engaged in the policy change process/debate from 1993. Most had previous involvement in issues concerning TB and challenged some basic assumptions of the RNTP. The Voluntary Health Association of India (VHAI), a national federation of State Associations, has articulated concern about the NTP since 1978-79 (Shiva*1996). Providing a platform for discussion on TB policy issues they organised a national consultation in 1994, smaller meetings between NGO's, with government policy makers, and with international organisations in 1995-96, bringing out publications and setting up a task force in 1996 (VHAI 1994& 1996, Shiva *1995/1996). The Nucleus for Health Policies and Programmes, Delhi was actively involved with preparation of critical documents (Banerji 1996) and in meetings. The Foundation for Research in Community Health (FRCH) with several research contributions since the late 1980's. Action Aid, India, was involved with advocacy at national level and training/field involvement through partners at State/local levels (Action Aid 1996).

Arguments raised by NGO's (from interviews and participation in several meetings 1994-96) concerned the fate of the majority 4/5th of the population not covered by the RNTP, unfair disparity between proposed budgets for a small segment of the population while the majority remain in an under-resourced NTP, sustainability of the programme beyond the loan period, furthering international debt problems by taking World Bank loans, the ethics of conditionality being imposed by multilateral agencies, lack of transparency regarding negotiations, inadequate protection of the interests of TB patients by national policy makers in pursuit of personal interests, promotion of commercial interests of pharmaceuticals and manufacturers under the guise of better quality, and above all the continued neglect of general health services through which any TB programme would have to function.

Academics critical of the RNTP hypothesised that community effectiveness would be around 55%, being dependant on several factors (best estimates as percentages): diagnostic accuracy 80%, treatment efficacy 95%, health provider compliance 90%, doctor compliance 90%, and coverage 90% (Joshi, at TAI 1995). It would probably be lower with lower rates for most factors (*ibid*). With poor organisational management,

possibilities increase of accelerating drug resistance consequent to introducing second line drugs on a mass scale (VHAI 1994).

International NGO's/consultancies: Smaller, less visible, players in the RNTP process were foreign consultancy firms/consultants/institutions to whom projects were subcontracted. Consultancy rates, access to national policy makers/information and non-participation in implementation were resented by officials in India, especially when inexperienced academics come and learn the basics of TB and its control, while being paid as consultants (interviews 1996). Many felt that the furthering of career and home country institutional interests were at the cost of the programme/patients in India, through diverting funds and utilising the time of national policy managers.

Examples of contracted consultancy groups include INMED, a US based NGO, contracted to develop strategies to involve NGO's and private practitioners in the RNTP. After a preliminary visit by INMED staff in March 1995, one day national meetings on the subject were organised in September 1995 and February 1996 (observations of meeting, September 1995). The morning sessions of one were devoted to participants being told about RNTP strategies and virtues with little discussion. Some consultants facilitating later working groups were inexperienced, asking participants (including Dr. Banerji and the NTI Director) why India needed an NTP, and continuing disastrously, till another person came to assist the facilitator. Senior Indian experts walked out of the session. Participants questioned the necessity and usefulness of expensive, uninformed consultants facilitating such meetings. A consultative process between powerful groups such as the public and private sector, with conflicting interests, requires strong and informed facilitation and mediation, if decisions and action are to result.

The IDA in its support to the RNTP provided funds from the Netherlands Fund. A Dutch consultancy group FEMCONSULT contracted to develop appropriate health education messages, conducted a mullet-centric rapid appraisal study assisted by local No's. Indian experts felt their findings, recommendations and outputs (FEMCONSULT 1995) did not add to existing knowledge (interview 1996).

Important Issues: Several programme staff felt that failure of the RNTP was inevitable, without improvement of general health services (interviews*1996). Others are apathetic and uninvolved, except a few in the Central TB Unit whose task it is to pilot the RNTP through.

Internationally driven, specifically detailed strategies, linked to conditionalities, are moving the programme towards a centralised, vertical structure. It is argued that conditionalities are mechanisms by which the interests of the poor are protected against corrupt governments (interview 1997). In the NTP curiously, corruption at top levels occurred on a large scale after negotiations for loans, and the accompanying conditionalities, were initiated (6.7).

The insistence on directly observed therapy elicited widespread doubts locally, nationally and internationally regarding its implementability and ethics (several interviews*1996, Porter and Ogden 1997). Short Course Chemotherapy is accepted as best practice, despite differences regarding dosages, regimens and duration of treatment. There is however little consensus regarding observed therapy. By official definition in urban areas, patients are required to visit the health centre three times a week for the first two months of treatment (24 visits/patient), and swallow nine tablets/capsules in the presence of a health worker or any government functionary. Treatment for the remaining 4-6 months is unsupervised, during which non-adherence could occur. In rural areas health assistants (in addition to other work) are to visit the patients' homes, covering distances of 3- 5 km, often walking in inclement weather, to supervise treatment for two months. Anticipating difficulties planners suggested involving family members, traditional birth attendants, school teachers, *panchayat* members, common standby's for public health problems in India. Previous NTI studies suggest that these are not sustainable alternatives. Staff suggest that observed therapy by a health worker is impractical in India. Many feel that attention to DOTS obscures and diverts attention from more important issues in policy implementation. Despite these arguments the stakes on DOTS are set very high by WHO and WB.

National Political Policy Processes:

A very small group of national policy negotiators made space for introduction of the RNTP (two of whom were classmates). Key Indian negotiators were rewarded for their role (Banerji 1996), with 2 getting jobs in the WHO-SEARO Office, another a sabbatical at Oxford, and another moving on to a higher, more prestigious position from where he still negotiates for the RNTP. More importantly, from an implementation perspective none stayed sufficiently long to see the project start. None of the present implementors, including the highest, were part of the decision making process.

The key government institution for the programme, the NTI, was distanced from the actual policy process. However staff from the Institute did not seize the opportunity proactively to make their views heard at important national and international meetings (interviews 1996). They suggested that decisions were made at levels beyond their influence. Hence, they adopted a wait and watch approach, pushing for inclusion of research to study the efficacy and impact of the RNTP (interview 1996). Institutional roles at different levels were replaced by short term contracts to national consultants/ annual contracts for supervisory staff in the field, often re-employing retired NTP staff making it likely that old methods will continue (interview 1997). A process of deinstitutionalisation disrupts relationships, reducing a sense of ownership, continuity and accountability.

The post of DDG-TB was frequently changed during 1991-96, the period of policy change, with resultant lack of continuity, stability and leadership. Dr A took charge from 1992-94. Dr. B, incharge of the National Leprosy Eradication Programme held additional charge of TB for a few months in 1994. Dr. C, 'not a TB man' then took over for about 3 months in early 1995 prior to his retirement. Dr. B was again given additional charge of TB till his promotion as Additional DGHS. Dr. D, from the Iodine Deficiency Programme then took over. Programme officers comment that "the NTP is orphaned at the highest level" and observed, 'we need a person at the top who can protect the NTP', especially during the crucial period of policy change. In July 1996 action was initiated by

the Central Bureau of Investigation (CBI) against Dr.B for possessing wealth beyond his known sources of income (Asian Age, interviews 1996). It was rumoured that this was not NTP money but from leprosy. However financial misconduct in drug purchase during the pilot phase slowed negotiations with the WB/WHO (interviews 1995, 1997). Drugs were ordered for the entire country and without following the prescribed regimens, (shifting from intermittent to daily regimen). It was the first time in history that the head of the NTP was implicated in a scandal.

During the same period a Public Interest Litigation (PIL) was filed in the Supreme Court regarding a Rs.70,000 million (US$2.1 billion) scandal in the import of equipment by the Directorate General of Health Services (Bhushan*1996, Lancet 1996;1548), calling into question the integrity of another key negotiator in the RNTP. A Health Secretary known for honesty who had objected to certain issues during the period had been transferred (several interviews 1996). This obviously had the concurrence of the Union Health Minister who has been cited as being 'one of the most corrupt ministers we have had' (several interviews with senior officials).

With this immediate political environment and quality of leadership it seems unlikely that the RNTP or the NTP will be able to achieve much. Staff are demoralised and demotivated and point to irresponsibility and lack of accountability of the national political, executive and technical leadership. Analysts draw correlation's between the large amount of external funds available with the Health Ministry and the sudden crop of financial scandals (Shiva 1996).

6.5 Context and Processes in Pilot Phase Project Sites

The Gulabi Bagh Pilot Project, the first Pilot Phase I site in the capital city Delhi, close to the seat of power, under pressure to be successful, reported 95.5% cure rates in the first year (TB Div.1995c). However numbers of patients were small (1197) and patient selection criteria left out problematic cases (VHAI 1994, discussions at national meeting on the NTP). The project had strong leadership/managerial authority, easy access to the central TB unit, international meetings and much publicity (*ibid*). Methods used did not

follow the global strategy and were not replicable. This pilot vertical programme, covering one million people, undertook active case detection. Health Visitors worked exclusively for TB, receiving financial incentives for case detection and treatment completion (Jhunjhunwala 1994). Implementation problems occurred early. Non-compliance for sputum tests at the second month was reported to be 11%, raising questions about sustainability of high cure rates. Recruitment of laboratory technicians for 5/10 subcentres was incomplete nine months after project initiation. Poor recording was observed with 22% blank entries for the third microscopy test. Delays in the working of the incentive system led to staff dissatisfaction *(ibid)*.

Bihar, economically one of the poorest states, with an estimated 1.2 million TB patients, known for poorly functioning government health services, was selected for the RNTP. The State government said it would participate only if the Centre provided all inputs including staff and failed to present its proposal for the RNTP grant, reportedly due to bureaucratic laxity, and finally was not included in the pilot phase (Blitz 1994).

Mehsana district, the only rural pilot site in Phase I, is a rich, powerful district in Gujarat, with 4 state ministers including the Health Minister hailing from that region in 1996. The district is highly industrialised, with a plant of the Oil and Natural Gas Commission, a large well developed co-operative dairy and a good highway connection to the capital city Gandhinagar and to Ahmedabad (an hour's drive). It is unrepresentative of India's 506 districts. Gujarat has been one of the best performers in the NTP, being the only State to invest in special additional TB workers (ICORCI 1988). The State Joint Director of TB, known to be enthusiastic about TB work for long, was earlier the DTO in the pilot phase district having old established links with general health service staff. These factors favoured success in the pilot phase, but reduced the probability of its achievements being replicable in other districts and did not facilitate identification of operational factors important in the implementation of the RNTP, an objective of the pilot phase. Cure rates were 81% in the first quarter and 66.5% in the remaining part of the first year (TB Div.1995c).

Certain implementation aspects do not get reported in assessments which limit themselves to outcomes such as cases detected, sputum conversion and cure rates, without specifying how these were reached. Active case detection in the first quarter ensured high rates. TB drug supplies were adequate, the problem being of over supply here and at other sites (personal visits, communications). One reason was the over estimation by national policy makers of patients likely to be detected. In Mehsana, in response to drug indents for 1000 patients supplies for 3000 were received (interview 1996). This was problematic as diversion of RNTP drugs to other parts of the State under the NTP required special permission and wastage was likely with expiry dates nearing.

Cure rates in Mehsana were 70% among smear positive patients, while 12% defaulted and 9% died (ODA 1995). DOTS was provided by a range of people- MPW's, ANM's, *Anganwadi* workers (child care workers), *sarpanch's* (*Panchayat* chairperson), *dai's* (traditional birth attendants), relatives and voluntary workers. Due to lack of a vehicle no field monitoring was done and because of the administrative structures, the DTO's did not have administrative control over the PHC staff (*ibid*). The problems of the NTP thus continue to operate within the RNTP. A field visit to a PHC during this study, found it locked with no doctor or patients. The laboratory technician when called from her house was knowledgeable, and the laboratory and records were well maintained.

In Pathanamthitta District, Kerala, staff, vehicles and resources from other parts of the State were diverted to the district during the pilot phase (TAI 1995), adversely affecting NTP services in those districts. Socio-economically the district was unrepresentative of the State, the patients identified/included in the first year too small, and duration too short to draw statistical conclusions (TAI 1995, Deccan Chronicle 1995). State government medical experts questioned the advisability of introduction of intermittent drug regimens. Alternatives proposed were that funds be used to extend existing SCC regimens to all patients and improve administration of the NTP (*ibid*).

At several pilot sites case detection were lower than expected. In Bombay, in 1994 of a target of 800 smear positive patients, only 180 were identified due to 'inefficiency and

apathy of those in charge.....and lack of motivation among staff' (The Daily 1994). This continued the following year (Uplekar*1996). Cure rates in the first year were 73% (TB Div.1995c). Madras also reported lower numbers of cases (Jagannath, TAI 1995). In Hooghly District, West Bengal, less than 20% of expected cases are detected and high drug toxicity rates are reported (Banerji 1997). Sputum conversion in new smear positive cases at three months ranged from 79.6% to 94.6% at the different sites (TB Div.1995c).

Several questioned the disproportionate time spent by the central team on RNTP pilot phase areas covering 2.4 and later 13.85 million people, with relative neglect of the remaining 900 million under the NTP (interviews 1996). Achieving success rates in order to finalise loan agreements appeared to be an imperative.

RNTP pilot projects in Madras and Bangalore, would reportedly not have been able to function as effectively without local NGO's participating (Radhakrishna*1996, Ranganath*1996). Their community work covered the absence/apathy of government health workers. Some NGO's had other motivations such as evangelism/witnessing, and were not always consistent/sustained in their work, being dependant on availability of funds and trained staff (interviews 1996).

6.6 Bottom-up Perspectives of Local Action

6.6.1 Patient Perspectives:

The Bangalore Municipal Corporation was a Phase I & II Pilot Site. During the first year in 1994, only 32 new sputum positives among 83 patients were detected from 250,000 persons (TB Div.1995c), several through an NGO. Reportedly one of the poorest performing pilot sites (Luellmo*1995), with leadership characterised by apathy, disinterest, poor supervision such that money remained unutilised (interviews 1996). For this study 15 RNTP/TB patients[8] from 3 Corporation Dispensaries, interviewed in their homes, included seven women and eight men, with average age 35 years (15-75), from

[8] Though the number of patients are small, they were carefully selected. It was considered important to have a bottom-up perspective, consistent with the methodology of the entire study. They add information and support the analysis in 6.7 and district level data in Chapter 8.

low to lower middle income groups and nine castes. Four had family members/close friends with TB. One third had been hospitalised (one for a non-TB condition) prior to the RNTP treatment. All patients, except one, were diagnosed elsewhere and referred to the dispensary. Four received previous TB treatment at government sanatoria/hospitals, while one was treated briefly by a private practitioner. Significantly, in all patients except two going directly to the public sector, private public referrals occurred for confirmation of diagnosis/treatment. Five referrals of 15 were to public hospitals/sanatoria and ten to dispensaries. Thus most patients made plural use of services. Many patients were initially sceptical about corporation dispensaries with poor perceptions of services even for minor diseases. With the RNTP inter-public sector referrals occurred from public hospitals to dispensaries nearer patients' homes, decentralising services to peripheral institutions.

Private public referrals occurred prior to the RNTP as is evident from patients with long histories of TB and active efforts by the RNTP, to work with private practitioners increased this. However patients in this study were selected from dispensary registers, therefore dispensary non-users treated completely by private practitioners were excluded.

Excluding three chronically ill patients (two with unrelated chronic illnesses), average duration of disease when interviewed was a long 14 months, suggesting the need for earlier diagnosis. It was shorter than rural patients possibly due to better urban access to services, greater awareness, better quality care in the RNTP with assured drug supplies/decentralised services or due to the selection bias towards new sputum positive cases preferentially included in the RNTP. None were cured when interviewed as current patients were selected.

Patients visited on average seven providers (4-11) for this illness. Of the 108 providers listed as visited (an underestimate since some could not remember all private practitioners visited), 34% were from the public sector. However among all, TB treatment was provided by the public sector, a pattern similar to rural patients in this study (under the NTP), indicating that private public referral and collaboration already occurs, and highlighting the predominant role of the public sector in TB treatment.

6.6.2 Gold Standards and Street Level Implementation of the RNTP

a) *Sputum Microscopy for Diagnosis* was unsystematic suggesting poor practice and supervision. In only one patient were the required 3 sputum samples examined (two early morning and one spot specimen). Three patients had 2 sputum tests done- one early morning and one spot in two patients and two early morning samples in one patient. Among eleven patients with just 1 sputum test, spot specimens were examined in seven and early morning samples in four. However, 8/15 patients had a sputum examination done elsewhere before referral to the MCD.

b) *X-rays for Diagnosis* done in 12/15 patients before referral to the MCD were utilised and second X-rays were not ordered. In only one patient was an X-ray advised.

c) *Monitoring Treatment with Repeat Sputum Microscopy* at second month was done in all patients showing sputum conversion in 12/15, while 3 remained smear positive. There were no records of sputum tests at fourth and sixth month in any patient.

d) *Patient Education by Doctors/staff* occurred with advice regarding duration and regularity of treatment, diet and negotiations regarding supervised therapy at the dispensary.

e) *Treatment*: All patients were put on one of three Categories of Short Course Chemotherapy. In some cases, doctors responding to patient requests for injections, added regular multivitamin injections, defying therapeutic and economic logic. A few patients 'tired' of taking nine tablets at a time, occasionally refusing to take them. Dispensary retained patient treatment cards, supposed to be signed by patients at each visit, were often altered with patients signing up for a week or more at a time, or not at all, according to circumstances.

During a visit to an MCD, awaiting the doctor, it was noticed from the treatment cards that several patients had stopped treatment 1-2 months ago. Later after discussions with the doctor, the set of treatment cards were returned and on a second look all had been

brought up-to-date! (Because of the schedule of the study this set of patients was not followed up.)

f) *Directly Observed Therapy*: was the most problematic aspect for all patients. Doctors always started DOT, but were flexible in responding to patient requests and most patients discontinued supervised treatment after varying periods. Individual difficulties faced included: elderly or chronic patients and pregnant women too ill or tired to walk; mothers unable to leave young children unattended; mothers overburdened with housework and childcare who discontinued on feeling better; a young person with a new job could not take time off three times a week; some felt giddy after the drugs and could not walk back and others thought the water was impure. Irregular and incomplete treatment, a problem that the RNTP was to resolve, was observed in this group of patients.

g) *Drug Supply*: TB drugs were available at the dispensaries. Wastage occurred when patients discontinued treatment as each patient had a separate earmarked box of drugs.

h) *Corruption*: Though some patients with other illnesses mentioned paying doctors in dispensaries, none of the RNTP patients paid anything, a contrast to frequent payment for 'free services' observed in rural NTP patients.

i) *Patients* felt positive regarding their experience with the RNTP, despite problems of delays/non-attendance by doctors and difficulties with supervised therapy. However many were irregular/discontinued treatment on feeling better, inspite of being forewarned about symptomatic relief and the necessity for complete treatment. While the word cure may have different meanings for patients, clinicians and epidemiologists, the life circumstances of people are important determining factors.

j) *Observations*: During field visits it was noted that doctors were absent/late on several occasions without notice; staff were often rude and impatient with TB patients; paramedical staff were often slept, read novels and sometimes closed the dispensary early; the TB work depended on the commitment of individuals; optical equipment of a

microscope was not functioning; patients scheduled to come for observed therapy on specific days did not come; directly observed therapy was not undertaken but patients took boxes of medicine home though records were written up otherwise, questioning the validity of routine records on which assessments are made; patients sometimes did not follow the treatment at home; some patients could not understand how and when the tablets should be taken, finding directions on the combipacks confusing (Fieldnotes 1996).

k) *Staff Perspectives*: Staff were trained and knowledgeable about technical aspects of the RNTP. Drugs, equipment and supplies were adequate. NTI staff were not entirely satisfied with the laboratory work or implementation. Urban areas lack field staff for patient follow-up. Nurses and group D employees, who often seemed to have time, could not be asked to home visit, a task not in their job responsibilities. Staff were deputed/seconded for short periods to the RNTP, and retired staff taken as field supervisors on short term contracts, raised concerns regarding sustainability of the programme. Doctors had additional public health and clinical responsibilities, sometimes attending two clinics, while some engaged in private practice.

It was disturbing and difficult to link intentions and actions from international to local levels. 'Implementation gaps' are observable in the RNTP inspite of priority attention, adequate resources, supply systems, training, and supervision. Day to day struggles in the lives of poor people, create complex social conditions wherein apparently rational actions are not simple or easily implementable.

In Summary,

- Policy content of the revised NTP is not very different to the NTP[9] and focusing on content does not address deeper underlying problems, particularly that the NTP was never fully implemented as intended. The RNTP is also not as cheap or cost-effective

[9] Other than the insistence on DOTS, though the NTP has offered intermittent supervised therapy as one of its regimens since more than two decades.

as expected, and there are technical conflicts concerning directly observed therapy and drug regimens.

- The Revised NTP did not emerge as a contained policy package at a point of time but evolved over several years, being driven by strong players and interests. International organisations in health, though appearing to play a purely technical role, also function in the politico-economic realm of international relations. Policy process was influenced using the leverage of funding and conditionalities. Negotiations regarding policy content/strategy involved bargaining and compromise and was characterised by conflictual processes.

- Positive contributions of the policy change process included widespread attention to TB from central and state governments, NGO's, the private sector and the media, increased national funding and consequently drug supplies.

- Despite substantial evidence in the literature since the mid-1980's regarding context, particularly close interactions of TB with poverty, there are few efforts by the public health community to engage with underlying political economy issues.

- The political and economic context in India with structural adjustment, privatisation and globalisation is more complex than in earlier years and the policy leadership will need to steer through it. The rapid change in national policy leadership during this crucial period does not suggest genuine political support/commitment to TB control.

- Policy processes at national level that are unconducive to good implementation included decision making by a small elite groups uninvolved with the programme, changing leadership, devaluing institutional frameworks, short term contracts, and corruption. Programme managers/researchers/implementors did not take proactive or assertive action in issues concerning their constituency. Pre-occupation with the RNTP led to relative neglect of the majority population under the NTP.

- Widespread use of discretion altered the revised policy considerably during implementation. Even in high profile, well resourced, pilot phase projects with close international and national attention, technical policy content was modified with

substitution of passive by active case finding, use of smaller number of sputum microscopy tests, modifications of DOTS and reporting systems, making it difficult to know what policy was actually implemented and assessed. Apathy and disinterest were already manifest.

- Desire to prove the model successful, influenced patient selection and suppressed negative feedback from implementation experiences. Critical input from academics and NGO's was unwelcome or ignored with little real policy debate. Implementation problems are likely to get accentuated in the shift from pilot to routine phase.

- The implementor-patient interface was a decisive point in the policy and one that is usually overlooked. In the RNTP the explanatory factors for poor implementation such as financial resources, drug supplies, staff vacancies, and government commitment had been addressed and were not problems but gaps persisted. Poor living/social conditions of patients and behaviour/attitudes/relationship between implementor and patient seem important.

- Contemporary policy discourse and planning regarding TB control continues an over-emphasis on policy content. While implicitly recognising the need for better management, it does not address the structural components of change required to actualise this. It has undervalued process and implementation issues, been naive about political commitment, and has become mired in an unproductive RNTP/NTP conflict with a dogmatic attachment to a particular package. Thus potential forces working towards improved TB care and control have become fragmented rather than combined.

CHAPTER SEVEN

IMPLEMENTATION AT STATE LEVEL

7.1 Contextual Historical Background

Mysore kingdom, ruled by Tippu Sultan, the last in the country to fall to the British, was not placed under direct rule, but became a semi-autonomous state by reinstalling its earlier non-brahmin royal family, the Wodeyars. A progressive, scholarly king in the late nineteenth century chose able, visionary '*Divans*'(administrators) (Gangamma*1996) and developed an enlightened civil service (Vyasalu 1995). Health services developed within a liberal, welfarist administration evidenced by establishment of the KrishnaRajendra Hospital in 1876, the College of Indian Medicine (*Ayurveda* and *Unani*) in 1908, a medical college (Allopathy) in 1930, all in Mysore city, besides hospitals in other cities/towns (GOK 1988). The first primary health units serving rural populations in India were pioneered in the state in the 1920's, the first being established in Ramnagaram (RamaRao*1994). Thus a tradition of state run health services was built.

Early TB Work:

A princess of the royal family succumbed to TB early in life. The Princess Krishna Jammani TB Sanatorium[1] was established in her memory in Mysore in 1918 by the Maharani of Mysore, Srimati Vani Vilas. With spacious buildings situated on an 85 acre campus on the outskirts of the city, and well trained staff, it offered treatment free of cost to the general public. This was the period when sanatoria were the 'state of the art' approach in TB care. In 1938 the Lady Wellingdon TB Clinic was established in the centre of Bangalore city (part of the State of Mysore) as an outpatient unit, also in keeping with latest trends in TB management (KSTA records). Very soon after formation of the TB Association of India in Delhi, the Government of Mysore through Divan Mirza Ismail, its administrator, started the Mysore State TB Association [2](MSTA) by

[1] Now run by the State Government and called the PK TB and Chest Disease Hospital.
[2] Changed to Karnataka State TB Association (KSTA) after the name of the state was changed.

Government Order [GO No.G 12735:9, Med.296.33.8] on 20th June 1939 with its office in Mysore (*ibid*). MSTA developed the Lady Wellingdon TB Clinic, provided financial assistance to private and public clinics and was registered as a Society in 1943. It followed the national pattern of government setting up a non-governmental association in which private, governmental and missionary/voluntary physicians[3] participated with royal patronage. '*Government leadership was responsible for the establishment and functioning of a voluntary movement*' (Sundareswara 1996;77). International events, particularly the Second World War into which India was drawn, did not allow for much activity by the Association (*ibid*). The MSTA/TAI were doctor dominated, accepting of current international methods of TB diagnosis and treatment, and unquestioning of the British governments non-involvement in TB work on a larger scale.

State Profile:

While the population below the poverty line reduced from 1960-1990, Karnataka is in the category of States with the lowest decline in incidence of poverty (Vyasulu 1995). Overall 40% of the population remains below the poverty line (WB 1996b). Regional concentrations of poverty occur, while infrastructural development, especially of roads, railways and industries, is unevenly distributed, being better in the southeast, the old princely state of Mysore (Vyasulu 1995).

Table 7.1 Current Demographic Profile of Karnataka

Variable	Current Status	Comment
Area	191,791 square km	In southwest India
Population	44.98 million (1991) 50 million (estimate for 1997)	Current growth a little less than a million a year
Rural Population	69.08 % (27,066 villages & 254 towns/urban areas)	decreased by 10% over 50 years
Scheduled Caste Population Scheduled Tribe Population	16.7% 6.7%	These 23.4% are most vulnerable economically
Literacy Rate (1991)	56.04% females 44.3%, males 67.2% rural 47.7%, urban 74.2%	Total literacy drive in past 6 years achieved 100% literacy in Dakshin Kannada district & improvements in others.
Per Capita Income (1995-96)	Rs. 7,155 at 1993-94 prices	Range Rs. 13066 in Kodagu to Rs. 4,910 in Bidar District.
Average District Income (1995-96) at 1993-94 prices	Rs.58512 million in Bangalore and Rs. 6416 million in Bidar	Inter-district variations affect infrastructure

Source: ICHI 1996, GOK 1996

[3] All three groups currently considered important in policy.

Table 7.2 Health Status Indicators in Karnataka, 1995

Indicator	Karnataka	India	India-Targets for 2000 AD
Crude Birth Rate	25.5	28.5	21.0
Crude Death Rate	8	9.8	9.0
Infant Mortality Rate	67/1000 live births	80/1000 live births	less than 60/1000
Life Expectancy at Birth			
Male	62.1	60.6	64.0
Female	63.3	61.7	64.0

Source: WB 1996b;46.

7.2 The Early Post Independence Period of Policy Formulation 1947-60

After Indian Independence in 1947 the State of Mysore joined the Indian Republic. The state capital shifted to Bangalore and in 1950 the TB Association shifted its office there for better coordination with the new government (Sundareswara 1996). Karnataka State (known till the 1970's as Mysore State) was created during the reorganisation of States in 1956. It incorporated the princely state of Mysore (the largest component); the northern districts of Bidar and Raichur from the Nizam of Hyderabad's State; Belgaum and Dharwad districts from Bombay Presidency, Dakshin Kannada from Madras Presidency, and Kodagu which was a Class C State (Vyasulu 1995). The Presidencies had been part of British India while the others were semi-autonomous. The political histories, traditions and administrations of these regions of the new State were very different. Reorganisation, an issue of 'high politics' (Walt 1994) entailing major administrative changes dominated the agenda of politicians, the executive and bureaucracy during the 1950's and 1960's. Since then regional and language issues[4] continue to enlist the support of different groups, influencing the politics of the State. The new State government built its health care infrastructure on the existing network of primary health units and hospitals (GOK 1988). Guidelines and financial support from the Indian government towards rural health

[4] Small political groups within the regions lobby for greater benefits or integration with neighbouring states because of historical differences. There are some disputes over which language should be the first language in specific regions.

services were based on population norms, a Primary Health Centre then covering 100,000 people (Park 1994) attempting to redress urban-rural disparities.

In the early 1950's, the BCG Campaign initiated and supported financially by the Centre was implemented in the State. With restricted resources, including of trained personnel, collaborative links between Government and NGO's in TB were close at national and state levels making the TB Association of India/the State Association appear like unseen arms of government. A State Government Order on 16/11/51 '*approved and adopted the TB Seal Sale Campaign...as proposed by the TB Association of India'* (KSTA records). This was a campaign to raise public awareness and money for TB work. While the TAI played a more independent proactive policy role (Chapter 4), the KSTA was a lower profile, less critical ally of government, supporting programme implementation.

In the late 1950's the TB Adviser to the Government of India[5] and the State successfully bid to locate the National TB Institute (NTI) in Bangalore, against competition with New Delhi and Mysore city (Nair*1996). The Mysore Maharaja who became the first Governor of Mysore State, after a good deal of negotiation, made available at reasonable rates the 'Avalon Palace' in Bangalore (belonging to the royal family) and its spacious grounds to house the NTI. The TB leadership showed its capacity to negotiate successfully with central and state governments. There was a political need to diffuse national institutes away from Delhi at that time and thus the NTI was situated away from the centre of power and influence. However, while establishing the NTI in Bangalore was a triumph for Mysore/Karnataka State, it can be argued that its distance from Delhi cut it off from national level decision making, reducing its influence/capacity to advocate its philosophy and strategy in policies concerning the development of health services and national programmes, on which the NTP was dependent.

While inaugurating the NTI in Bangalore in 1959 Prime Minister Nehru said, *"I have come to inaugurate an idea, not an institution"* (Issac*1995). This reflected the thinking, questioning and challenging of relevance of then current global concepts in TB control to India by a small group. The Prime Minister aware of this ferment, approved attempts to

[5] A South Indian but not from Karnataka.

develop ideas and strategies relevant to prevailing Indian conditions. The Institute showed independence in its work developing the National TB Programme (Chapter 4). Dr. Halfdan Mahler worked at the NTI as WHO consultant for two years and several international TB workers came to Bangalore every year for courses and official visits to the NTI.

Early NTI studies conducted in Tumkur district made Karnataka a partner in the formulation of the NTP (DH&FW/GOK 1996). The NTP based on a philosophy of putting people first contained seeds of the primary health care approach (Banerji 1993). This is acknowledged in a portrait of Dr. Halfdan Mahler near the WHO library, Geneva, which has India as background with primary health care emerging out of Bangalore (Issac*1995, observation). With collaborating State officials exposed to the philosophy and strategy, and the NTI as a resource for training and advice, implementation of the NTP in Karnataka was better informed and could potentially be optimal, but *"the truth is different"* said a senior official (interview 1996) as seen later.

As the new programme was being formulated, existing policy processes continued. Besides the BCG campaign, State governments were encouraged by the centre to start TB Hospitals and Clinics (GOI, 1st and 2nd Plans). With health constitutionally a State subject, the Centre gained policy leverage through the instrument of part funding, sometimes from external sources. In 1960 Lady Wellingdon TB Clinic, which had been transferred from the MSTA to government (KSTA records), was upgraded with UNICEF support into a State TB Demonstration and Training Centre to demonstrate model outpatient domiciliary TB management and train key personnel from health institutions in the State (DH&FW/GOK 1996).

The infrastructure of 'TB Institutions' in the State, in 1964, at the time of policy change (Table 7.3) indicates earlier policy emphasis on specialised institutions/hospitals.

Table 7.3 TB Institutions in Karnataka, 1964

Institutions	Numbers	Beds
Sanatoria	12	1,895
Hospitals	2	52
Centre	1	-
Clinics	11	100
General Hospital wards for TB patients	6	190

Source: TAI 1964

All these institutions, except six sanatoria, were run by State government, making the public sector the biggest player in organised TB care. It was perhaps not surprising that the NTP focused primarily on the public sector. The six sanatoria run by the voluntary sector, with 392 beds totally, were small (Bellary-40 beds, South Kanara -60, Bangalore 80, Belgaum District -150, Mangalore - 40, and Gadag -22 beds) (TAI 1964). Government sanatoria were larger (two in Bangalore 430 and 184 beds, Bellary 240 beds, Mysore -389, Kolar 160, Mangalore 100) with a total of 1503 beds (*ibid*). Including its general hospital TB beds, government accounted for 1845 beds (82%) of a total of 2237 beds, representing substantial public investment in capital and running costs. These early policies developed a life of their own, backed by specific stakeholders. Thus institutional care by TB specialists through sanatoria[6], continued alongside integration of TB services with general health services, playing a prominent role even after three decades of policy change (Chapter 8).

NGO's: The Mysore State TB Association was largely non-functional in the 1950's with a part-time clerk at its office located within the premises of the Bangalore Sanatorium (KSTA secretary). It did not play a role in policy formulation of the NTP nor did other State level NGO's. NGO's in general health services then were fewer, involved with service provision and not public health, and not yet organised into State-level associations. After retirement in 1962, the first TB Advisor to GOI lived in Bangalore, initiating a reorganisation of the MSTA and building collaborative linkages (*ibid*). This points again to the role of individuals with dynamism, energy and organisational

[6] Later renamed TB and Chest Disease Hospitals.

competence. The office was shifted, a full time secretary appointed, and a committed active Secretary chosen. Office-bearers included government and NTI staff. The MSTA in 1962 implemented a pilot project in Tumkur district to *'find out how voluntary organisations could assist the government in the NTP'* (Benjamin 1965;1). The study guided by a committee of State government and NTI staff, was supported by the International Union Against TB (IUAT) and a member of the National TB Association of the USA (*ibid*). The Executive Director of the IUAT, Dr. J. Holm visited Bangalore, the project site and the NTI. Overlaps and cross cutting linkages, even then, between government, voluntary sector and private professionals is striking at organisational and individual level, both nationally and internationally.

7.3 Implementing the District TB Programme (DTP) 1960-1990's

Karnataka initiated implementation of the DTP (the functional unit of the NTP) in three districts in 1963, supported actively by State Health Minister Dr. Nagappa Alva (DH&FW,GOK 1996), a physician involved with the freedom movement. By 1968-69, thirteen more districts were included, and by 1974 the last three were covered, making Karnataka one of the first states to cover all its nineteen districts (*ibid*)[7]. This did not mean that entire districts were covered or that all people had equal geographical access as implementation at peripheral institutions was prolonged and is still incomplete (Chapter 8).

To execute the DTP, District TB Centres established at district headquarters, with teams trained at NTI, were to train staff on site, set up supply systems, initiate recording and reporting systems in a phased manner in all government peripheral institutions. Infrastructure and training for DTC's were financed by central government; staff salaries and maintenance by state government; while drug supply was undertaken jointly. Administrative, financial, and technical processes were complex in a federal government system. As part of policy change by 1971, of 15 BCG teams 10 were integrated into the

[7] Other states took longer to cover all districts.

DTP's, and 5.4 million vaccinations had been done since inception of the campaign (DH&FPS 1971).

State expenditure on the NTP was substantially more than the Centre, even when it was a 100% centrally sponsored programme (Table 7.4). Its contribution continued increasing during 1966-68, covering the drop in central government funds during the period of drought and central political instability[8].

Table 7.4 State & Central Expenditure on the NTP in Karnataka, 1960's

(Rs. in millions)

Year	State	Centre	Total
1963-64	2.1	0.8	2.9
1964-65	2.3	0.9	3.2
1965-66	2.5	1.0	3.5
1966-67	3.7	0.2	3.9
1967-68	4.4	0.4	4.8
1968-69	4.9	0.9	5.8
1969-70	3.3	0.6	3.9

Source: DH&FPS 1971

Structural and functional changes in the State health services in the 1970's, transformed the NTP, affecting the working of the DTP. A restructuring of the State Directorate of Health and Family Welfare took place in 1978, reflecting conflicting interests between clinicians and public health specialists (Baily*1995). Clinicians felt that a public health training (including the Diploma in TB) provided faster promotion avenues towards top administrative positions which had greater prestige, power over finances, better salaries and locations at district or state headquarters. Clinicians, even with postgraduate degrees, often working for long periods at PHC's, *taluk* or district hospitals found entry into administrative positions more difficult. To equalise the situation the 19 District TB Officers (DTO) posts were abolished. Instead 48 Assistant District Health Officers (ADHO's) posts were created, including 19 ADHO's posted to DTC's (Krishnacharya

[8] Increased central support to the family planning programme (Rao 1994) inflated the central health budget.

1995). ADHO's at DTC's no longer required qualifications in TB or public health. A retired Joint Director (TB) termed its impact on the NTP detrimental, *"ADHO's are not trained to manage the DTP as expected* (*ibid*;11). ADHO's at DTC's reporting to the District Health Officers, lack authority over the PHI's which report to it on the NTP. In contradiction to NTP plans, wherein two medical officers were to be posted to a DTC (one to manage clinical work, the other to visit PHI's, organising training, recording and reporting systems and supply lines), only one ADHO was posted (Gnaneshwar*1995). At the same time in 1978 the top State position of Assistant Director (ADG) of Tuberculosis was abolished and merged into a single post of Deputy Director of TB and Leprosy (Krishnacharya 1995). Powerful clinical lobbies and local pressures obscured the interests of the NTP and of rural TB patients. One could speculate whether these lobbies representing older interests and conflicts made use of a political opportunity offered by a changed party in power to further their position, with the first non-Congress State government in power then. In 1978 the Central government (Janata Party) introduced a monitoring system for the programme, following the 1975 ICMR evaluation, but with the basic structure weak and eroded in the State, the quality of monitoring reports and its impact on implementation are questionable.

In 1980 the State government recreated the post of Assistant Director (TB) at a higher level of Deputy Director (TB) (Krishnacharya 1995), subsequently changing it to Joint Director (TB) (as were similar positions for leprosy, malaria, MCH). This position also lacked sufficient power in the health health services. Posts of District TB Officers were not recreated *(ibid)*. ADHO's at DTC's functioned *'like any other medical officer in the system'* doing primarily clinical work, without authority and with little interest in Peripheral Health Institutions and their staff (Sundareswara*1995). The NTP had no powers to alter these structural changes made by the State.

Administrative and financial responsibility for **BCG vaccination** shifted in 1978 from the NTP to the central government Expanded Programme of Immunization (Park 1994). However State health services are utilised for its implementation (Krishnacharya 1995).

Though comprising a part of government effort at TB control it is not included in financial analysis.

In 1982 the Lady Wellingdon TB Demonstration and Training Centre was upgraded into the State TB Centre (STC) to supervise and monitor the NTP/DTP's in the State (DH&FW,GOK 1996). This appears to be a response to a need to monitor the NTP, put on the Prime Ministers Twenty Point Programme. The STC continued compiling reports routinely from DTC's, as it had from 1978, routing them to the Central TB Unit, GOI and the NTI. Most DTC teams in the State did not have Statistical Assistants recommended by the NTP and records and reports were maintained by untrained Treatment Organisers. The incomplete and confused state of registers and records in two districts (Hassan and Mysore) made analysis difficult (NTI 1994b). This was also noted in the mid-1980's by TRC staff in Raichur district as part of the 18 district Short Course Chemotherapy study (interview1995). The NTI frequently raised the point that coverage and quality of monitoring from most states including Karnataka needed improvement (NTI Newsletters). There were few efforts by the STC to check/improve quality of reports, undertake cohort analyses, or more importantly take action on findings (interview 1996). Training components of the STC declined, with no long-term training programmes for treatment organisers/other staff since 1973 (Chikaiah*1995). It continued mainly outpatient, domiciliary clinical work, a service used for research studies by the NTI. It did not play the nodal leadership role envisaged by the NTP for an STC at State level. Whether this was possible in the given circumstances is another question.

Short Course Chemotherapy was started in Karnataka during 1985-86 in a phased manner as part of its introduction nationally (DH&FW,GOK 1996). One district was part of the national 18 district pilot phase in the mid-1980's and by 1995, 17 districts of Karnataka were reportedly covered, barring Kodagu, Bangalore Rural and Uttar Kannada (Mahadevappa 1995). However a key drug Rifampicin was expensive, often not available even in larger hospitals and unavailable in sufficient quantities or irregularly available at PHI's, DTC's and at the TB hospital even in 1994-95 (interviews with staff). Availability of Short Course drugs in the market, used by urban private practitioners and given on

prescription by doctors in public health facilities (*ibid*), furthered stratification in access to treatment in favour of those with ability to pay. Coverage through the NTP was partly notional and unscientific with dangerous consequences of drug resistance.from irregular supplies and treatment.

Expansion: The number of districts in Karnataka increased by one, in 1987, to twenty[9]. As the NTP planned DTC's for the average district with 1.5 million people, the Government of Karnataka expanded the number of DTC's for districts with populations over 2 million (despite a constant number of districts) creating six additional DTC's, mainly in economically disadvantaged regions (JD(TB) records 1996, Table 7.6). Mysore district with 3.1 million people was not included, because of the TB hospital and large number of public and private health care facilities available. The State government financed the expansion. In Districts with TB & Chest Disease Hospitals (Sanatoria), DTC's offer investigative and outpatient domiciliary services, while in districts without TB Hospitals, DTC's have inpatient facilities. Supply and maintenance of equipment in the 20 main DTC's was adequate in 80% (Table 7.5). However their usefulness is undermined by poor drug supplies, insufficient trained staff (Table 7.15) and corruption (interviews).

Table 7.5 Equipment at DTC's in Karnataka, 1995

Equipment	Availability in 20 main DTC's
X-ray Machines with Odelca Cameras	18 available of which 2 are not functioning
Microscopes	20
Refrigerators	18 of which 2 are not functioning
Vehicles	19 of which 3 require repairs

Source: JD (TB) 1995

The infrastructure in 1995 through which the NTP functions/could function (Table 7.6) suggests that the structural base for the NTP through widespread peripheral institutions has been laid by government.

[9] This is different to other States like Orissa and Tamil Nadu where districts increased over the years requiring the establishment of new DTC's.

Table 7.6 Public Sector Infrastructure for the NTP in Karnataka, 1995

Type of Health Facility	Number	Comment
TB Centres (DTC's)	20 (in every District)	Plus 6 additional DTC's *.
X-ray Centres	178	Includes *Taluk* general hospitals, district hospitals, teaching hospitals, TB hospitals.
Microscopy Centres	826	Includes PHC's.
Referral Centres	748	Primary Health Units (with Dr's) and sub-centres (staffed by HA's).
TB Beds	2966	+ 609 in Volag TB hospitals, voluntary sector can get Government grants in aid.

* located in economically poorer districts (Dt.s) in Sira (Tumkur Dt.), Davangere (Chitradurga Dt.), Koppal
(Raichur Dt.), Hospet (Bellary Dt.), Yadgir (Gulbarga Dt.) & Sirsi (Uttar Kannada Dt.).
Source: JD(TB) records 1996, Krishnacharya, 1995

Table 7.7 Changed Infrastructure for TB in Karnataka Over Time

Public Sector	1964	1995	Comments
Sanatoria	6	7+2*	Renamed TB & Chest Disease Hospitals.
Sanatoria beds	1503	2148	
General hospitals with TB wards	6	19	Excludes medical college/ specialist hospitals.
General hospital TB beds	190	698	Wider spread in districts
Centre/Clinic	1+11	-	
District TB Centres	-	26	New nodal point for public health approach to TB.
Peripheral Health Institutions	formally uninvolved in TB work	Table 6.6	Integration could increase access to TB care.
Voluntary Sector			TB care through general clinics,
Sanatoria	6	7	unertake community health/
Sanatoria beds/% of total beds	392 (18%)	609 (17%)	development work also.

Source: TAI 1964, JD(TB) reports 1995, (*run by ESI & a Municipality)

Incremental changes occurred from 1964 with considerable infrastructural development. Sanatoria continued, though transformed into TB and Chest Disease Hospitals. Ten districts have TB hospitals/sanatoria (by government or NGO's), of which better developed districts Bangalore, Belgaum, Dakshin Kannada and Kolar have more than one each (JD-TB 1995). BCG continues under the Universal Immunization Programme through general health services, 26 new DTC's developed State-wide, increased numbers of peripheral health institutions enhanced potential access to TB care with only 12.5% of the 2082 peripheral institutions not covered by the NTP (JD-TB 1995). However political policy processes altered the NTP at State and district levels, disempowering key institutions (State and district TB Centres), diminishing their influence over peripheral institutions, which were also disabled by staff vacancies, competing interests of other programmes using the same infrastructure and poor drug supplies.

A USAID supported time bound '*Expanded Programme of Health Education in Tuberculosis'* was channeled by the GOI to the TB Association of India/its State Branches, in another instance of Government NGO collaboration (Krishnacharya 1995). From 1987-90 the Karnataka State TB Association (KSTA) conducted refresher/orientation courses in 15 districts, covering 1709 government and private physicians, 3169 paramedical staff, and orientation courses for 6108 community leaders, standing first among 25 States in India which implemented the programme (*ibid*). This project revived the KSTA though *'unfortunately the tempo is not maintained by the KSTA to continue the health education programme as recommended'* (interview 1996).

The Bangalore Municipal Corporation was one of the Pilot Phase I sites selected in 1993 for the Revised NTP by GOI/GOK supported by the NTI and STC. As part of this process a Dutch group FEMCONSULT conducted part of its field study in Bangalore in December 1994 to develop appropriate health education material for TB. The Joint Directorate(TB) seemingly unaware of the study or its outcome talked of developing their own audio-visuals (interviews 1996). During the earlier USAID project several educational materials developed by the TB Association were translated into Kannada, the

state language, by the KSTA with local illustrations. Absent linkages between different initiatives suggest a lack of policy management.

Performance Indicators of NTP/BCG in Karnataka:

a) Official data regarding BCG coverage (Table 7.8) base on targets fixed as percentages of eligible population. Coverage of eligible infants is 73.1% compared to all India coverages of 92.6% (WB 1996b). Community based cluster surveys conducted by medical colleges as part of monitoring mechanisms indicate lower coverage's of 60% in some regions (Patel*1995).

Table 7.8 BCG Coverage in Karnataka

Year	Target	Achievement	% Achievement
1989-90	11,01,100	10,67,960	97.0
1990-91	12,01,700	12,25,048	101.8
1991-92	11,48,400	11,33,730	98.7
1992-93	11,85,800	11,89,461	100.3
1993-94	12,29,367	12,54,385	102.0

Source: DH&FW, GOK 1995

b) The percentage of positives obtained from sputum microscopy of chest symptomatics is low in Karnataka (Table 7.9, NTI 1994d) suggesting poor selection of patients, poor quality laboratory work or altered patterns of respiratory diseases.

Table 7.9 Sputum Positivity Rate in 1992 in Karnataka for SCC Districts

	DTC's	PHI's	DTP's
Expected	18%	8%	-
Achieved	13.6%	5.6%	6.9%
National Average	14.1%	6.1%	8%

Source: Krishnacharya 1995

c) The proportion of bacillary cases detected by the public sector is low as are treatment completion rates (Table 7.10) questioning the quality of functioning of public sector services.

Table 7.10 Public Sector Case Detection and Treatment Completion in the 1990's

Year	Total Cases Detected	Bacillary Cases	% of Treatment Completion (all forms)
1992	69,380	17,407 (25%)	22.7%
1993	67,040	16,386 (24%)	22.5%
1994	76,541	17,546 (23%)	31.6%

Source: DH&FW, GOK, 1995

Though targets increased, new TB case detection decreased steadily from 78,400 in 1989-90 to 67,040 in 1993-94 increasing the following year (DH&FW 1992-93, 1995). This was a period of economic crisis, political instability and budgetary stagnation/decline.

Targets comprise 50% of sputum positives expected in a district. It is estimated that there are over 890,000 TB patients in Karnataka (1995) of whom 180,000 are infectious or sputum positive (Mahadevappa 1995). Thus 10% of the total expected number of cases were detected in 1994-95 by the public sector. If 50% of patients complete treatment government effort would account for 5% of patients cured. In 1991 treatment completion by patients on Short Course Chemotherapy was 46.5% against an expected 85%, and less than the national average of 48.8% (Krishnacharya 1995). Rates are lower with the Standard Regimen 20.1% in 1992 and 30.1% in 1994 (JD-TB reports).

Table 7.11 TB Case Detection in Districts of Karnataka, 1993-94

	Division/ District	Target	Achievement	% Achievement
I	**Bangalore Division**			
1.	Bangalore	9676	9187	94.9
2.	Bangalore Rural	3166	1195	37.7
3.	Chitradurga	4372	3689	84.4
4.	Kolar	4450	4342	97.6
5.	Shimoga	3823	3068	80.3
6.	Tumkur	4375	3274	74.8
II	**Belgaum Division**			
7.	Belgaum	7064	4907	69.5
8.	Bijapur	5858	4076	69.6
9.	Dharwad	7022	4590	65.4
10.	Uttar Kannada	2316	1258	54.3
III	**Gulbarga Division**			
11.	Bellary	3778	3568	94.4
12.	Bidar	2378	2638	110.9
13.	Gulbarga	5164	5238	101.4
14.	Raichur	4386	2933	66.9
IV	**Mysore Division**			
15.	Chickmagalur	1934	1030	53.3
16.	Dakshin Kannada	5118	3773	73.7
17.	Hassan	2978	1451	48.7
18.	Kodagu	922	457	49.6
19.	Mandya	3300	3914	118.6
20.	**Mysore(study district)**	**6000**	**3202**	**53.4**
	STATE TOTAL	88,080	67,790	77.0

Source: DH&FW, GOK, 1995

Districtwise TB case detection (Table 7.11) is very variable, being low in the study district. Thus core policy components of case detection/complete treatment are far from being achieved in the State.

The present Janata Dal State Health Minister, holding office from December 1994, publicly reiterated commitment to the NTP, *"The DTP...has come to stay as an effective approach to tackle the problem on a community basis"* (Mahadevappa 1995;3). In 1995-96, government planned to extend Short Course Chemotherapy to three remaining districts. A proposal for six Additional DTC's in 1996-97 was being considered for better implementation of the DTP. Negotiations were underway with the GOI for World Bank Assistance to start the Revised National Tuberculosis Programme under Phase III, in 6 districts in 1997. These announcements at public meetings portray plans as having been sanctioned and receive press coverage. The fact that the World Bank-GOI loan itself was still under negotiation at the time are seldom referred to. Public images thus created differ from realities. For example a Department report states, *'GOI has been approached for sanction of RNTP for the remaining 14 districts of the State'* (DH&FW,GOK,1996;38) giving the incorrect impression that 6 were already covered. However progress is being made with improved drug supplies in 1996 in some regions (Sudarshan*, Acquinas*1996).

The TB programme should be located within the context of State health policy in the Eighth Five Year Plan (1992-97) which states, *'Health for the underprivileged may be the key strategy for HFA by the year 2000. The structural framework for the delivery of health programmes must undergo a meaningful reorientation in a way that the underprivileged become the subjects of the process and not merely its objects. This can only be done by emphasising community based systems.'* (GOK 1991).

The Voluntary Sector/NGO's:

Health and health related voluntary organisations in Karnataka[10] increased in numbers over the decades, working largely with the poor, but often located in better off districts

[10] They are predominantly indigenous as in India in general, though using foreign financial resources.

(Narayan 1988). Districtwise distribution of a sample (Table 7.12) shows an uneven spread, with smaller numbers in economically disadvantaged districts (Bidar, Bijapur, Bellary, Gulbarga, Raichur, Dharwad, Chitradurga). Several have moved beyond medical care to community health, community organisation and development with a broad range of community based interventions, into which TB care is integrated. They range from welfare/service agencies, social development organisations, grassroots organisations, to advocacy groups and networks (Walt 1994).

Table 7.12 Distribution of Health NGO's in Districts of Karnataka, 1988

1. Bangalore (Urban& Rural)	158	11. Hassan	8
2. Belgaum	19	12. Kodagu	8
3. Bellary	9	13. Kolar	12
4. Bidar	3	14. Mandya	12
5. Bijapur	7	15. Mysore	36
6. Chickmagalur	10	16. Raichur	10
7. Chitradurga	1	17. Shimoga	5
8. Dakshin Kannada	35	18. Tumkur	5
9. Dharwad	14	19. Uttar Kannada	18
10. Gulbarga	0		
		TOTAL	370

Source: Narayan 1988

State networks and associations, providing forums for discussions and an organisational framework for joint action include the Voluntary Health Association of Karnataka formed in the 1970's, the Association of Voluntary Agencies for Rural Development, and State branches of the Christian Medical Association of India, the Catholic Health Association of India, among others. There are resource NGO's providing training, information and research support to others. Besides undertaking treatment of TB patients locally NGO's are involved in broader TB issues through their national networks.

The Karnataka State TB Association, focusing specifically on TB, is involved in TB control and educational activities in dialogue with government (Sundareswara 1996). It organised National Conferences on TB in 1952, 1962, 1971 and 1996 (*ibid*). The USAID Health Education project helped renew the KSTA from 1987-90. Subsequently there was

a problem with possible financial misconduct requiring resignation of an office bearer (interview 1995). Renewed activity took place with a new Secretary from 1993. At the service level it supplies treatment cards, follow up booklets, TB drugs, BCG vaccine to NGO's and to government, and conducts training programmes for teachers (KSTA secretary). It has adopted Multi Drug Resistant patients for treatment with expensive drugs not available under the NTP (Mahadevappa 1995). These activities are conducted through District TB Associations with DTO's as Secretary. During the past year KSTA organised a State Conference on TB, supported continuing education meetings at Gulbarga and Mysore for paramedical and medical staff, renovated a ward at the SDS TB Hospital, Bangalore at a cost of Rs.230,000 collected through the TB Seal sale campaign, and conducted public awareness raising activities on 'World TB day' on 24th March and during the 'TB week' in February (Sundareswara 1996). The annual TB Seal campaign, conducted since 1951, sells TB Seals/Stamps to the general public for Rs.1[11]. District Commissioners, DTO's and public sector undertakings are involved, with 40% of funds raised being kept by the District TB Associations for local use, and the rest shared by the state and national Associations (Gnaneshwar*1996). In 1996 the State government held discussions with KSTA and the STC to start a Monitoring Cell for the State (KSTA officials*1996). The STC is officially mandated to monitor the NTP, but NGO's may help improve quality of reporting.

General Health Services in Karnataka

The development and functioning of health services is critical to integrated programmes like the NTP designed to *'sink or sail with general health services'* (Banerji 1993;66). Karnataka developed a widespread network of services over four decades (Table 7.13 and 7.14).

[11] In 1995 the Karnataka Association collected Rs.300,000 with 99% from public sector employees, less than States like Kerala with collections of Rs.800,000 in 1995 (Visweshwariah*1996, presentation at KSTA meeting).

Table 7.13 Development of Public Sector Health Services in Karnataka, 1951-1987.

Health Institutions	1951	1987
Hospitals with above 30 beds	23	134
Teaching Hospitals	0	23
District and Major Hospitals	20	30
Hospital beds	5,481	26,646
Dispensaries+Primary Health Units	282+125	1310
Primary Health Centres	0	465
Prmary Health Units with 6 beds	20	106
X-ray Plants	15	126
Nursing Schools	5	9
Health & Family Planning Training Centres	2	5
Auxiliary Nurse Midwife Training Schools	3	19
Laboratory Technician Training Units	0	4
X-ray Technician Training Units	o	10

*Source:*GOK 1988

The terminology for health institutions changed and further changes are in Table 7.14 Substantial additions were made during this phase of infrastructural development that occurred nationally.

Table 7.14 Public Sector Health Services in Karnataka, 1992

Type of Health Service	Number
Hospitals- district, subdivisional, rural referral	239
Tertiary hospitals (specialised, teaching)	17*
Maternity Units	143
Primary Health Centres	1198
Primary Health Units	654
Subcentres	7793

*there are additional specialised hospitals for TB, leprosy, infectious diseases, mental health under the Directorate of Medical Education.

Source: GOK 1991; WB 1996b

Studies show that over 45% of patients utilising public sector health services in Karnataka had annual incomes below Rs.15000 which is close to the official poverty line, while over 90% had incomes below the taxable levels of Rs.50,000 (World Bank 1996b).

Existing private sector services grew during the 1980's. Located primarily in urban areas (80%) they account for 33% of hospital beds (World Bank 1996b). Majority of patients using private clinics in Karnataka belong to the middle and upper socio-economic classes (World Bank 1996c). Thus the public sector has the most evenly distributed, widespread services, covering all districts and rural areas and is utilised to a larger extent by the poor.

7.4 Implementation Issues

This section looks at political, policy and institutional leadership in the State; resource availability in terms of trained personnel, drugs and finances; and political processes of decentralisation, societal factors and social movements.

7.4.1 Current Political Leadership and the TB programme

Political leadership in the State is important in supporting the execution of the TB programme. The present Janata Dal Health Minister Dr. HC Mahadevappa, a physician, is reportedly sympathetic to the *Dalit Sangarsh Samiti* (social movement of the oppressed, see later) and the necessity to provide specially for the medical needs of the poor, for which a 'Green Card' scheme has been initiated providing annual medical check-ups and free access to treatment (Japhet*1996). He takes an active interest in activities of the Karnataka State TB Association as its President. During the past year he attended several meetings on TB, staying for the entire period (observation). With his active support KSTA hosted the 51st National Conference on TB and Chest Diseases in Bangalore organised by the TB Association of India. He attended sessions and presentations and the organisers said they have not had such active participation shown by any State Health Minister in the past (TAI 1996).

However political analysts in Karnataka report that '*institutionalised corruption*' over the years by the political leadership has adversely affected civil services (Pinto 1992;1837, 1993). The current Minister has not escaped censure on this point. Contradictory

governmental positions promoting commercial interests and supporting the medical lobby (primarily clinical) suggest an inconsistent role in protecting the interests of the weakest. Since the mid-1980's Karnataka with ministerial support and connections has privatised education in health sciences and has the largest number of private capitation fee medical colleges, dental colleges, schools for nurses and laboratory technicians. It has permitted use of government hospitals as practical training sites for these colleges, which are in heavy arrears to government for the same. Experienced government staff leave and join private colleges for higher salaries, shorter working hours and private practice.

7.4.2 Upgraded Posts and Downgraded Authority and Skills

The top TB post in the State, though upgraded to Joint Director (JD) level, is primarily advisory to the health services with little authority over staff. The Joint Director has relatively little control over resources and budgets which are held by the Health and Finance Secretaries. A recent example cited below indicates how undervalued the post is. The incumbent, who functioned from 1993 till March 1996, was 'Acting JD' till about 6 weeks before his retirement. During this period he was also Medical Superintendent of a 300 bed Government TB Sanatorium on Bangalore's outskirts, a full time 9-4 job, after which he came to the State TB Centre for an hour to deal with pending work[12]. The succeeding JD, the last of the TB/public health cadre, held position for 3 months before retiring. An important change in 1996 was that qualifications and experience in TB/NTP or public health are no longer requirements for the top post, henceforth allocated on seniority in the State cadre (interview with senior official). Thus an orthopaedic surgeon or gynaecologist could be incharge of the State TB programme. This suggests another victory for the clinical lobby and indicates the weakening status of public health in the State. The justification given is that any doctor can perform what is seen as an administrative task. The public health and technical competence and leadership required for the task is inadequately recognised by the State government. Preoccupation with personal interests and goals at this level (seeking post-retirement jobs and consultancies,

[12] His non-availability at this office during the day affected staff work behavior adversely, e.g. not being present during office hours or whiling away time (observation).

building houses) adversely affects supervision and quality of work of the programme and staff morale (interviews 1996). Issues concerning inadequate leadership, commitment to the programme, dynamism and capacity at the top therefore arise. Good leadership with adequate authority and resources are widely recognised as essential for policy implementation (Crosby 1996).

This trend repeats itself at District level, with District Health Officers now being appointed on seniority (with administrative training) and not on the basis of public health training (the study district DHO was previously a surgeon in a large city hospital). The consequences of equating public health with administration in the context of growing infectious diseases and TB can be speculated upon. At the next level the ADHO(TB) lacking power and administrative links with PHI's plays largely a clinical role at the DTC and a nominal role with the PHI's, *" we need to have an administrative link between the PHI's and the ADHO-TB (DTO's) ....we should have the same powers as DHO's to take action when a PHC-MO says I can/will not do any TB work."* (ADHO-TB*1995). Inadequate drug supplies to meet patient demand/needs leads to prescribing, altering a key policy goal of provision of free treatment to TB patients. At the crucial PHC-patient interface the NTP functions minimally with inadequate resources, poorly trained staff and little technical support. Medical officers often work without laboratory technicians because of vacancies, have poor drug supplies and lack authorisation to purchase drugs locally. Without supervision, support and systems of accountability they either refer patients or prescribe. This is the weakest level in implementation of the NTP (see Chapter 8). Programme/policy ownership, a factor identified as being important for implementation (Brinkerhoff 1996) is inadequate at state, district and peripheral levels.

7.4.3 Institutional Leadership by the State TB Centre (STC)

State TB Centres were envisaged by the NTP planners to provide technical and administrative leadership to the State programme. Poor functioning of this institution has left DTP's inadequately supported (Krishnacharya 1995). From 1965-1972 the State TB Centre conducted annual one year training courses for TB Treatment Organisers (the name given by the NTP to paramedical workers in the DTC team. Their designation in

the State cadres subsequently changed to Senior Health Assistant.). This was influenced by the retired TB Advisor to GOI and conducted by a committed and able doctor during whose time *"the STC was very efficiently run and maintained"* (interviews 1996), pointing to the role of personalities with abilities to execute even within constraints. It was a multi-skilled course wherein para-medical workers were trained to handle all the operational elements of the NTP. Presently only one day orientation courses regarding the NTP are organised for Health Assistants as part of the general training (covering all programmes) at the State Health and Family Welfare Training Centre. While the NTI conducts training for DTC staff to maintain a standard approach nation-wide, it was envisaged that STC's would supplement training at State levels. This did not occur for most of the period. The Joint Director TB/STC could not prevent transfers of NTI trained staff from the NTP to other sections. Hence inspite of adequate numbers being trained at NTI, shortages of trained staff occur at DTC's. The STC library and journal collection stopped in the 1970's with no current literature available. The officer in charge did not even know where the collection was located (observation). Being up-to-date with concepts, the national and international TB situation and trends in training, is not considered important by the nodal State Centre. The training component of the Karnataka STC, envisaged in the NTP as a key role at State level, is currently almost non-existent.

Operations research is undertaken at the STC, primarily initiated by NTI staff for field studies and clinical studies. These brought in project funding, additional staff and facilities such as a laboratory for culture and sensitivity, drug supplies and contact with outside experts. There is little evidence that these resources fed into the State programme.

7.4.4 Health Personnel for Implementation of the NTP

Trained staff are a critical resource for implementing a programme. In the State there are shortages of some of the most important categories at DTC's and in the general health services. Several senior staff echo the statement, *'the DTC team has disintegrated'* (Ramesh*1995).The full team as planned are not posted/appointed, not fully trained (Table 7.15) or do not have the necessary authority.

Table 7.15 Trained Staff Position at DTC's in Karnataka, 1995

Staff Category	DTC's with trained staff	DTC's with untrained staff
District TB Officer	9	11
Laboratory Technician	12	8
X-ray Technician	11	9
Treatment Organiser	15	5
Statistical Assistant	10	10

Source: JD (TB) records 1995

Presently District TB Officers (ADHO-TB) need no specialisation or experience in TB. The few Statistical Assistants in the programme are usually seconded to the DHO's Office. Treatment Organisers the mainstay of the TB programme, have fewer new entrants getting trained at NTI. As discussed earlier staff trained in the NTP get transferred to other departments. A detrimental process of deskilling is occurring. A concern expressed by a senior NTI official is that when the cohort of senior staff disappear from DTC's and state levels there will be no one left who understands the technical basis and operational aspects of the programme.

Seventy percent of Laboratory Technician's posts are presently vacant across the State Health Services, (RaviKumar*1996, Krishnacharya 1995), with 85% vacancies at PHC's. This adversely affects the diagnosis of pulmonary TB. According to a reliable source in mid-1996 there were 44 senior laboratory technicians posts vacant and 620 junior laboratory technicians posts vacant. The last regular recruitment was in 1986, though a few appointments were made in 1995 (DTC-LT*1996). Vacancies exist since 7-8 years following a ban on recruitment since 1987, with the State Government saying it had no money to increase its salary payments. Most Laboratory Technicians and Male Health Assistants in PHC's were appointed under the National Malaria Eradication Programme as malaria microscopists (there are a smaller number of pathology microscopists). Since the early 1990's with part of the malaria budget transferred to the State 'non-plan' sector (Mishra*1997), difficulties are faced in finding salaries for these staff who are important for the NTP as well. A related feature is that training facilities for Laboratory Technicians and X-ray technicians in the public sector are poor and inadequate (Krishnacharya 1995).

Concerns regarding staff shortages are repeatedly raised in the State Assembly by legislators (Karnataka LA Debates 1994-95). A recent government circular was cited in which a 10% reduction in permanent posts was planned over time (interview 1996). As part of its negotiations for a World Bank loan the State Government agreed to fill medical officers posts by appointing doctors on short term contracts. Contract appointments were advertised and the first batch appointed on 10/2/92 with short term contracts. The total emoluments of these staff is lower than permanent staff, they lack job security, and receive no in-service training to manage an array of public health programmes operating from PHC's. With the short drug supplies available to them their role is minimised. Doctors on contract among those interviewed at district level did not treat TB patients, while regular appointees did, performing at least some elements of the NTP (though with inadequate drug supplies and no follow-up/defaulter retrieval). Appointing authorities for contract jobs varied. One year it was the Directorate of Health Services and the next year the District Commissioner (interviews). Contract medical officers have formed an association pressing for regularisation of their tenures. This is uppermost in their minds and agendas.

Several appointees on contract jobs, both doctors and other health personnel, failed to report for work, having found better alternatives. For official records posts are 'filled', though in reality there is no-one working there, adversely affecting general health services and the NTP. This along with absenteeism explains the difference between official and unofficial data regarding vacancies. This discrepancy has been raised in the State Legislative Assembly. It was brought out that doctors especially with postgraduate qualifications prefer not to serve in rural areas. Health Ministers and the government in power do not reveal these aspects in their replies to questions raised in the Assembly. Only when Members of the Legislative Assembly bring information from their constituencies, with which they pursue the discussion does a truer picture emerge.

A certain terminology of staff designations was developed for the NTP. Differences arose as States developed their own cadres and new thinking/ programmes from the Centre created new categories of health personnel with specific roles, sometimes related to

sources of funding especially for family planning and malaria. Names changed and so did responsibilities. Reports from DTP's follow the old NTP terminology. In Karnataka a Treatment Organiser at the DTC for the NTP is a Senior Health Assistant in the State health services, the employer. They perform duties with/ without additional training. The State TB Officer (STO) in the NTP manual is the Joint Director (TB) and the DTO the Assistant District Health Officer in Karnataka. Staff in the general health services have undergone numerous changes. The Auxiliary Nurse Midwife (ANM) and Basic Health Worker with no NTP responsibilities were converted into Multi-Purpose Workers (MPW) and subsequently to Junior Health Assistants responsible for BCG, sputum smears, motivation and follow-up of TB patients. This is indicative of the continuous change taking place to which the NTP responds and through which it is transformed.

The private sector:

Karnataka has pioneered establishing private medical colleges especially since the 1980's (SCHARA 1995). Of 18 medical colleges in the state 4 are run by government and 14 by private bodies (*ibid*). During the past 5 years, private colleges in dentistry, nursing, pharmacy and laboratory technology have mushroomed. The growing capitation fee lobby is influential in state politics, not just in promoting higher education and learning, but running commercial businesses and furthering caste and class interests (Pinto 1993). The 'capitation fee'[13] for a medical college seat was about Rs.4 million in 1996 (interviews). It has altered the socio-economic background of students entering the profession and career choices are geared to making return from the investment made, with few willing to work in the public services. The majority of PHC doctors interviewed in this study were from Government medical colleges or from government seats in private medical colleges[14].

Additional dimensions of the 'informal economy' raised by respondents are payments made for getting jobs (sometimes) and for transfers. There are fixed rates for different

[13] Money required to be paid to get a seat in most private colleges, unlike government run colleges where entrance is on merit and social reservation.

[14] As a bargain to getting government recognition to run a medical college, private managements have to keep a proportion of seats for government candidates without payment of capitation fees.

posts and different regions. These financial investments affect work motivation and attitudes besides becoming a necessity to recoup the amount. This is a possible explanation for widespread private practice by government health personnel.

State government staff are not allowed private practice, but get a non-practising allowance as compensation. However a retired Joint Director(TB) publicly stated that '*private practice by medical officers in government service creates a problem in successful implementation of DTP*" (Krishnacharya 1995;15). Respondents in this study say private practice is widespread on government premises, with patients also seen at home or at other private clinics. Medical representatives from pharmaceutical companies were seen visiting government doctors even in remote PHU's, who do not officially purchase drugs (observation). Of concern too is that a proportion of all grades of paramedical staff engage in practice, raising other legal and ethical issues. For policy purposes boundary lines between the public and private sector are difficult to draw. In this process of bargaining and accomodation patients rights as citizens to free health/TB care is forgotten.

The Chief Minister who promoted privatisation of various sectors, including amending Land Regulations, said in the Assembly after a scandal about kidney transplants, *'There are sufficient medical institutions in the private sector. There is a necessity to control the working of the private sector. In this regard my government proposes to bring a comprehensive legislation to make the private sector work more responsibly'* (Karnataka LA Debates 20/3/95). No regulations were introduced and he moved on as Prime Minister of India for a short period.

TB Drug Issues:

The State Health Minister stated '*Good quality, adequate and regular supply of drugs are key factors for the success of the programme. The drugs are given free'* (Mahadevappa 1995;5). A senior central Government official says of Karnataka *'In all my 10 years I have always found a shortage of TB drugs in every health centre that I have visited....Rifampicin is expensive.... States don't buy it, but depend entirely on the Central*

Government. for its supply.' This illustrates the gap between policy and practice. Short Course Chemotherapy is introduced into 17 districts by the State, yet the main drug necessary, Rifampicin, is usually in short supply.

Sources within and outside Government indicate that for 2 years from 1991 the State did not supply Isoniazid, a vital bactericidal drug in both the standard regimen and short course chemotherapy. This is easy to produce, and costs a few *paise*. Shortages were experienced and recorded in Mysore district. It was the reason for one of the NGO's ,VGKK, to initiate a campaign on TB drugs and related issues with the Voluntary Health Association of India (Chapter 8). Officials say that a tender given to a certain company was not honoured for a long time. Drugs are purchased in the public sector under the Rate Contract System under which the lowest tender has to be accepted. Several sources state that lowest tender may in fact be the costliest to all concerned with bribes paid at various levels, tenders rewritten/ falsely written, the same company putting up 3 tenders, false or doctored quality control certificates being produced etc. This goes on at State and Centre inspite of an elaborate system in place to prevent such occurrences.

Drug companies played prominent roles in meetings organised by the KSTA/TAI, with large banners announcing their products and sponsorship of events, meals. Delegates to the national conference were given expensive gifts, sight seeing programmes were organised and for the technically oriented a variety of interesting quizzes were organised. A senior official said that after sponsoring one such state level event the concerned drug company was trying very hard to get the tender for drug supply to the state government (interview 1996).

The top 3-4 drug companies have initiated continuing education programmes for doctors during the past 3-4 years. Some bring out regular newsletters and a variety of health education material for patients in different languages to be displayed in doctors clinics (interviews with pharmaceutical representatives and observation).

The State government in 1995 waived the Sales Tax on single ingredient TB drugs (Mahadevappa*1996) in order to help reduce drug prices that had been showing a rising

trend over 5 years. Drug companies are now trying to get tax exemptions for combination drugs which are not promoted by the NTP/RNTP because of potential problems with bioavailability (TB Day meeting, 1996).

Until recently shortages of laboratory supplies, X-ray films, and drugs, were reported with some improvements during 1994-95 (Krishnacharya 1995).

7.4.5 Government Health and TB Budgets

Nationally 80% of public spending on health is by the States, 20% being from the Centre (Mahadevappa*1996). In Karnataka 18% of the state health budget comes from the Centre (*ibid*). In Karnataka unlike other States real growth rates in health expenditures were reportedly sustained at 4.4% annually in the 1980's, 5.7% in 1991/92 and 13.4% in 1992/93 (WB 1996b). However government health and family welfare expenditures are low (Table 7.16).

Table 7.16. Expenditures on Health and Family Welfare in Karnataka

	80/81	85/86	89/90	90/91	91/92	92/93	93/94
Expenditure on H&FW as % of State Domestic Product	1.26	1.33	1.25	1.18	1.11	1.29	1.29
Per Capita expenditure on H&FW (in 1980/81Rs)	19.00	22.12	26.00	24.12	25.01	27.83	30.20

Source: WB 1996b

Seventy percent of the annual public sector outlay is under the *Zilla Parishad* sector e.g. in 1992-93 of Rs.2260 million, Rs.1600 was through the *Zilla Parishads* while Rs.660 million was under the State sector (GOK 1991).

In 1995-96 the public health care budget was about Rs.4,872 million (WB 1996). During the year Central Government Assistance to the State TB programme for drugs was Rs. 16,870,000 and the State government allocated a matching amount of Rs.16.8 million for salaries, chemicals, stains, drugs, purchase of vehicles etc. (Mahadevappa 1995). This follows the pattern of Class II Centrally Sponsored programmes i.e. 50% central support

(other programmes such as family planning considered high priority by central government receive 100% support).

External Sources of Financing: In the mid-1980s there was a financial deficit in the State, as at national level. In 1991 after liberalisation measures were introduced nationally by Congress Prime Minister Narasimha Rao and Finance Minister Manmohan Singh, the Congress Ministry in Karnataka (one of the few that remained) followed. The State government health sector received larger external funding than before (Karnataka LA Debates 1994a). In September 1994 the State Health Minister announced in the Legislative Assembly that foreign funding amounting to Rs.10,440 million over five years had been/ was being negotiated with several international agencies (*ibid*). He attributed this to the better health infrastructure and expertise available in the State, attempting to demonstrate good performance during a debate when members raised questions regarding inadequate availability of health services, staff vacancies, and drug budgets.

Loans being negotiated in 1994-95 included (Karnataka LA Debates 1994-95): a) Rs.1330 million for the India Population Project (IPP) IX for development of primary health care infrastructure. b) Rs.420 million from Germany through their foreign ministry for secondary care at district hospitals; c) Rs. 1000 million from the Dutch government for development of accident care/ emergency centres every 40km along the highway in response to the high incidence of accidents; d) Rs. 7000 million from the World Bank for development of secondary care institutions at *taluk* and district headquarters; e) Rs.300 million from World Bank for improvement of health facilities in Bangalore city. Interest rates on the loans ranged from 4-6% with deferred repayment over 15 years. Criticism by officials within the health sector were that India would get further into the debt trap, suggesting that efficient utilisation of local resources would be preferable. In Karnataka, interest payments on debt accounted for 12.7% of total revenue expenditure in 1994/95 and public debt was 27% of State domestic product in 1994/95 (WB 1996b). Just one of the projected WB loans (State health systems development to upgrade secondary care hospitals) represents 4.7% of the current debt (*ibid*).

A large part of the proposals concern construction and repair of buildings, including staff quarters, and purchase of equipment. Besides increased staff recruitment on contract, drug budgets have increased for different levels of health services. State budgets and expenditures for drugs (general) are in Table 7.17.

Table 7.17 Karnataka State Drugs Budgets and Expenditures, 1991-95 (In Rs.)

Year	Budget	Expenditure
1991-92	154.68 million	154.28 million
1992-93	153.93 million	152.93 million
1993-94	220.54 million	220.45 million
1994-95	300 million	n.a.

Source: LA Debates 1995

In 1992-93 national budgetary cuts in health and education following structural adjustment (SAP) were criticised with subsequent changes made through the social security net of SAP (Chapter 6).

Drug budgets for the following institutions rose in 1993-94 from:

PHU..... Rs.20,000 to Rs.30,000 per year,

PHC..... Rs.30,000 to Rs.50,000 per year,

Taluk General Hospital..... Rs.200,000 to Rs.250,000 per year,

General Hospital (District)..... Rs 250,000 to Rs.300,000 per year.

Given the rise in drug prices the real increase is not significant. This may mask urban-rural differentials.

In 1991-93 with growing national fiscal deficits/problems out of central plan budgtary allocations of Rs.5 million for the NTP in Karnataka only Rs.2.3 million were expended, and of Rs.2.5 million in the State plan Rs.2.1 million were spent (JD-TB 1996). Gaps continued in the State plan budget in 1993-94 (Rs.1.3 million spent of 5.7 allocated) (*ibid*). The '*quiet diversion*' of Plan funds for urban hospitals/non-Plan purposes has been observed in several states (Chopra*1995). By 1994-95 higher allocations reached the State as part of government to the Revised NTP. Central allocations tripled from 5 to 15

million and State Plan allocations from 2.5 to 8.5 million while expenditures also rose (JD-TB 1996).

Expenditure for the 450 bedded SDS TB Sanatorium in Bangalore city during 1994-95 was Rs.3.2 million for drugs and Rs.3.3 million for equipment (LA Debates 1995). This is from the medical education budget of the State government as it is a teaching hospital. Together with staff salaries and maintenance the expenditure of just one urban institution would be about 50% of the state share of the NTP budget. Better gains from domiciliary treatment are being lost by this policy. Expenditures of the SDS and PKTB Hospital are not reflected under the TB budget. This suggests that State governments spend more on TB than available figures indicate. Actual expenditure is hidden partly because of the method of reporting and partly because expenditures incurred on TB patients diagnosed and treated in *taluk*, district and teaching hospitals are not fully represented in the NTP budget and expenditure statements. Considering that State government investments exceed national and international contributions, it does not play a strong policy role.

An Indian consultant to another WB project says that '*lack of financial resources is not the reason why work does not get done*'. Other reasons such as lack of management skills, apathy and corruption were cited as reasons for delays and derailment of projects.

7.4.6 Democratic Decentralisation and Health Care

India's ancient system of local governance through *panchayats* at village level received Constitutional recognition in 1950 after Independence. Most State governments legislated on *Panchayati Raj* by the 1960's but the system could not develop adequately due to insufficient political support, power and funding and an emphasis on developing a strongly centralised system. Elections to these bodies were not held for years.

Greater powers to *Panchayati Raj* Institutions were devolved by the first non-Congress Janata Dal government during its tenure from 1983-89. The State Assembly approved the Karnataka *Zilla Parishad, Taluk Panchayat Samiti, Mandal Panchayat and Nyaya Panchayat* Act, 1983, which took effect from April 1987 (Vyasulu 1995). Elections for 3 tiers of government below the State government were held.

Government health care services came under the purview of *Panchayati Raj* Institutions, comprising the *Zilla Parishad* (district council), *Mandal Panchayat* (*taluk* council) and *Gram Panchayat* (village council). There were several instances of confrontation between elected representatives and government health functionaries. Representatives raised questions at different levels of the 3-tier political structure and at the State Legislative Assembly regarding the functioning of PHC's, doctor/staff absenteeism and short working hours, inadequate and irregular drug supplies, and the need to address specifically rural medical problems such as snake bites. A mid-term evaluation reported some improvements in health services, including increased attendance by health personnel by 60%, as a result during that period (Chandrashekar*1996).

Strong negative reactions to this policy arose from the State Government Medical Officer's Association with objections to what was described as political interference. The government health services described as *"being highly politicised themselves"* (Jayaram*1996) were preoccupied by this political change that impinged on their functioning. Their advocacy for change was met sympathetically by powerful policy elite, close to the medical lobby and health was removed from the purview of *Panchayati Raj,* reflecting the State's divided interests. Political instability for other reasons led to a change of Government and in late 1991 the Congress passed an ordinance superseding Panchayati Raj Institutions, which was challenged in Supreme Court (Vyasulu 1995).

However it had caught the imagination of people, including the Congress at the Centre who perhaps saw it as a possible vote catcher. Central government tried to legislate on the subject attempting to create direct links from Centre to local government at district, bypassing State governments. This was widely opposed and the Bill was not passed. After much debate and modification the Constitution (73rd Amendment) Act 1992 came into effect from 1993, delegating greater powers, functions and resources to elected local government, increasing the potential for autonomy and accountability. Three tiers of elected Local Government were set up below the State level. Following the earlier example of Karnataka, there were reservations of 33% of elected seats for women and reservations for Scheduled Castes and Scheduled Tribes in proportion to their population.

The subsequent Karnataka *Panchayat Raj* Act of 1993 reportedly reduced the *Panchayats* autonomy, making Members of the Legislative Assembly active participants and increasing powers of the Chief Executive Officers/bureaucrats (Krishnaswamy 1993). There are 5,655 *Gram Panchayats*, 175 *Taluk Panchayats* and 20 *Zilla Parishads* in the State (GOK 1996).

In Karnataka 30% the entire State budget is transferred to the *Zilla Parishad* sector (WB 1996b), while 70% of the health budget goes to the *Zilla Parishad* from the State Treasury[15] (GOK 1991). The President of the *Zilla Parishad* has the rank of a State cabinet minister and the office has officers from the Karnataka Administrative Services to execute its programmes. Government health staff including the District Health & Family Welfare Officer function under the administrative control of the ZP which is empowered to take action against them if necessary (Chinnaswamy*1996). There are once again reports of surprise visits by elected representatives at *Zilla Parishad* to health centres and hospitals. A *Kuruba* (tribal) man died of gastro-enteritis in Mysore District during the fieldwork of this study. The response from the local PHC was swift and energetic, with daily visits by health staff to the affected village for public health action. This was reported to be in part due to fear generated by *Zilla Parishad* action and extensive media coverage in the district newspaper. The previous year two doctors were suspended temporarily due to inadequate response following a similar episode. Issues of staff vacancies, non-availability of staff during working hours, low drug budgets, non-functioning equipment, non-payment of bills, poor sanitation and drinking water supply are frequently raised in the State Assembly (Karnataka LA Debates 1995). The State Government Medical Officers Association has again opposed administrative control by the *Panchayati Raj* institutions. One of the demands during a one day strike in December 1995 was '*removal of political interference*'(Gnaneshwar*1995, newspaper reports).

Some NGO's work with *Panchayati Raj* representatives creating an awareness specifically about the NTP and general health (Sridhar and Sudarshan 1996). The potentially positive impact of *Panchayati Raj* institutions through peoples participation in

[15] Compared to other sectors a greater and increasing proportion of the health budget is transferred.

improved supervision, functioning and accountability of government health/TB care is widely recognised (Antia 1994, WB 1996c, Rangan *et al* 1997). The State NTP leadership does not appear to have responded to these political changes during the 1980's or 1990's.

7.4.7 Societal Factors and Social Movements

Several societal groups in Karnataka, as elsewhere, compete for social, economic and political gain. The State is also rich in social movements working towards social, economic and political justice, gender, environment, and health issues. If the social and economic roots of TB are accepted then the contribution of these movements/groups to its control will be recognised.

The dominant powerful caste groups in Karnataka are Lingayats constituting 15% of the State population and Vokkaligas with 11%. However they account for 9 of 13 State Chief Ministers so far, more than 50% of seats in the Legislative Assembly (53% currently), with their legislators presently comprising 56 and 67% of the two major political parties (Shastri 1996, Pinto 1992). Their representatives comprise about 50% of the Council of Ministers holding core ministries of finance, revenue, home, commerce and industry while others get welfare ministries including health. They also garnered benefits from the reservation policy of positive discrimination meant for socially marginalised groups (Natraj 1994). Historically disadvantaged groups, the Scheduled Castes (16.7%) and Tribes (6.7%) are under-represented with 7% of seats currently (Shastri 1996). With increasing community/political organisation, social analysis and reservations in formal education, they have gained greater awareness and assertiveness. Discrimination against them is increasingly resisted at individual and group levels, sometimes causing a backlash. Rising numbers of atrocities/incidents of violence have been reported against them (Sitaraman 1994). This may be partly due to increased reporting to the police and greater media coverage. The majority are still economically the most disadvantaged and are likely to have the highest rates of TB. However poverty affects all caste and religious groups though to different extents.

The *Dalit Sangarsh Samiti* (DSS) is a State level movement started by untouchable youth in 1979-80 as a struggle (*Sangarsh*) of oppressed (*Dalit*) social groups. It works towards raising awareness and consciousness of the socially oppressed particularly Scheduled Castes and Scheduled Tribes regarding the causes for their social situation and their basic rights for equality and social justice. It is stronger in certain districts (Gulbarga, Mysore, Kolar) than in others. Over the years it has grown into '*an articulate and widely representative organ of the depressed classes'* (Pinto 1994;897). Their attention has not yet been directed towards health and health care issues according to state level student co-ordinator (Heggade*1996).

The *Karnataka Rajya Raitha Sangha* is a movement of landed farmers in the State. They lobby on issues such as fertiliser subsidies, inter-state sharing of water/ riparian disputes, against the entry of and monopoly by Multi National Companies in seeds etc. They have a widespread network but have also not taken up health issues.

Environment groups such as the *'Apiko'* movement organise people against deforestation of the Western Ghats and have also participated in water and life movements. There is an active movement against the *Kaiga* nuclear power plant. Some environment groups include the preservation of medicinal plants in their ambit and are presently having to battle against the patenting by US based MNC's of traditional remedies.

Social movements have increased in numbers and in analytical and organisational abilities over the years. Their strength is that they are organisations of affected people. They are not yet actively involved in issues of access to health care and equity and social justice in the health domain. This space has been occupied by volags/NGO's. There are links between the two groupings since individuals in NGO's may also be members of a movement. Potentials of forging alliances with these groups and *Panchayati Raj* institutions for improved health, health care and TB care lie ahead.

In conclusion,

- Karnataka state has developed several strengths, some created through policy interventions, beneficial to the NTP. These include a tradition of state health services in Mysore, the NTI as a technical/informational resource, a data base from NTI studies conducted in Karnataka, a widespread network of health services, a better developed *Panchayati Raj* system than most States, an ability to negotiate funding and a fairly active voluntary sector. Its additional financial investment towards TB care, through TB hospitals and 6 extra DTC's, are underestimated. In comparison with 1947 there is greater availability of services, but in the NTP performance is only moderate[16] (ICORCI 1988) with low sputum positivity, case detection and treatment completion rates (DH&FW,GOK 1995, NTI 1994d). Explanatory factors for this are discussed below.

- Political processes altered TB policy negatively in the State such that core technical elements of early case detection and complete treatment/cure are not achieved. Though the transformation of District TB Officer's posts to ADHO's has been justified by some as being a part of integration, the lack of authority/power and training/qualifications at this referral/managerial level harm the programme. The loss of public health skills in key positions (State and District TB Officer's) following conflicts with the clinical lobby, lack of a sense of policy ownership and weakening of key institutions like the State and District TB Centre's adversely affect technical and organisational support, training, supervision and meaningful monitoring required for the programme. This and lack of budgetary powers diminished the leadership roles of these institutions and led to gross neglect of peripheral health institutions and their teams.

- The medical professional lobby functions as a strong interest group in the privatisation of the health/medical education sector, and in resistance by government

[16] It could be argued that the expectations against which gaps are measured are unrealistic.

medical officers to accountability to local government. Alliances between the medical lobby and State political leaders resist local government roles.

- Institutionalised corruption, politicisation of different health cadres, apathy and lack of response to field problems are additional process factors crucially affecting implementation

- These factors/forces were not challenged or addressed by the State leadership of the NTP or the NTI. Exclusive focus on techno-managerial factors further masks these implementation factors. There are few mechanisms by which the NTP and the interests of TB patients especially the poor are protected. There was no evidence as yet, from the NTP in the State of willingness or ability to work with *Panchayati Raj* institutions. Developing linkages with social movements in the State are an opportunity to address underlying social roots of TB (Table 1.3).

- Additional state resources for TB are spent on urban hospitals and not on rural peripheral institutions which provide better and more equitable returns.

- Disempowered and under-resourced at State, District and hence peripheral level, the framework of the NTP has been eroded. The strength of powerful social groups is evident and the inability of the NTP in the State to hold its own against this could question its values and commitments.

CHAPTER EIGHT

NTP DYNAMICS AT DISTRICT LEVEL

8.1 Introduction

This chapter provides a bottom-up view of TB policy and practice, with perspectives from patients, elected representatives, front-line government staff, NGO's and private practitioners[1], covering aspects often neglected in policy analysis.

District Profile: Mysore district, profiled in Table 8.1, the largest of 20 in the state, exceeds the average district population of 1.8 million[2].

Table 8.1 A Profile of Mysore District

Population	3.1 million	Crude Birth Rate	26/1000
Scheduled Castes	5,97,921 (18.9%)	Crude Death Rate	9/1000
Scheduled Tribes	1,02,102 (3.2%)	Growth Rate	2.15%
Area	11,954 sq.km.	Maternal Mortality Rate	2/1000 live births
Density per sq.km.	264	Infant Mortality Rate	70/1000 live births
Literacy Rate	40%	Gender Ratio	953
Urban population.....30%		Hospital bed/population ratio	1:1040

Source: Mysore DH&FWO records, citing 1991 census; DH&FW/GOK 1995a.

Per capita income during 1991-92 was Rs.6500, compared to Rs.5898 for the State. Endowed with natural resources it is one of the prosperous districts (FREHM 1996). In the 1990's the district achieved national health policy goals for 2000AD for crude death rate and demographic growth rate. Social stratification referred to in Chapter 7 exists, with tensions/clashes between dominant and disadvantaged groups in the study *Taluks* (Singh 1992).

Fairly extensive Government health care infrastructure covering 11 *Taluks* of the District include a medical college with 5 teaching hospitals, 3 sub-divisional hospitals, 8 *Taluk*

[1] A star following a name indicates that the source of information is an interview.
[2] The NTP was planned with an average district population of 1.5 million in 1962 (Nagpaul 1989).

general hospitals, 9 Community Health Centres, 125 Primary Health Centres (PHC's), 50 Primary health Units (PHU) and 732 sub-centres, 52 urban dispensaries and maternity homes and one mobile health unit (DH&FW/GOK 1995a, FREHM 1996). Specialised, institution based services are urban, more accessible to 30% of the population. Of 3502 hospital beds, 56% are in Mysore city, the district headquarters (*ibid*).

8.1.1 TB in Mysore District

In the absence of a notification system, annual prevalence is estimated, with calculations used by the NTP for planning since 1962, and for developing targets since 1983.

Table 8.2 Estimated Magnitude of Problem of TB in Study District, 1996

Estimated prevalence of sputum smear positive/infectious TB patients (4/1000*)	12,400
Estimated prevalence of TB suspects with X-ray shadows (16/1000*)	49,600
Estimated incidence of infectious pulmonary TB (1/1000/year**)	3,100

*ICMR 1959, **TB Division/DGHS 1995

Extrapulmonary and childhood TB are additional. The NTP is expected to detect 50% (6,200) sputum smear positive patients annually.

Based on 1955-58 survey data (ICMR 1959) the method assumes a static epidemiological situation over four decades, and uniform epidemiological patterns in diverse regions and socio-economic groups. Estimated utilisation of government health facilities[3], extrapolated from 1960's research, discounts increased availability of public/private services, greater awareness and ability to pay and altered proportions of patients detected/treated by different sectors.

8.2 The Mysore District TB Programme (DTP):

Actors/Institutions and Implementation Processes: The NTP conceptualised a framework of relationships between institutions, building from Primary Health Centres, District TB Centres to the State TB Centre (STC). The DTP was introduced in Mysore District in 1966. Planners envisaged a 5 year period for DTC's to become functional and

[3] The method assumes that a substantial proportion use government services.

implement the DTP in the 50 Peripheral Health Institutions (PHI's) estimated in an average district (Nagpaul*1996). This included constructing[4]/equipping DTC buildings, positioning a trained DTC team, while implementation at PHI's included on-site staff training and organising supplies, recording and reporting systems (*ibid*). Of Mysore district's 240 PHI's (1996), 125 (52%) are incorporated under the DTP, leaving 48% of PHI's and their populations uncovered (Mysore DTC records 1996). Suggestions for an additional DTC made at a meeting of District TB Officers has not been taken up (interview 1996).

The NTP assumed rapid development of general health services and their involvement in TB work. This is only partly actualised 35 years later. In the 1980's expansion of primary care infrastructure took place nationally and is evident in the study area. PHC's in HD Kote *taluk* increased from 1-11 between 1984-1995 (Mysore DH&FWO records, 1996). Several Primary Health Units[5] were upgraded to PHC's, and a PHC at *Taluk* headquarters town converted to a 50 bed General Hospital in 1990[6]. While structures exist, lack of real resources of trained staff and drugs (FREHM 1996), and excessive focus on family welfare[7] diminishes their functional efficacy. Only half the health facilities in the district are involved in the NTP (Table 8.3).

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[4] In the 1980's on average there were 60 PHI's/district with 1.8 million people (Nagpaul 1989).
[5]an earlier pattern of smaller medical care units, without beds, fewer staff and no community based services.
[6] An NGO collaborated by donating an X-ray machine and constructing a building for health education activities. It has also supported some PHC's in the *taluk* with furniture, equipment, TB drugs and occasionally buildings (MYRADA director*1996).
[7] Expenditure on family welfare grew at 23%per year, primary health at 18% and secondary/tertiary care at 16% (DHFW/GOK 1995a). Primary health infrastructure development was to facilitate family welfare and paid for by the India Population Projects (*ibid*).

Table 8.3 Peripheral Health Institutions Implementing the DTP in Mysore District

Peripheral Health Institution's (PHI's)	X-ray Centres*	Microscopy Centres* (PHC's)*	Referral Centres* (Sub-centres)	Total
Total number	17	45	178	240
Implementing DTP, use Short Course Chemotherapy	17	30	14	61
Implementing DTP, use Standard Regimen	-	15	49	64
Total implemented	17	45	63	125

*Source:*Mysore DTC records 1996 *X-ray centres include 4 District/teaching hospitals/DTC, 10 *Taluk* General Hospitals, and PHC's with X-ray facilities. Microscopy centres are PHC's equipped with microscopes. Referral Centres are PHU's and sub-centres without diagnostic facilities.

Peripheral Health Institutions with capacity to participate in the NTP are just over 62 (Table 8.3). The majority 178 referral centres/sub-centres staffed by one/two health assistants, without microscopes/TB drugs have negligible NTP involvement (interviews/observation 1996). Short Course Chemotherapy is available only from 66% (30/45) of PHC's and 25% (61/240) of all PHI's (Mysore DTC records 1996).

The TB Hospital treats large numbers of patients from different parts of the district with SCC. Treatment of those coming from Standard Regimen areas gets altered during the shift back to PHI's/private practitioners, causing irregular/incomplete treatment. Patient/doctor interviews (public and private) indicate that *taluk*/district hospitals, particularly the Mysore TB Hospital are important referral centres providing diagnostic services, inpatient facilities and specialist consultation. The NTP focus on the DTC, classifies hospitals as PHI's in the same category as PHC's not according recognition or role to their expertise/specialised facilities.

Staffing: Shortages of PHC *Medical Officers* in the district occur for various reasons. With no appointments by the Karnataka Public Service Commission since 1990, the State government appointed 500 doctors on one year renewable contracts[8] from 1994, of whom

[8] They receive lower fixed emoluments with no increments. Only 341/500 reported for duty, thus shortages continue, though for the records posts have been filled (Mahesh*1996).

53 are in Mysore district (comprising the majority of government medical officers in 1996) (Basavaiah*, Mahesh*1996). While serving short-term purposes of providing primary medical care, these doctors untrained in national programmes/the NTP because of brief tenures, are unfamiliar with administrative procedures of indenting, reporting etc. They are also preoccupied with extending contracts through organisation of an Association (interviews 1996). These local processes affecting the DTP have not elicited any response from State TB programme managers.

The *taluk* hospital with 50 beds and 7 sanctioned Medical Officers posts, had 2 MO's working during the study period. Although recently changed rules post specialists to *taluk* hospitals (where their expertise can be used) rather than PHC's, the private sector still attracts with better financial returns. There are shortages of women MO's with only one each in the two *taluks.*

Forty five percent of the 70 *Laboratory Technicians* (LT's) posts in the district were vacant in 1996 (DH&FWO records 1996), the percentage being higher in other districts. 32 serve 3.1 million people (1/100,000). HDKote Taluk had two Laboratory Technicians in the public sector for a population of 215,000 while Yelandur *taluk* had none for its population of 70,000. A significant proportion of microscopists/LT's paid by the National Malaria Eradication Programme spent most of their time working for it, though HD Kote *taluk* is free of malaria[9] (*ibid*). Salary payments have recently been transferred to the States which may freeze/reduce the number of posts (Mishra*1996). Vertical programmes thus affect integrated programmes in the field.

Resource constraints in Karnataka led to a freeze on new recruitment's for permanent posts (Jayaram*1996). Litigation regarding the reservation policy also delayed appointments. Mandal Commission recommendations[10] of 65% reservations for Scheduled Castes, Scheduled Tribes and Backward Castes were challenged, with Supreme Court ruling that reservations should not exceed 50%. Legal proceedings took

[9] Targeted numbers of routine blood tests for malaria parasites are done for patients with fever.
[10] Reservations for socially disadvantaged groups in central and state government jobs introduced after Independence as a form of positive discrimination.

several years during which proportions of posts could not be worked out, delaying appointments (interviews 1996). Thus a variety of processes affect the NTP.

The system of continuing on-site education and quality control does not work. During supervisory visits which are infrequent, slides are not cross checked. The State Laboratory Technician's Association, with district branches, concerned primarily with salary issues, is weak due to small numbers.

Other vacancies (Table 8.4) adversely affect national programmes including the NTP.

Table 8.4 Staff Vacancies in Mysore District

Staff Category	Vacancies
Health Assistants (Male)	15-92% in different *taluks* (48% in HDKote *Taluk*)
Health Supervisors (Male)	32-75% in different *taluks* (67% in HDKote *Taluk*)
Health Assistants (Female)	16% in three *taluks*
Health Supervisors (Female)	14.6% in the district
Clerical Staff	34% in the district

Source: FREHM 1996

Equipment: Poorly functioning X-ray machines/radiographic facilities in the public sector are compensated by the voluntary/private sector in the study area (Table 8.5).

Table 8.5 Radiographic Diagnostic Facilities in Study *Taluks*/Mysore District

Health Facility	Observation
HDKote General Hospital .....(public)	Not working during study period, X-ray technician had no work.
Yelandur PHC ,,	Unutilised since installation 18 months ago, no technician.
PKTB & Chest Disease Hospital, Mysore ,,	Not working for 3 months during study.
DTC, Mysore ,,	Functioning, miniature films only taken.
One NGO hospital in each *taluk* & in Mysore	Machines in working order.
Private diagnostic centres in Mysore and neighbouring *taluk* headquarters	Machines working, get referrals from public hospitals and private practitioners.

These factors severely handicap diagnosis/monitoring of treatment under the NTP, adversely affecting technical content/conduct of the programme. Though raised by evaluations (ICMR 1975, ICORCI 1988) these issues have not been acted upon.

Health Education: There was no health education material on TB/NTP at the District Health Education Office, though abundant material was available on Family Planning, immunisation, with a smaller range on leprosy, malaria, AIDS and Japanese Encephalitis.

Case Detection under the DTP in Mysore District: Table 8.6 gives the number of sputum examinations and case detection at the Mysore DTC over time. From 1983-84 targets were established and monitored for these two aspects of the NTP, assuming that cases detected would be completely treated.

Table 8.6 Diagnostic work under the Mysore DTP over time

Sputum Examination				Case Detection					
Year	Target	Achiev-ement	Percen-tage	Target	**Bacillary**	X-ray	Extra-pulm.	**Total**	%*
83-84	12600	11875	94	5172	**136**	1314	762	**2212**	43
84-85	12600	22056	175	5544	**158**	2325	571	**3054**	55
85-86	12600	19763	157	5544	**607**	2680	304	**3591**	65
86-87	13200	12853	97	5604	**576**	5321	231	**6127**	109
87-88	15600	27094	174	5564	**829**	5359	177	**6365**	114
88-89	13200	30592	231	5556	**1364**	4817	408	**6589**	118
89-90	12000	14855	124	5940	**1762**	4859	498	**7119**	120
90-91	12000	15462	133	5940	**2450**	6942	243	**9635**	162
91-92	12000	21042	175	5940	**1313**	2914	253	**4480**	72
92-93	13027	13086	101	6000	**715**	2293	279	**3287**	55
93-94	13225	15191	115	6000	**956**	1921	301	**3178**	53
94-95	13050	18883	145	6336	**976**	2529	330	**3835**	60

Source: Mysore DTC records, * percentage achievement

Despite large and increasing numbers of sputum tests, the proportion of sputum positive cases detected was low, with an average of 5.7% (less than the expected 10%). The ratio of bacillary to non-bacillary cases improved from 1:15 in 1983-84 to around 1:4 from

1990-91, the shift occurring after leadership change at the DTC. A doubling of X-ray positive cases occurred after 1886-87 when a new X-ray machine with Odelca camera from a SIDA grant replaced the older machine from the 1960's.

Records showed that monthly variations were marked. A majority of sputum tests were done at larger urban specialist/teaching hospitals/*taluk* hospitals rather than rural PHC's. Sputum examinations reported as part of the monitoring system, include 3-5 repeat tests done for hospitalised patients. The total number thus does not indicate increased diagnosis in the periphery closer to patients homes, as expected by NTP planners.

Though PHC's have targets for sputum examinations[11], these were infrequently done at PHC's (patient interviews 1996). Validity of routine monitoring data is questionable. A pilot cohort analysis in Mysore district reported wide discrepancies between different records maintained, such as the TB Case Index Register and Quarterly DTP Reports (NTI 1994b). National and international analysis for assessments and policy making, based on such data, could mislead.

In 1994-5, the Mysore DTP detected 976 new sputum positive cases (15.7 % of the target of 50% or 7.8% of estimated prevalent cases in the district). Given low treatment completion in the public sector (Table 8.7), 2-3.5% of prevalent infectious TB patients complete treatment in Mysore District. The natural history of the disease achieves a 33% spontaneous cure (NTI 1974).

Treatment Completion: A cohort study found treatment completion rates in Mysore district lower than the national average (Table 8.7). Cure rates could not be calculated due to lack of data on treatment outcome and on final sputum smear examination (NTI 1994b).

[11] 2% of outpatients, though this was dropped in 1996 with adoption of the target free approach (Basavaiah*1996).

Table 8.7 Treatment Completion Rates in the Mysore DTP

TB Classification	Completion Rate
Bacillary TB	
On Standard Regimen	17.0%
On SCC	43.8%
X-ray suspects	18.8%
Extrapulmonary TB	24.7%

Source: NTI 1994b

Speculation on Possible Impact of Interventions on the Epidemiology of TB: Programme planners estimated that the NTP should detect and cure a number equivalent to the incidence of infectious pulmonary TB to begin to impact on the problem (Nagpaul*1995). In Mysore district 3,100 new patients with infectious pulmonary TB need detection and treatment annually. Though average annual case detection between 1992-95 was 3433, detection of bacillary cases was 882 on average i.e. 28% of potential incident infectious pulmonary TB patients. With current treatment completion rates (Table 8.8), 4.8%-12.4% of the 3,100 incident infectious cases (Table 8.2) get cured. Using NTP estimates that the private/voluntary sector treat an equal number, and assuming similar performance, 10-25% of incident bacillary cases are cured annually as a result of medical intervention. This is insufficient to influence disease transmission.

TB drug shortages were a major problem cited by staff and borne out by records. 'This causes us, the health system to default. In addition to patients defaulting it results in us producing (drug) resistance' (DTO*1996). DTC's receive drugs worth Rs.100,000 per year, 60% from central government, for which DTO's indent annually, based on number of cases treated. Supplies are from the Madras General Medical Stores. These had not been received though eight months of the year were over. Forty percent is from the State Government, supplied from Bangalore. The DTC retains a fair share of the supply for its own use distributing smaller quantities to PHC's, resulting in greater shortages closer to the periphery, particularly for expensive drugs like Rifampicin. Resorting to prescriptions, an act of discretion, is justified because of circumstances perpetuating

medical and pharmaceutical interests. There is no evidence of government health personnel lobbying government to improve drug supply or create legal local alternatives. The issue was taken up with the State Health Secretary by NGO's (Sudarshan*1996). By late 1996 the drug supply situation improved in the DTC with the State Government increasing its budget partly in anticipation of external aid.

DTC staff observe that the large majority of patients treated by them are poor. Income levels are not recorded to validate this, but observations over 12 visits did. Economically poor patients and elected representatives say they depend on government hospitals for treatment, most often at the TB Hospital. Public providers felt that incomplete treatment was more common among the poor, linking it to an inability to pay.

Qualitative Aspects: Several visits to health institutions for staff interviews/information (Table 8.8) provided occasions for observations.

Table 8.8 Visits to Health Facilities

Type of Health Facility	Number of Visits
Visits to Sub-Centres	21
To PHC/PHU's	27
To the *Taluk* General Hospital	6
To PKTB & Chest Disease Hospital	3
To the DTC	10

Timing and Availability: Recorded observations reveal that staff often came late and left work early. If this was the doctor, other staff just waited or left. Sometimes Health Assistants and untrained staff treated patients. There seemed to be informal agreements between staff regarding their absences. In some PHC's found closed, doctors were reported to come once in a few days or for 2-3 hours/day (interviews 1996). Patients were not informed in advance regarding absences, nor were there notices or alternate arrangements. Besides misusing salaried time, and wasting resources of the entire unit, credibility with patients was lowered. This is an important factor driving patients to the private sector. Staff often commute from nearby towns for lack of staff quarters (especially in sub-centres), water supply, or personal reasons such as children's

education. In contrast private practitioners who also commuted, are available for longer hours, often working a seven day week (interviews).

Staff Patient Interaction (observations): While some doctors were polite, kind and thorough, others were mechanical, 'disposing' patients quickly and casually. There was often no opportunity for patients to ask questions. Some Health Assistant's were rude and brusque, particularly with poor patients, resulting in occasional arguments.

A policy relevant finding is that the public sector does not provide free treatment. Taking money for services was common at every level except from the really poor and destitute. The amounts were small[12] with staff accepting whatever patients gave. Money collected does not go to the centre to improve services but to staff on government salaries. Doctors sometimes bought medicines from Mysore with their personal money, dispensing them to patients on payment, interpreting this as social service. While compensating for poor drug supplies and saving patient's trips to the nearest town pharmacy, doctors benefited as well. Thus there was a process of accommodation on both sides. Many felt there was nothing wrong in receiving/giving small amounts of money.

Staff Perspectives: Staff salaries were reasonable with PHC medical officers getting Rs.9,500/month, junior health assistants starting with Rs.3460/month and junior laboratory technicians Rs.3,315/month. However staff quarters were inadequate/non-existent and house rent allowance very low. The PHC buildings were poorly maintained, sometimes with water supply and electricity problems. There were no telephones or transport[13] and health workers walked to cover the villages under their care. Vacancies were greater in remote centres with only 3/14 staff working in one PHC. Payment of money for getting jobs and transfers is common practice. A major problem concerned drug supplies in general. Annual drug purchase budgets of Rs.50,000 for a population of 25,000 or Rs.2/head was insufficient, *'stocks for the year are enough to last 2-3 months only'*. Also, *'we give our indents but we get whatever they have'*. Doctors perceived the drugs they received as being of poor quality, *'people throw away the tablets because they*

[12] Commonly Rs.2 for sputum cups, Rs.5 for sputum examinations, Rs.10-20 for X-rays, Rs.5 for a few drugs with prescriptions for the remaining drugs available from private pharmacies.

[13] A new scheme is to provide loans to health workers to purchase personal mopeds (interviews).

don't work and then lose faith in us.' Non-responsiveness to local need caused reduced credibility, '*The main stress at the PHC is on prevention, though the main needs of the people are for curative care. I see so many Acute Respiratory Infection's these days, but have no antibiotics/drugs. And I am supposed to concentrate on cholera when we hardly have any cases.'* Thus resorting to private prescriptions was justified by them. On the other hand they made little effort to pressure government to improve this situation. Health workers felt dependent on doctors, suggesting that much depends on their personality/ability. Field workers expressed uncertainty, *'when we refer patients to the PHC we can never be sure if anybody will be there, if the sputum test will be done, or any action taken'*. Working conditions were difficult.

Thus, implementation processes resulted in extremely weak peripheral institutions. With underdevelopment of the institutional framework within which it functions, compounded by a lack of power/authority and resources, the DTC cannot play the key role assigned to it. Other public sector actors were also ignored as discussed below.

Local Resources- Role of the TB and Chest Disease Hospital: With 470 beds and 164 staff this specialist hospital (administratively/financially under the State Directorate of Medical Education), trains medical students, nurses, Diploma/MD students in TB and Chest Diseases and provides a substantial proportion of patient care in the district (Table 8.9).

Table 8.9 Five-year Patient Statistics, TB Hospital

Year	Inpatients*	Outpatients*			
		Men	Women	Children	Total
1991	3148	7674	4660	1847	14,181
1992	3818	7685	4819	1820	14,324
1993	4315	7776	4948	1796	14,520
1994	4242	9231	5299	1848	16,441
1995	4135	10755	6299	2269	19,323

*Source:*PKTB &Chest Disease Hospital records. Repeat visits/non-TB chest conditions are included.

It has chest physicians, cardiothoracic surgeons, post graduate students, 44 trained nurses and student nurses on its staff. It offers laboratory and radiographic services with diagnosis usually being made within a day. It runs its own pharmacy. Inpatients are given free treatment, food, and accommodation on a nominal charge, but outpatients often have to purchase medicines. Patient retained record booklets, providing information/health education, printed by the Mysore District TB Association, are available to patients at a charge of Rs.1. Additionally the Employees State Insurance Hospital and Railway Hospital have agreements with the PKTB and Chest Disease Hospital for admission of patients. Outpatient, domiciliary treatment is undertaken by them.

The hospital is a major resource and actor in TB treatment and care in the District, widely known among patients, families, people, elected representatives, and private medical practitioners throughout the district even in remote areas (interviews 1996). PHC doctors refer patients here rather than to the DTC. However for the NTP it is just another Peripheral Health Institution. NTP programme managers and others critique TB hospitals for prescribing irrationally. At worst it is unlikely to be more irrational than other institutions, and if true, there are few NTP efforts to alter practices. They appear to be remnants of historical underlying conflicts between clinical and public health approaches.

In Karnataka 9 TB and Chest Disease hospitals are financed by State Government (JD-TB reports 1996), of which three are attached to medical colleges, providing post-graduate education. This study reveals that TB hospitals treat a large number of TB patients in the district, particularly the poor, and need more active involvement in the NTP particularly in training in which it could support and supplement the DTC[14]. Referral links exist but more balanced institutional linkages with the DTC would help.

From a policy perspective, a major player at district level is marginalised by the NTP, as is the role of *taluk* general hospitals. Government is not a single actor and different subgroups if not competing, do not usually collaborate and co-ordinate sufficiently.

[14] Besides training it could take care of all TB patients co-infected with HIV in the district. Upgraded laboratories with culture and sensitivity facilities could monitor drug resistance, and cross-check slides from peripheral institutions.

National analysis does not take account of these subplayers within government, part of the overall effort in TB control.

In summary, the institutional base for primary care through which the NTP could function has increased particularly in the 1980's. However 48% of peripheral institutions are not involved in the NTP, and the work of other PHI's is minimised by lack of real resources, suggesting that in the field 'the emperor has no clothes'. Primary care institutions are funded and driven by the family welfare and malaria programmes and are apathetic towards TB. Institutions with better TB care capacity continue to be urban based, though their role is underestimated by the NTP. Political forces influence staffing. Processes of accommodation occur between patients and providers, though patients appear to have little choice. Leadership (DTO's and MO's) at DTC's and PHC's has little power or authority. This weak base promotes patients to use the private sector.

8.3 Patient Perspectives

Patient Profile: The Scheduled Castes and Tribes *(Nayakas* and *Soligas*), the majority of the sample[15], were predominantly landless labourers. A few had small plots of land, usually dry and un-irrigated. Daily wages in the area were low, Rs.15-20 for women and Rs.25-30 for men. Employment was not always available, being largely seasonal or related to projects such as digging of a canal, and work was physically demanding. This group represents the poorest segment, with one person being destitute. *Lingayats* and *Vokkaliga's* higher up the social hierarchy, owned some land. Though links between poverty and TB are recognised, what came as a surprise was the extent to which the disease led to indebtedness, landlessness and further impoverishment among this group (Table 8.18). On a national scale the magnitude would be enormous. Without social security patients and their families, victims of circumstances are left to fend for themselves. About 18% (11/68) in this study had a family history of TB, accentuating the vicious social cycle. A demographic profile of the patients is given in Table 8.10.

[15] Selection given in Chapter 3.

Table 8.10 Demographic Profile of TB Patients

Characteristic	Yelandur *Taluk*	HDKote *Taluk*	Total
Total Number	42	26	68
Gender			
Female	22	10	32
Male	20	16	36
Age Groups			
00-18 years	3	5	8
19-45 years	26	13	39
> 46 years	13	8	21
Caste Group			
Scheduled Caste	27	8	35
Nayaka (S Tribe)	8	14	22
Lingayat	4	2	6
Vokkaliga	2	1	1
Other	1	1	4
Marital Status			
Married	26	18	44
Unmarried	8	6	14
Widow	5	2	7
Widower	1	-	1
Deserted	2	-	2
Villages represented	24	17	41

Patient's initial choice: A wide range of health providers were approached (Table 8.11).

Table 8.11 First Health Provider Ever Approached

Health Provider	Yelandur *Taluk* n=42	HDKote *Taluk* n=26	Total
Public	11	14	25 (36.7%)
Private	17	6	23
Voluntary	1	2	3
Herbal/ Home remedies	6	3	9
Temples/ Astrologers	7	1	8

This refers to the first visit only, with subsequent visits to other providers, shifting more to the public sector. The continuing shift between health providers during different phases of seeking a cure from the 'bazaar' of TB treatment is striking.

Role of Community Health Volunteers and Health Assistants: Community Health Volunteers[16] play no role in the NTP as 'health confidantes' situated in villages, during early symptom stages or later in the treatment. No patient used their presence/services. In the study area they do no health work presently, although they continue to collect a monthly honorarium of Rs.50.

Junior Health Assistants (HA's) make home visits and five patients, significantly the poorest and in greatest social need, approached them for help. However effective action did not result other than being given a couple of tablets (possibly paracetamol) which 'didn't work' and being told to go to the PHC. HA's paid routine home visits to 54 out of 68 patients indicating an established presence in villages where many patients know them by name. However, having gone there, no initiative was taken to identify 'chest symptomatics' and in no patient was a sputum smear taken at home. Interestingly, many of the patients histories referred to the period in the 1980s when policy shifted to active case detection, targets, monitoring with involvement of HA's in motivation, sputum smear collection during home visits. Positive action by HA's was limited and included a smear taken from one patient later in the PHC; a referral letter given to another, and in a third the patient and family were actively persuaded to go to hospital.

During the treatment phase 5 patients were injected streptomycin by the HA's. Not legally permitted to inject, other than for immunisations, they made pragmatic decisions.Three patients said the injections were given free of charge and two paid a little. Two HA's were said to have given health education (how to prevent airborne spread of infection, giving up smoking/alcohol), and in helping overcome negative and suicidal feelings. Thus HA's potentially play positive roles, though presently this occurs occasionally.

More generally, HA's had low credibility among patients/their families, not having established reputations of being helpful:

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[16] Introduced in 1978 they were links between communities and government health services. 1worker looked after 1000 people, after a 3 month training, playing an educational role and providing minor ailment treatment.

~They are most often dismissed as being '*of no use*'.

~The almost universal reference to them was as '*those people (who come unasked*, said one) *write on the walls and go away'* (a recording system for the malaria programme).

~'*they did not enquire about our health and we did not say'* was common;

~or even if they asked '*we did not tell them anything'*.

~Patients said '*TB is a big disease and they do not anything about it'*;

~'*if trained big doctors are of no use, what can these people do'*;

~'*we do not take tablets they give, being afraid that something may happen'*;

~'*government has not trained them to treat TB, they do not know sputum testing, they can do nothing about TB'*;

~'*the tablets they give are only worth 15 paise and are useless'*;

~'*these people talk unnecessarily and go and tell all the neighbours'*;

~'*even after telling them about having TB, they did not give me TB tablets but non-TB tablets'*;

~One young man, studying for his B.Sc. and Secretary of the Ambedkar Youth Association said he got very annoyed with the HA threw away his pencil, scolded him and warned him not to come again. He felt that HA's offered no real help or service and it was a waste of government money to pay them a salary.;

~In another better off patient's case, the HA '*used to visit 2-3 times a week and have butter-milk',* but the mother did not disclose anything about her daughter's TB, *'as there would be no gain and why talk.... it may affect the marriage prospects of my daughter'*.

~ More serious comments, though infrequent, were that one or two HA's '*run private clinics and make a lot of money'* and '*the HA is not available for us Scheduled Castes, she injects everybody but not our caste'*.

They were identified by one or two as doing family planning work and caring for mothers and children. In 2 patients a blood smear was taken and a few more received 2 tablets for fever (presumptive treatment for malaria) which either 'didn't work', caused giddiness, or were not taken at all. They did not visit remote hilly tribal regions of the *taluks,* these populations being covered by voluntary organisations. Thus national/international health

programmes get transformed and altered at grass-root level and the script continues to be rewritten further on.

On the whole Health Assistant's did not play an effective role in the NTP. It is important to question why this is happening as health workers were effective in the NGO's in the same *taluks*. On the one hand government workers did not receive adequate supervision/support/feedback regarding the NTP from medical officers. The PHC/DTC did not provide leadership, precept, motivation or ongoing training required for the purpose. Medical officers themselves were hindered by poor drug supplies/resources, inadequate powers, little support and an over-emphasis on certain programmes. On the other hand there was a lack of accountability to people and to the health system.

Diagnosis: Table 8.12 indicates the type of health provider at which TB was first diagnosed in this group of patients.

Table 8.12 Health Providers at which Diagnosis of TB was First Made

Health Provider	Yelandur *Taluk* n=42	HDKote *Taluk* n=26	Total n=68
Public Sector	24	8	33
PHC	1	1	2
DTC	0	0	0
Taluk Gen .Hospital	8	3	11
PKTB&CDH	11	4	15
KRHospital, Mysore	4	1	5
Private Sector	14	9	23
Within *Taluk*	4	2	6
At Mysore	3	7	12
Neighbouring *Taluks*	7	0	7
Voluntary Sector	4 VGKK 2, KTrust 2	8 SH 5, Camp 1*,HMH 2**	12

*Camp organised by MYRADA with technical inputs by the DTC

**MYRADA had a referral arrangement with Holdsworth Mission Hospital, Mysore

The crucial finding is that negligible numbers were diagnosed at PHC's closest to people's homes, envisaged by the NTP to be the anchor of the programme[17]. Geographical access to health care, which was at the heart of the philosophy of the NTP, has not been actualised in the process of implementation.

The role of the DTC also was minimal with no patient diagnosed there. Only 2-3 visited later during treatment for drug collection, being referred by a voluntary organisation or the TB hospital. Even allowing for selection bias and chance, if substantial diagnosis was taking place at the DTC, it is unlikely to be completely missed in this sample.

A shift can be noted from the pattern in Table 8.11 (first health provider ever) in comparison to Table 8.12. Patients who used herbal medicines, temples etc. became redistributed among the 3 sectors, with larger proportions of patients diagnosed by the public and voluntary sector. Though the number going to private providers remains the same, they are not the same patients or the providers that appeared in Table 8.11. Private providers first visited were often those closest, usually within the *taluk*, and rarely made the diagnosis. Diagnosis tended to be made in Mysore or *Taluk* Headquarters. Issues of competence and quality of care[18] among private and public providers needs consideration in policy making, which presently speaks rather generally about these sectors.

Diagnostic Methods and Treatment: Despite concerns regarding over-reliance on X-rays instead of sputum microscopy, in this sample 66/68 patients had sputum tests done for diagnosis. The first sputum test was done by public providers in 54% and the remaining by private and voluntary providers (Table 8.13). Most patients had repeated sputum tests, usually at public hospitals, as they shifted from one provider to another. The TB and medical college (KR) hospitals do sputum tests at admission, midway during

[17] This was realised by planners in the 1970's though according to their figures about 70% of case detection was occurring at the DTC's and about 30% at peripheral institutions and this was increased to 50% after targets for PHC's were introduced in the 1980s. All institutions in the district other than the DTC are classified as peripheral institutions. Thus secondary/tertiary care institutions situated at district headquarters were equated with rural PHC's and provide much of the TB care.
[18] Besides issues of equity, mandate, lack of organisation and accountability.

hospitalisation and before discharge. An important finding is that PHC's do a negligible number, which is not what policy makers had envisaged.

Table 8.13 Provider at which Sputum Microscopy was First Done

Provider	PK TB Hospital	*Taluk* Gen.Hospital	KR Hospital	PHC	NGO	Private	Not tested
Number	21	8	5	3	12	16	2 ?+1

The Logical Link between Diagnosis and Treatment: Of concern is the large number of providers used by each patient and the disjunction between providers making the diagnosis and those undertaking the major part of treatment. Only in 17 out of 68 patients was diagnosis and treatment largely completed by the same provider. The range narrowed down in this group with 8 patients being 'held' by voluntary services and 9 by the government TB hospital. Seven additional patients relied partly on the public sector. Patients made several visits to a range of health providers in their search for a cure, an observation made by other studies (Uplekar and Rangan 1996). The actual visit at which diagnosis was made varied (Table 8.14) and was often only after repeated visits, due to doctor delays[19] and inherent difficulties in diagnosing TB early.

[19] Diagnostic delay is the duration of time from symptom onset to institution of effective therapy. Its two components include patients delay from symptom onset to seeking care and doctors delay from first presentation to institution of adequate therapy. Long delays increase transmission (Murray 1994).

Table 8.14 Visit at which TB was Diagnosed

Visit Number	Yelandur *Taluk*	HDKote *Taluk*	Total
Visit 1-3	22	7	29
1	8	1	9
2	6	2	8
3	8	4	12
Visit 4-5	14	13	27
4	8	8	16
5	6	5	11
Visit 6-9	5	6	11
6	1	2	3
7	2	3	5
8	1	1	2
	1	0	1

Analysis of the main provider loop revealed that most TB treatment was provided by public providers, especially the TB Hospital linked to PHC's/General Hospitals/pharmacy prescriptions. The DTC, the pivot of the programme, was conspicuous by its absence in this picture. Voluntary agencies provided complete TB treatment to the smaller number of patients they catered to. Only one private provider completed treatment to cure, but in exchange for rights over the patient's (a widow) land for a period of 5 years.

Diagnosis and treatment is thus provided largely by secondary/tertiary care hospitals rather than primary care networks. At PHC's there were problems of drug shortages, of all or some drugs; negative staff attitudes and behaviour (*'they treat us like sheep'*, *`the nurse scolded me'*) and less frequently non-availability of doctors. Patients spoke with strong feelings about these experiences, most often discontinuing treatment at these times. Concepts held by policy planners of good quality, humane services, available close to peoples homes, free of cost, that would reduce suffering and help control disease are yet to be realised.

Hospitalisation: A major surprise was the high rate of hospitalisation (73.5%) in this sample (Table 8.15), in contradiction to a cardinal feature of domiciliary/ambulatory treatment of the NTP.

Table 8.15 Hospitalisation of TB Patients

Hospitalisation	Yelandur *Taluk* n=42	HDKote *Taluk* n=26	Total n=68
No. not hospitalised	8	10	18
No. hospitalised	34	16	50
No. hospitalised once	23	14	37
No. hospitalised			
twice	9	0	9
three times	2	1	3
4 times	0	1	1

This could possibly be due to delayed diagnosis in this group of poor patients resulting in more advanced disease. Of the 18 non-hospitalised patients, 9 were treated by voluntary agencies, even though they had hospital facilities.

No gender difference was observed in the functioning of the programme towards this group of patients.

Role of Voluntary Organisations:

Table 8.16 TB Patients Treated by Voluntary Organisations/NGO's

NGO Treatment	Yelandur *Taluk* n=42	HDKote *Taluk* n=26	Total
Entire treatment by NGO	2	3	5
Treatment mainly by NGO	8	1	9
Part treatment by NGO	5	3	8
a) discontinued (poor impression)	3		3
b) approached by HW:not gone	2	3	5
c) plan to go	1		1

In Yelandur *taluk* where TB treatment is provided by the voluntary sector under contract to government, 15/42 patients (37%) had been to the NGO and ten were very satisfied. For the main part of their treatment others used public services at district headquarters or neighbouring *Taluk* General Hospitals. This *Taluk* does not have a Government General Hospital. Barring two *Soliga* tribal patients, all the others used a mix of public and private providers.

Herbal Remedies, Temples and Astrologers: 32/68 patients used one or more of these at some time, though none experienced relief from their use. In a small but significant number diagnosis and onset of treatment was delayed consequently. However in several cases traditional healers advised patients that *'this was a hospital disease'*, recognising that the problem was beyond them and referring patients.

Disease, Dispossession and Disability: There were distressing socio-economic problems prior and consequent to getting TB (Table 8.17), impacting on treatment and progression of the disease process. These findings were revealed by unstructured interviews, (not specifically sought/probed but raised spontaneously by patients), and probably underestimate the true dimensions of the problem.

Table 8.17 Social Consequences of TB and Effect on Treatment

Impact	Yelandur *Taluk* n=42	HDKote *Taluk* n=26	Total n=68
Economic Effect *mortgaging/selling assets; taking loans	23	16	39 (57%)
Disability& Inability to work	8	10	18 (26.5%)
Effect on Treatment (delayed, irregular, or incomplete)	23	13	36 (53%)

TB increased impoverishment and indebtedness because patients had to sell/give up their livelihood. They sold small pieces of land/one or two cattle they owned, *mangalsutras* (necklace which is a sign of marriage), homes, furniture and even household utensils. They took loans from family, friends and neighbours. Inability to work meant a loss of income for landless labourers, usually increasing the burden on the wife/husband, who also had to be care giver and look after the children. Uplekar and Rangan (1996;29) report TB related indebtedness among one third of patients studied. It is also reported from a study of poverty in Ahmedabad (meeting 1996). Quantitative data cannot grasp or express the suffering that patients/their families went through or the efforts made in seeking a cure. The fairly widespread magnitude of social consequences was experienced as a problem as big as the disease. This aspect was not directly addressed by any sector, except a few *panchayat* members who directed developmental loans to affected families. Nationally and internationally this problem is submerged by the predominantly technical frame of TB control strategies[20].

In summary, patients lack confidence in health workers and peripheral institutions and use a range of provider services. Public sector hospitals play an important role in the treatment of TB patients, particularly for the poor and hospitalisation rates are high. The social consequences of indebtedness and disability were distressingly high.

[20] It is worthwhile recalling that in most industrialised countries social security was provided in addition to free treatment.

8.4 Local Government as a Political Resource

Local Government at District Level and Health: The *Zilla Panchayat* (District Council) with a President, Vice President, Secretary, Treasurer, leader of the Opposition and members, has Standing Committees *(Sthai Samiti's)* on various subjects including health, which meet every month (the State Health Minister was present at a meeting attended by the researchers).The President of the *Zilla Parishad* has the rank of State Cabinet Minister, wielding considerable power.

The Mysore *Zilla Parishad* raises about Rs.10 million per month from local taxes. The State Government of Karnataka provides an annual supplementary budget of Rs.80-100 million. The *Zilla Parishad* allocates Rs.20 million annually to health, with Rs.150-200,000 to each *Gram Panchayat*. The proportion of the State health budget for the district coming through the *Zilla Parishad* (ZP) has increased to 70% (DHO*1996) indicating a transfer of power to local government. ZP budgets vary according to population, area and taxes raised.

Health is under the purview of *Panchayati Raj*, with the District Health Officer/his staff reporting to the ZP. ZP members sit on Committees such as the Drug Purchase Committee and district health staff attend meetings of the ZP Standing Committee on Health. ZP members reportedly visit health institutions, raising questions regarding functioning of government health centres at Standing Committee meetings. A few staff members have been suspended pending enquiries. Political mechanisms increase the potential of accountability between health services and people. Patient's and peoples interests can and have been represented and mediated at ZP and state assembly levels. However party and personal interests, traditional vested interests, drug company and doctor's interests also play a part, with members sometimes supporting and promoting certain interests.

This political process of learning, negotiation and accommodation between different interests offers a window of opportunity for active/constructive participation at state/district levels by political actors health, for long the preserve of professionals.

The State Health Minister[21] felt that health facilities were sufficient in number but with low quality service, insufficient drugs/equipment, personnel shortages, and inadequate ZP budgets (interview 1996). Ascribing these to defects in the administrative machinery, he felt they could be remedied. At a Standing Committee meeting attended by him, he emphasised the need for total improvement of quality of services (observation of meeting 1996). He outlined steps taken by government including the appointment of doctors on contracts, and the World Bank loan for development of district hospitals. Both he and the ZP President talked of problems faced by *gram panchayats*, need to solve internal conflicts, misuse of power, and transfer of officials involved. The ZP President said that good health required pure drinking water, unpolluted air, well ventilated housing. The public works department was behind schedule requiring attention. They thus articulated broader interests.

The ZP Vice President, a 29 year old woman lawyer and business owner from the scheduled caste community with social involvement's before being elected, is described as '*dynamic, fighting for the poor, possessing an ability to redress the common person's problem, interested in women's issues'*. Officers from the Karnataka Administrative Services comprise the executive wing.

Role and Functioning of Gram Panchayats (GP) regarding Health: GP's cover a population of 10-15,000 with representatives for every 1000. They meet every month to discuss developmental programmes channelled by state and central government through them, identifying individuals/families who can avail of loans/schemes. *Gram Panchayats* play a negligible role in health, with members not authorised to look into the affairs of the PHC. Only the President/Chairperson sometimes does so.

Ten percent (Rs.15,000) of the annual GP budget of Rs.1,50,000-2,00,000 can be used for health, while education gets 15%. The health budget is used primarily for preventive measures such as environmental sanitation, drainage, chlorination of water, DDT spraying, responding to epidemics of gastro-enteritis, cholera, Japanese Encephalitis if

[21] Who comes from the study district.

they arise. The budget is only for group or collective measures and not for individual support to patients from severe/chronic diseases. GP funds are utilised in collaboration with PHC staff. There can be a collusion between the two to misuse funds (interviews). GP's are empowered to raise local taxes from fairs, temple festivals, use of common water tanks and common lands, new constructions etc. However these are most often not levied.

There was a general feeling that GP members lacked powers to do much. '*You cannot execute anything without money*' they said (interview 1996). Discussions centre around Integrated Rural Development Programmes, *Bhagyajyoti* (electricity) etc. and rarely cover health. *'We are basically politicians, we have to do programmes which can get people's attention quickly.'* Within *Gram Panchayat's*, power is concentrated in the President, Secretary and Treasurer. Budget information may not be revealed to members. Differences of opinion sometimes delay programmes. Younger articulate members saw their role as raising critical questions in meetings and getting programme benefits from the ZP to the periphery.

Eighteen elected representatives from *Gram Panchayat's* in the two taluks, four from the *Zilla Panchayat* and eight staff members working in the *Zilla Panchayat* office were interviewed. What was striking was their youthfulness, enthusiasm and confidence. The sample was skewed in favour of SC's and ST's to reflect their perspectives in particular.

Feedback on General Health Services: Five of 18 felt that general health services at PHC's were satisfactory, though with shortcomings. Older respondents mentioned the increased number of services, improved quality and increased transport services making access easier, over the years. The majority were dissatisfied saying: *'PHC's are not answerable to anyone; they do not function to their fullest potential; they are of no use to the poor; they are useful only for headaches, coughs and colds; government only emphasises Family Planning through the PHC's; there is not one person who has said that his disease was cured at the PHC; it is only a name-board- there is nothing inside; only very poor people go to PHC's and even for them no useful purpose is served there;*

Government believes in PHC's, but those who live there cannot. The PHC's are there only to give employment.' One outspoken tribal graduate said, *'If the government is good all the departments will be good. The (policy) statements of governments only lie on paper and in lectures delivered in Delhi. Public health facilities are of no use to the public.'*

Drug supplies: The majority (14/18) were dissatisfied about drug supplies, widespread practices of giving prescriptions, inferior quality of drugs '*fit only to be thrown out'*, and the need to pay for drugs/services, saying that '*one may as well go to private doctors'*. These comments were not specific to TB suggesting that inadequate and irregular supplies of TB drugs, brought out by all other aspects of the study, are part of a wider problem of availability and quality of drug supplies to government health facilities.

Health staff including their attitudes and behaviour received strong adverse comment from the majority. Doctors were too few, absent during working hours, unavailable at night since most commute, ('*do diseases only come during the daytime*?' asked one) interested mainly in earning money, lacking interest in and concern or respect for patients and the public, besides being involved with local political conflicts, ('*doctors look upon Gram Panchayat members with contempt and GP presidents boss over doctors- politics should not enter the health services'*). Another said that '*doctors function under rules and face punishment if they do not*' and should be more responsible.

Negative attitudes/rude behaviour of other staff received more adverse comment, with several experiences cited, '*nurses treat us like animals, they shout; they consider people as slaves; it will be good to abolish the designation of Multi Purpose Worker's, instead of wasting money paying salaries. They are of no use regarding public health matters; The intention of MPW's may be good but their timing is not; I have not seen or heard of them testing sputum or blood;*' and finally, '*PHC's are working as if they are dead*'.

Payment for free services was widespread, '*staff are not honest'*, '*every PHC takes money'*, *'there is more of corruption than anything else.' "though called a poor man's*

hospital, they extract money from everybody', 'people have to pay for services or get inferior medicines which cause problems', 'they prescribe medicine for which also we have to pay'. Other felt *'Nobody will ask for bribes openly, they take money secretly. Which department does not take money to get work done? But in the health department if you say with courage that you will not give money, work can be done; Giving Rs.5-10 is not a large amount. It is not a bribe at all, it is only enough to buy coffee or cigarettes'.*

While the four fold increase in number of Peripheral Health Institutions in HDKote *taluk* over the years was appreciated, several commented on the lack of admission, X-ray and surgical facilities. Others problems mentioned included mal-administration, overcrowding, long waiting times, poor condition of some buildings and distance for the elderly and children.

All elected representatives, except two, knew TB patients in their area by name. Four had relatives with TB, one of whom had died. In their experience, the government TB 'sanatorium' in Mysore was identified as the primary source of treatment, particularly for the poor, by 12/18. Only two each mentioned the voluntary and private sector as alternatives. Four said patients go to PHC's especially in the early stages, implying later shifts. Some specifically mentioned the PHC's incapability of treating TB, acknowledging that, *'treatment at local hospitals'* would be most convenient for people. A few GP members intervened actively, taking patients to hospital or securing loans under developmental schemes for the family[22].

The majority were sceptical of the role of private practitioners in TB treatment especially for the poor. Comments included: *'Private clinics are not to be trusted; I am disgusted with private hospitals, people have made their profession crooked for earning money; If one gets admitted to a private hospital he is as good as a pauper; Though the disease may be diagnosed they don't disclose it to the patient, because they want to extract as much money as possible; and finally they are referred to government hospitals.'* The link with the profit motive was quite apparent to them and not particularly favoured.

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[22] Pointing the way to innovative, supportive roles at village level that could make a difference.

Comments regarding a voluntary sector hospital provide insights into the effects of attitudes/behaviour, '*They treat patients with respect. Even if one is a stranger they ask you to sit with a smile. They respond to our needs and offer friendly advice.*'

The *Panchayat* system provides mechanisms for greater accountability, for broader support to patients/their families, and for integration of health with development efforts. The NTP has not yet responded to this renewed opportunity.

8.5 Voluntary Organisations as Actors in TB Care & Control

Both *taluks* have voluntary organisations working in health and development, within which specific components of TB control are embedded. Prioritising work with marginalised sections of society, they base on philosophies of empowerment, self reliance, and community organisation (interviews). Each organisation evolved its own strategies of intervention regarding overall work and for TB, including relationships with government.

Yelandur *Taluk* (population 71,715 over 40 villages) has two related NGO's: *Vivekananda Girijana Kalyana Kendra* (VGKK, Vivekananda Tribal Welfare Centre) based in BR Hills works for integrated tribal development, including community health, with the *Soliga* people of Mysore District since 1981. A related, autonomous Karuna Trust started in 1987 covers the entire *taluk,* which was hyper-endemic for leprosy, with a leprosy control programme. Following the National Leprosy Control Programme it used a vertical approach with special para-medical workers and house to house survey, education and treatment (SET), using multi-drug therapy. Prevalence rates dropped from 21.4/1000 in 1987 to 0.39/1000 in 1993 and incidence rates from 3.82 to 0.75 in 1992 (Karuna Trust records, 1996) and over 1000 patients were cured (ShivaKumar*1996). District Health Office records indicate a reduction in the number of leprosy cases in all *taluks* during the period with increased case detection and treatment.

The programme increased the experience, expertise and credibility of the NGO team. Success resulted in insufficient work for health workers, as occurred in several leprosy

control projects[23]. Karuna Trust expanded activities to cover epilepsy (from 1/4/1990) and community mental health, for which there were no facilities in the public/private sectors in the *taluk*. The vertical approach was continued in the new programmes, though the project later aims to develop into a community based comprehensive health project. Processes in all projects included use of experienced consultants, linkages with national training and research institutions, national professional associations, and the state government.

The NGO team found TB a problem in the community with the NTP functioning poorly. Government PHC's detected 3 cases in the *taluk* in 1990, 5 in 1991 and lacked basic TB drugs, isoniazid and thiacetazone (Sudarshan 1994). Following a decision in 1990 to start a TB control programme, discussions were initiated by the NGO with the State Government at Secretariat level.

Agreement with Government: A government letter dated 15/10 /91 from the Joint Director TB instructs the DTO, Mysore, 'to implement the TB Control Programme at VGKK....(as) there are facilities for detection of TB with laboratory and X-ray units, and administrative staff'. The TB programme was to start from 1/11/91. This was a relatively limited mandate with authorisation to function as a peripheral health institution in the NTP. Following negotiations with the State Government, *'responsibility for implementing the NTP in Yelandur Taluk was officially given to Karuna Trust from 1/4/92'* (Sridhar and Sudarshan 1996;39). The Directorate of Health Services supplied a microscope and agreed to provide drugs and laboratory reagents through the District TB Centre from where regular collections were to be made. The entire team received training and manuals from the National Tuberculosis Institute at Bangalore. All other expenditures (salaries, transport) were the responsibility of the Trust.

The programme *objective 'to reduce the prevalence of TB in the community to a level where it ceases to be a public health problem'* (Sridhar and Sudarshan 1994;39) is the

[23] The Indian Council of Medical Research, GOI, in the 1980's had experimented with the integration of leprosy and TB control partly to overcome this.

same as that of the NTP. However modifications to the NTP strategy were made. The programme does not function through government PHC's but has an alternative structure with the Karuna Trust Health Centre at *taluk* headquarters as base with a doctor, microscopy and a team of paramedical workers. The relationship between the two structures at field level for TB work is unclear. The MO of the programme had never visited the government PHC's till this researcher's visit, though field supervisors/paramedical staff are in regular contact. Initially DTC staff visited Karuna Trust, 'acting very bossy....labelling patients as lost very easily, without making any efforts for defaulter retrieval and wanting to take the treatment cards away to the DTC' (Krishnan*1995). The Trust supervisor refused and there were few subsequent visits. Thus a relatively conflictual relationship exists at a key level.

The *vertical approach* of previous intervention programmes continued for TB, though the NTP is integrated with general health services. Since infrastructure and staff existed, it could be implemented. Instead of passive case finding, active case detection was undertaken with house to house visits by paramedical workers on an ongoing basis. Six paramedics cover 14,000 households (travelling on bicycles), collecting sputum specimens from chest symptomatics, and sending smears to the Karuna Trust Health Centre, with each round taking a year. Self reporting patients come to weekly Sunday chest clinics (the market day) or to daily OPD's. Most cases are *diagnosed* by sputum microscopy with approximately 30% requiring X-rays, the latter done at the VGKK hospital at BR Hills (Sridhar*1996). All investigations/treatment are free of charge.

An NTI consultant visits occasionally to discuss management of complex cases. Standard technical procedures were followed: a) Sputum microscopy: overnight sample with instructions regarding specimen collection, repeat examinations, cross checking by doctor, b) minimal use of X-rays, c) recording system with local data analysis to guide the programme.

NTI *chemotherapy* guidelines are followed. Short Course Chemotherapy used for newly diagnosed sputum positive TB patients was later expanded to all sputum positives.

Finding incomplete treatment among a substantial number and based on an understanding of the psychology of patients, clinic based supervised treatment for 2 months was introduced with biweekly, ambulatory, intermittent chemotherapy[24] (Sridhar*1995). Missed doses are reportedly followed by home visits by paramedics. In case of genuine inability to attend the clinic, paramedics give supervised treatment in patient's homes. Supervised treatment has been difficult even in the intensive two month phase and incomplete treatment continues (Sridhar*1995).

In 1992-93 there were serious problems with *drug supplies* from the DTC (Sudarshan 1994). Alternative local arrangements ensured uninterrupted drug supply through donations, free supplies from drug companies and local purchase by the Trust, leading to formation of a 'drug bank'. Currently attempts are being made to decentralise drug distribution through drug depots (for leprosy, TB, epilepsy) located within 2-3 km from people's homes. About 25% of drug requirements were supplied by the DTC (Krishnan*1995). Different drugs were not available at different times. Even sputum cups were in short supply. Visits to the DTC for drug collection were tedious, 'the DTO was usually not available', taking a whole day to get some drugs. Varying strength of drugs supplied in different batches occurs, with patients having to change the number of tablets they take, causing confusion. Staff members commented on private practice and use of government drug supplies by DTC staff, who keep TB drug stocks especially of Rifampicin for themselves. Private practice at PHC's was also reported (several interviews 1996). Further enquiry by VGKK revealed State and country-wide drug shortages in 1992-93 (Sudarshan 1994, VHAI 1994). Explanations given were that the Centre had problems in drug purchase (for unspecified reasons), and that States had not contributed their 50% towards drug purchase (Sridhar and Sudarshan 1996). A campaign was initiated with the Voluntary Health Association of India nationally concerning drug supply and other issues regarding the NTP/RNTP (Chapter 5). Dr. Sudarshan, Founder and Secretary of VGKK[25], Vice-President of the VHAI at this time was active in the

[24] 2 (SHRZ)2/4(RH)2 or 2(EHRZ)2 /4(RH)2
[25] Recipient of the international Right Livelihood award and national awards.

national advocacy process. Repeated representation at State and Central levels improved the drug supply situation (Sudarshan*1995).

Family folders are maintained with regular recording and reporting systems. From December 1991 till March 1995 i.e. in 40 months, 254 TB patients (all forms) were registered for treatment. The estimated prevalence of sputum positive TB in a population of 70,000 is 280 patients and of X-ray suspects 1,400 while the estimated annual incidence is 315. Speculative reasons for the lower than expected case detection, inspite of community based efforts include reduced prevalence following treatment by the private sector/government institutions in Mysore leaving only incident cases, missed diagnosis due to health worker (investigator) and diagnostic errors, and patients still attending government institutions and not disclosing their illness to health workers conducting surveys.

Table 8.18 TB Case Detection at Karuna Trust

Period	Total Cases	Bacillary	X-ray Positive	Extra-pulm.	Comment
1991-92	15	5	10	-	preproject
1992-93	103	61	35	7	1st survey
1993-94	80	53	19	8	ongoing ,,
1994-95	56	43	11	2	,, ,,

Source: Dr. Sridhar, Dr. Sudarshan & team/VGKK & Karuna Trust records

Table 8.19 Epidemiological Rates of TB in Yelandur Taluk (Karuna Trust)

Year	Rate	Bacillary	All Forms
1992-93	Prevalence rate	0.85 /1000	1.4/1000
1993-94	Incidence rate	0. 70/1000	1.1/1000
1994-95	Incidence rate	0.57/1000	0.70/1000

Source: Dr. Sridhar, Dr. Sudarshan & team/VGKK & Karuna Trust records

Data collection was by a team trained and experienced in the conduct of surveys. However the complexities of TB including case definitions are often underestimated. Rates are lower than expected and have apparently reduced further within 3 years.

Table 8.20 Treatment Outcome at Karuna Trust

Year	Cured	Lost	Died	LCA
1991-92	10	2	2	1
1992-93	65 (63%)	27	9	1
1993-94	39 (48.7%)	29	5	3 (4 missing)

Source: Dr. Sridhar, Dr. Sudarshan & team/VGKK & Karuna Trust records

Treatment non-adherence is 27.5% (19.1% among sputum positives, 36% among sputum negatives), while it is 2% for leprosy (Sudarshan*1995). Patients often continue and complete treatment with private practitioners (*ibid*). Project staff hypothesise that similar results could be obtained with an integrated approach. *Treatment failure* of 5.8% is reported, mainly among patients who had taken Rifampicin containing regimens irregularly previously (Sridhar*1996). Two patients on second line re-treatment regimens are regular.

The total annual *expenditure* of Karuna Trust was Rs.450,000 for implementing leprosy, epilepsy, TB, mental health, dental health, and eye care programmes (Sridhar and Sudarshan 1996). The average expenditure was Rs.6.25/person/year (about 10 pence) make the approach highly cost-effective (*ibid*).

Staff salaries are modest and less than those of the government. Paramedics receive a monthly salary of Rs.1,500 while government Junior Health Assistants receive Rs.3,500-4000. Staff turnover is not very high. Local tribal youth have been trained for the base hospital (including as laboratory and X-ray technician) at BR Hills. Factors responsible for gains of the programme are cited as a combination of committed health workers and medical staff, motivation, leadership, working environment, honesty and sincerity at managerial level. Others in the organisation say it is not dedication, but jobs to be performed, employment opportunities when there is unemployment, and the management demanding certain levels of performance (interviews/correspondence*1996).

Special features included village awareness programmes once in 3-4 months, flexible working hours/days with workers going at 7 am to meet people before they leave for

work, and special Sunday clinics, close team functioning, supportive leadership and a willingness to engage in broader issues.

There are two main NGO's involved in TB work in the second *taluk*[26]. One has a hospital in a remote area, working primarily for the *Jenu Kuruba* tribe and the rural population in the area. It provides good quality diagnostic and therapeutic care to patients reporting to it and is given a grant by the second NGO for free TB treatment. The second NGO involved in development work throughout the *taluk* has created a network of grassroots peoples' organisations, and collaborates with government in various programmes particularly poverty alleviation[27]. It sees its TB work in the provision of housing for the poorest. It also provides SCC TB drugs to the local PHC, covers TB treatment costs at the other NGO hospital and helps in the organisation of TB detection camps in collaboration with the DTC. Seriously ill patients are referred to a mission hospital in Mysore, and their hospitalisation/treatment costs met. There are eleven other NGO's, several with dispensaries treating individual TB patients and most of them also involved with community organisation/education and development work impacting indirectly on TB.

Policy lessons from the TB work of NGO's

NGO work in the district was initiated in response to perceived need and by the initiators' own need for social engagement. Leadership was strong with a deep spiritual/philosophical base and a developmental approach. Teamwork was closer with members manifesting a greater sense of ownership and involvement, even working on lower salaries. Their rapport with people was crucial, especially '*treating patients with affection*'. TB was one dimension of their health/development work (such as community organisation with formation of *sangha's*/women's/farmers groups, co-operatives, income generation, children's educational activities, water supply and irrigation) through which

[26] The Vivekananda Youth Movement running Shankar Hospital and other programmes and MYRADA-PLAN.

[27] An evaluation of 12 years work showed that poverty levels decreased by 20% though 35% of the population was still below the poverty line defined as below Rs.11,400 per capita per year (D'Souza*1996).

they participated in the social, economic and cultural life of the *taluk*. NGO's took the initiative in the relationship with government.

Inspite of wide-ranging work involvement, the attention paid to the TB programme was greater than the PHC's. However the rapid increase in and large number of programmes may dilute specific programmes like TB. The importance of the smallest functional unit and on the people (staff) working there, of evolving local innovations such as drug banks, of local analysis and utilisation of data can be applied at DTC level. Vertical approaches with active case finding have not achieved gains. Adequate, uninterrupted drug supplies/finances have not completely reduced implementation problems, suggesting the role of additional factors. The conflictual relationship with government, with collaboration at some levels seems inevitable and perhaps necessary in the circumstances.

8.6 The Private Health Sector in TB Care

The private sector comprises a very diverse group in the *taluks* and district headquarters. Mysore city has high technology hospitals like the JSS Medical College/Hospital, Basappa Memorial Hospital doing kidney transplantation's and the Bharat Cancer Hospital. At *taluk* level, GP's with widely different training, run single practitioner clinics. Yelandur *Taluk* (population 70,715) has 17 private practitioners with 8 allopaths (MBBS degrees), 5 Registered Medical Practitioners (RMP's), 2 homeopaths, 1 *ayurved*, and 1 GCTM (Certificate in Traditional Medicine). There was one nursing home with 25 inpatient beds, three doctors (MBBS), nursing assistants, a laboratory where doctors and an untrained assistant did simple investigations, and their own pharmacy. 12% of patients sought health advice/treatment from folk practitioners, wandering mendicants/*'Yelavara's'*, astrologers and priests forming part of local health traditions (private, low cost). There were 3 private pharmacies, 2 at the *taluk* headquarters and 1 in a large village.

There are differences between this geographically compact, better off *taluk* well connected by road transport, relatively close to Mysore city, and HDK *taluk*, socio-economically the poorest in the district. In HDK there are fewer private practitioners, a

smaller proportion with an MBBS degree, with clinics located in the headquarters town or larger villages along the highway[28]. More practitioners commute from Mysore/elsewhere. Private pharmacies established during the past 5 years at *taluk* headquarters and larger villages stocked TB drugs in both *taluks*. Medical representatives from pharmaceutical companies interviewed regularly visited/supplied private practitioners (who sell medicines from their clinics) and government PHC medical officers in the area even in remoter areas[29].

TB treatment practices: Six out of 17 private practitioners in Yelandur *taluk* and 5 out of approximately 20[30] in HDKote *Taluk* were interviewed.

Initial investigations for TB were done by referrals to private diagnostic centres in nearby towns, with links usually established between particular centres and doctors. After diagnosis, patients were often referred to the PKTB and Chest Disease Hospital in Mysore, to Karuna Trust in Yelandur or to the HD Kote General Hospital, the free treatment being considered a better option for poor patients. Long and expensive treatment, with rising drug costs, was problematic. One doctor estimated the cost of treatment to be Rs.7000. Some practitioners felt that a large proportion (upto 75%) of referred patients did not actually go.

Five doctors treated very few TB patients, up to 3-5/year and the others less. They estimated that 20-25% of their patients get cured, with incomplete treatment being common. They all felt that poverty and under-nutrition were important reasons for incomplete treatment and for inability to control TB. *TB patients are forced to earn their livelihood inspite of their disease, making it difficult for them to come regularly for treatment.* They suggested that excessive smoking and alcohol consumption, especially by men, adversely affected treatment completion and outcome. Working single handed, with a part-time assistant for cleaning and odd jobs, they do not follow up patients, nor keep records (except the nursing home). Their strengths as perceived by patients was availability, including evenings and weekends and friendlier attitudes.

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[28] Public sector facilities/doctors are better distributed geographically than private doctors.
[29] This suggests private practice as PHC drug supplies are from district headquarters.
[30] In a *taluk* with a large geographical area and population.

They felt people had little faith in PHC's due to drug shortages and other problems. They however referred to the government TB 'sanatorium' patients with advanced disease, complications or the poor for whom free food/accommodation were an important need. One said, *'If TB is to be controlled, the poor have to be first fed with nutritious food. And TB drugs must be available free of cost. TB is curable but it is important that government policies are systematically implemented. It is best not to discuss this issue because if I go into the politics of it I may take recourse to foul language'.*

Levels of professional knowledge varied, with the trained allopaths being the best. The others had patchy knowledge about the disease, knew the names of one or two drugs, and not the duration of treatment or dosage. Their ability to provide good quality services for a complex disease like TB is questionable. Voluntary sector doctors commented on '*the negative impact of private practitioners...due to their irrational diagnosis and regimens, lack of follow-up, and the heavy financial burden on patients.'*(Sridhar and Sudarshan 1996;42). There is a qualitative difference between private practitioners in cities and remoter rural areas and no regulation of practices.

Practitioners were not members of the local branch of the Indian Medical Association, except one who gave up its Presidentship considering it 'useless'. Organisational mechanisms were deficient for contact, information dissemination, and educational strategies for this dispersed and varied group. Interest too was low with no practitioner attending continuing education programmes of the Mysore District TB Association during 1994-96.

Competition between practitioners exists with five practitioners starting practice on a one kilometre stretch of road in HDKote *taluk* over the past 6 years. As one mentioned they have to share the patient load between them and are not on talking terms. One also lamented that the nearby Government PHC got more patients than all of them put together. None of them refer patients to the PHC even for simple laboratory investigations though this is the one PHC with a trained laboratory technician. The PHC

MO has not taken the initiative to meet the practitioners. Interestingly all of them commute from Mysore.

It would be instructive though difficult to study cure rates/treatment completion in the private sector. It is curious that policy makers, concerned about poor cure rates in the public sector, advocate greater involvement of the private sector whose achievements in this respect are unknown or worse. It also seems insufficient for policy to make general recommendations/references regarding 'the private sector', involving practitioners with diverse training, expertise and skill.

The private sector is a complex non-homogenous group and strategies to involve them should base on ground realities in each district.

In conclusion,

- An implementation gap with incomplete population coverage (52%), low case detection/treatment completion is evident in this relatively well-off district, in a State with moderate socio-economic development and fairly widespread health services. Even in the best scenario situation, of the NGO covered *taluk,* implementation was lower than expected, suggesting there are inherent difficulties in TB programmes.
- The public sector plays an important role in TB treatment, especially for the poor, but not in ways envisaged by the NTP. Cardinal features of integration, availability of services closest to peoples homes, domiciliary and free treatment are not being practised. Public sector health institutions closest to peoples homes in rural areas, with very limited real resources, are non-functional in key tasks of the NTP of case detection and treatment and TB care is not integrated at this level. Patients express preferences for utilising PHC services but find them ineffective. They then use a range of providers, for both diagnosis and treatment. Instead of the planned route from peripheral institutions to District TB Centres, a majority of patients go to private providers or PHC's in the early stages, bypass the DTC and then go to the TB/district/*taluk* general hospitals, which offer better professional and diagnostic and

therapeutic facilities. Thus urban secondary care institutions financed and managed by State government play a dominant role in TB care. Hospitalisation rates were high.

- Implementation altered policy fundamentally and State/district programme managers were unable or uninterested to influence this process.

- In spite of increased numbers of health facilities over time (public/private/voluntary), this improved access to medical care, by itself was insufficient to improve TB control significantly, pointing to the need for specific policy inputs in the operational units.

- While techno-managerial factors such as lack of sputum microscopy and irregular drug supplies are immediate explanatory factors for poor programme execution, underlying factors that emerged include:

  ~ Negligible ownership of the programme at DTC and PHC level. Frontline staff/ institutions do not value good TB care/control, accept the status quo, and make few efforts to give feedback, bring about change or lobby for improvement.

  ~ A disempowered DTC cannot provide the leadership or organisational/technical/ moral support and supervision required for the programme. This is repeated at PHC level where doctors function irregularly. Staff behaviour and organisational problems drive people elsewhere including the private sector.

  ~ Staff vacancies and inadequacies are caused by socio-political factors (reservation policy, focus on malaria programme, short-termism with doctors on contract) .

  ~ Health Assistants, preoccupied with competing programmes and personal goals/ practices, neglect the NTP, though workload (numbers of TB patients) in their areas are small.

  Lacking direction and support they are unable to play a potentially positive role.

  ~ Burden of payment for 'free' services at public health facilities, even for sputum cups and sputum tests, in addition to indirect costs of treatment, are disincentives for poor patients completing regular treatment.

  ~ Ill-developed systems of financial/technical/programmatic accountability result in no pressure on the system to perform.

~ Patients, particularly the poor, are helpless, unprotesting, unorganised players in this process, paying the price of prolonged suffering/ill-health with socio-economic consequences of indebtedness and invalidism. They could play a more assertive role as the biggest stakeholders in the programme. No steps have been taken by the voluntary sector or the Gram Panchayats to organise them. The policy takes little cognisance of the social causes and consequences of the disease .

~ Inability of the NTP policy managers at state or national level to respond to these contextual and process issues weakens policy implementation.

- Lack of power, real resources, capacity and accountability engender disinterest and apathy at PHC's and the DTC, making them weak partners/links in the NTP. Standardised, simplified methodologies evolved for use in peripheral institutions are rendered non-functional by these factors.

- Private for profit providers, a mixed group, with varying educational backgrounds, types of health facilities, often undertake plural practice (modern medicine and other systems) with little regulation. Substantial proportions in the *Taluks* untrained to diagnose/treat TB with allopathic medicines, referred patients to hospitals and were explicitly unwilling to undertake follow-up. Private practitioners qualified in modern medicine referred poorer TB patients to public hospitals for financial reasons. Their role in TB care particularly treatment was limited in this group of patients.

- NGO's were liked by patients and demonstrated better achievements (though less than expected), with low programme costs and positive health worker contributions, within supportive programmes. Their critical, issue raising role, deriving from grassroots work was a constructive contribution to policy process. Integration of TB work not only with health, but with development and awareness raising are feasible at local level.

- Decentralised local governance providing opportunities for accountability and local participation, is yet to be utilised by the NTP.

- NTP's neglect of implementation weaknesses, apparent after three decades, suggests that the policy is strongly influenced by the power of dominant interests promoting select programmes, keeping services in larger urban institutions, and starving peripheral institutions of resources. Values of social justice in the care of TB patients are not evident.

CHAPTER NINE

CONCLUSIONS

Introduction:

This study set out to explain the factors underlying the acknowledged gap between the goals of the National Tuberculosis Programme (NTP) in India and its actual implementation. The choice of TB as the focus of study was because of the continuing magnitude of the problem in India and elsewhere, which demanded an ongoing quest for more effective methods to alleviate suffering related to the disease. The application of a technical method or package for TB control at national level is through policies and their processes. While progress has been achieved in the development of policy content, there has been little work on policy process in TB control. The focus on the implementation gap was to further understanding of the interplay of deeper forces, so as to inform policy process.

Although a number of analyses and authoritative evaluations identified weaknesses in the TB programme from the 1960s, and made recommendations, implementation problems continued to exist. This study hypothesised that these problems and gaps cannot be explained only by technical or managerial deficits, but that societal and political issues, played an important role. This, if established, would have broader policy implications.

Therefore a *policy analysis approach* was adopted, focusing analytically on the nature of the problem, on policy content and particularly on policy processes, actors and context. Though TB and its control is a highly researched area, this is the first time this framework is being applied to TB control policy. A specific contribution of the study is that it incorporated a participatory, bottom-up approach, with views from TB patients, particularly the poor[1], from elected people's representatives and front-line staff. It has

[1] They have been considered and valued as partners and subjects in the study and not as beneficiaries or objects.

thus adopted an integrative approach looking at the interaction between all levels of the policy process, including international influence on policy, national and state level policy, as well as what actually happens at district and *taluk* level and how patients are affected. It thus differs from much policy analyses that tend to remain at national or macro level and are implicitly top-down. Because this study explicitly adopted a value base of social justice and equity, and the poor are disproportionately at risk of TB, a sample of impoverished patients was consciously selected and the focus was on the public sector which is mandated to deliver free services.

It was necessary to use this analytic approach with the biological and epidemiological aspects of the disease as backdrop. The study therefore started with a review of these aspects (presented in Annexe 1 and Chapter 1), and then explored how these were translated into TB policy and practice.

An *implementation gap* identified in quantitative terms is reported in this thesis at national (Table 1.4), state and district levels. Epidemiological, public health and operational parameters all point to a gap, although unrealistic expectations due to the use of prevalence rates of the 1950s, may accentuate its dimensions. Additionally, considerable suffering due to TB, observed among impoverished patients, adds a tragic qualitative dimension to the gap. Deficits were observed, to a smaller extent, even in the best scenario situation, where an GO used community based TB interventions with assured drug supplies and finances, in a compact *talk* for over three years, suggesting that the problem is complex.

The *gains* made by the government's TB programme in India since 1947, and particularly the NT., are recognised and reported in this thesis. These include research studies evolving the concept and content of the NT.[2], infrastructural growth, institutional development, and aspects of the pharmaceutical policy.

In this chapter the discussion of policy and implementation processes is presented within the framework used for the study, namely, the nature of the problem, policy content,

[2] Contributions that influenced international thinking included studies on chemotherapy, the concept and operationalisation of National TB Programmes, and protective efficacy of BCG.

context, and processes (including actors), though they all interact and overlap. A policy approach is necessarily broad in scope and needs to consider several aspects influencing mass interventions. Some insights concerning the biological aspects which were not primarily studied here are based on the literature.

9.1 Kaleidoscopic Complexity of the Problem of TB

Certain *biological aspects* of the problem are important in the context of TB control. Several factors such as the ancient coexistence of *Mycobacterium tuberculosis* with humankind, its ability to lie dormant intracellularly, to mutate in its efforts for ecological survival, and the incompletely understood mechanisms of pathogenesis, suggest that it is biologically difficult to eliminate TB[3] (Annexe 1). Furthermore with one-third of the global (and Indian) population infected and at lifelong risk of developing the disease, the possibility of elimination becomes more remote. Even control programmes require long-term sustainable strategies.

When applied within an overall framework of improved living conditions through development, history shows that *public health approaches* could accelerate the natural decline of a TB epidemic. However in TB treatment and control it has been repeatedly seen that several technical approaches promoted as being scientific at the time, were later disproved, in serious doubt or of limited value. These included experiments with immunotherapy, gold therapy, various surgical procedures, sanatoria, drug monotherapy, BCG, use of thiacetazone and standard or conventional therapies[4]. This followed from an incomplete understanding of disease processes and suggests that continued research is important. Despite more recent scientific advance, knowledge gaps persist and hence rigid approaches to policy content require caution. Interest groups and conflicts were associated with the promotion of different technological methods such as mass miniature radiography, hospitalisation etc. On the other hand sustained care for TB patients,

[3] The TB programme in India never considered elimination, but this has been discussed in the USA and other countries.

[4] Accelerated reduction in industrialised countries from 1950-70 occured with standard drug regimens often considered obsolete today.

community level and national action have shown positive results over the past four decades, with use of varied methods, suggesting that factors other than technical content also play a role.

Globally, historical and current evidence shows that *social forces* play a powerful role in the development and transmission of TB. These include unequal societal relations and structural factors resulting in impoverishment with poor nutrition and housing, social or political disruption, instability, and war or conflict.

This study finds that besides it being a factor associated with the causation of TB, *societal relations* are also strong mediating mechanisms, influencing the adoption and implementation of TB control programmes. This is evident in urban-rural disparities in health services reducing access to rural patients, the lack of coverage of 40-50% of the population by the NTP through non-implementation at peripheral institutions, stratification of TB services with better care for the organised sector and government inaction on policy recommendations deriving from evaluations. The strength of dominant social groups is further evident in the privatisation of medical education and health services providing access to private care[5] for those with ability to pay, in the influence of medical professionals over policy and continuing dominance of clinical over public health approaches, in older policies that support institutional care over domiciliary treatment, in keeping the NTP under-resourced and in the disproportionate attention given to family planning/welfare. This comprises an important set of explanatory factors for the implementation gap, particularly from the perspective of deprived social groups. Although the NTP policy is to provide universal services, its implementation is deeply affected by these structural and societal factors.

Values of social justice and equity are yet to be realised in practice. That the NTP in the 1960s tried to shift the balance of power from urban to rural, from vertical to integrated, from specialist to generalist is also part explanation for the implementation gap, as it elicited resistance from strong forces described earlier. Thus, not only is TB linked with

[5] Which is not necessarily better quality.

poverty but this study shows that powerful societal forces and interests resist the widespread application of TB control measures by non-decisions, non-action or non-implementation.

More recently, international social forces under a sense of threat from rising TB rates in established market economies, especially among immigrants and ethnic minorities, are initiating and pressing for policy changes during the 1990s, using the leverage of funding and conditionalities. Current strategies such as directly observed therapy, shift the burden of responsibility to the most powerless, namely to patients and front-line health workers, without providing the means (resources beyond those required for drugs, such as for staff, transport and compensation for wages lost etc.) for the strategy to work.

Impact of poverty: Improved socio-economic and living conditions have consistently resulted in the disease declining in different regions of the world. In India, the fruits of economic growth have benefited 60% of the population (though disproportionately even among this group), while disparities have widened. About 400 million persons or 40% of the population living below and around the poverty line continue to be impoverished. The interaction between poverty and TB and its effects on families was evident at local level. This study found high levels of indebtedness due to TB among poor patients, enmeshing them further in the poverty cycle. Poverty was a bigger problem than TB faced by these patients. Importantly they depended on the public sector, with all its weaknesses, for TB treatment.

The problem of poverty, inequity and hence of TB in affected groups could be exacerbated in the present period, inspite of its overarching goals of economic growth because of insufficient commitment (national and global) to reducing disparities in wealth, health and health care[6]. Further as argued earlier, societal factors were overshadowed by policies determined by a strong biomedical paradigm. Though links with

[6] In various parts of the world there is evidence that TB is associated not only with HIV, but clearly with growing poverty/social disruption for certain sections of society. This is evident in Eastern Europe. In India, because of lack of notification of TB and of analysis of monitoring data by social class, and because of widespread acceptance of its links with poverty, population based data/trends by social class is more infrequent.

poverty and TB are repeatedly reported and acknowledged, politico-economic and developmental approaches to its control were inadequately pursued by policy makers. Opportunities to change policy direction were missed. For instance health being integral to development as part of Primary Health Care in 1978 provided a chance to place TB control in a wider context. However vertical disease and problem based approaches and selective interventions received stronger support from national political, bureaucratic and technocratic decision makers, reinforced by international financial support and policy advice. The impact of these policy choices, for instance the family welfare and malaria programmes on the functioning of the health care system and its impact on the NTP, has been described. More recently, efforts towards Renewal of Health For All in the 21st Century have again brought issues concerning development, equity and sustainability into the public health debate (WHO 1997c[7]). However the TB public health community (Indian and global) is uninvolved in the international and national meetings and processes connected with this initiative.

Finally, this biological and societal complexity is further overlaid by the *technical and operational difficulties* of diagnosing and treating TB. The diffuse spread of TB patients throughout India (2-3 sputum positive patients spread over 600,000 villages); clinical difficulties in diagnosis (dependant on the training and clinical acumen of several thousand doctors and the availability of diagnostic facilities); problems with treatment adherence (representing an interplay of doctor, system and patient factors); programmatic complexities such as ensuring uninterrupted drug supplies; and problems of drug resistance and co-infection with HIV, all make TB control a challenge both at macro and micro level.

This study supports those policy analysts who suggest that *the nature of problems* influences policy performance. Complex, interdependent problems (such as TB), rooted in many causes, with large diverse target groups, and many actors involved over a prolonged period, make it difficult for programmes to meet their objectives (Howlett & Ramesh 1995).

[7] The researcher attended three such international meetings.

9.2 Policy Content

Policy content in the health sphere comprises of the scientific rationale for the interventions based on an assumed understanding of cause-effect relationships, and the specific technical components. The concept of an NTP and some of its key elements were developed in India, contributing also to global TB policy. Conflicts in the choice of specific technical elements are clearly discernible. These included a focus on sputum smear positive patients with lower quality drug regimens for the remaining 50% of sputum negative patients; choice of less expensive though less effective drug regimens such as isoniazid monotherapy and isoniazid+thiacetazone combinations; controversies over the use of mass miniature radiography. Recent tensions are around blister packs, drug dosages and use of intermittent therapy in the SCC regimens of the RNTP. Sometimes state interests over-rode the interests of patients and society and at other times commercial interests prevailed indirectly, with market availability influencing practice of technical content.

As with any radical policy change, the NTP which could be described as a research based conceptual model, differing from existing practices and policies, faced resistance. Because the NTP standardised and demystified methods, relying theoretically on generalists in countrywide government health services to treat TB, the individualised practices of TB specialists and dominant medical professionals that were sometimes irrational were challenged, though unsuccessfully. As discussed, within government health services, policy content was greatly altered during implementation. Old policies and approaches continued, modifications were made and the NTP was reinterpreted at State, District and peripheral health institutions, such that original NTP concepts concerning policy content were not practised or were unrecognisable. Thus policy intent was far from what was executed. The NTI and TRC who developed the policy content and strategy, lacked administrative authority and were powerless to correct the policy distortions that took place. The initial group of policy makers and researchers had also moved on and some of the passion was lost.

Further, due to lack of attention to societal factors, policy content has been exclusively concerned with the medical and public health aspects of the problem, identified earlier as surface phenomena (Table 1.3). Technical interventions did not work as optimally in the field as under research or rigorous programme conditions (Chapter 4, 5)[8]. The main components of policy content of the NTP such as early diagnosis, passive case finding, reliance on sputum microscopy, domiciliary treatment with short course chemotherapy, integration with general health services, have been officially accepted policy in India for long. But inadequate attention was paid to their detailed implementation in practice, diluting their potential impact.

Thus in the field, as discussed in Chapter 7, diagnosis is often delayed by providers, with patients visiting several providers before diagnosis. This increases the potential for disease transmission. Sputum microscopy was most often not done in primary health centres and quality control not maintained (through cross checks, use of concentration, back-up with culture). Poor drug supplies, poor quality drugs, erratic availability of short course chemotherapy to only a small proportion of patients, and high hospitalisation rates revealed chaos in therapy. Inadequately functioning general health services, as attested by patients and elected representatives, adversely affected the functioning and credibility of an integrated programme like the NTP. Data from the district suggests that increased access to medical care by itself does not improve TB care or control, which requires specific policy inputs.

Further, computation of expectations of number of cases or targets for districts in India are based on old data, on prevalence rates, and on all-India extrapolations from studies in specific geographic areas, though regional variations occur between districts, *taluks* and social classes. These led to wrong estimations, particularly overestimation's of the problem, accentuating perceptions of the implementation gap. The gap is probably smaller than appears at first sight. Over-estimations were noted in the RNTP pilot phase

[8] Reasonably good outcomes from TB programmes using existing knowledge and technology have been demonstrated in countries/situations with strong government committment (Cuba) external financial assistance (IUATLD programmes), though the populations of the countries were small and achievements have not been sustained in some.

areas where case detection was always much lower than expected. The NGO with a community based programme for over 4 years in the district study had the same experience[9]. With increased public and private health services during the past 40 years and greater access to care, moving from prevalence to incidence data may be more realistic in developing expectations of potential cases. The use of targets based on those assumptions have thus resulted in overdiagnosis, particularly of sputum negative X-ray suspects, and unnecessary treatment.

Assessments of programme implementation rely primarily on epidemiological and public health indicators e.g. case detection, sputum examinations, treatment outcomes, case holding, buttressed by extrapolations and estimations from epidemiological surveys regarding impact. Little attention is paid to how such data are collected. Routine data from the monitoring system used for analysis is incomplete and unreliable, as this study showed at the district, reducing the accuracy of assessments and becoming misleading. This is demonstrated even in the revised NTP pilot sites. Data also relates only to the public sector. The absence of a notification system further limits an understanding of the problem. Information concerning finances and drug supplies at district level are not available. Analysis of processes and policy process indicators are lacking. Information gaps are major lacunae in the organisation of a programme, and systems need to be built up that can be used meaningfully at district level, as has been done by the NGO (Karuna Trust) in the district.

Finally this technocentric approach for the NTP foreclosed the need to build alliances with social movements and the need for intersectoral linkages. Rehabilitation was given up in the 1960's and issues such as social security and financial support for poor patients marginalised.

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[9] This has been the experience of other NGO's as well. Missed diagnosis and inadequate implementation may account for some of the difference.

9.3 Policy Context

As discussed in Chapter 4, there was political support during the BCG Campaign and the formulation of the NTP until 1962. Soon after, during the critical period of early implementation, the policy context (1962-70) became particularly unfavourable. Two wars, three successive years of severe drought, the death of two Prime Ministers, and economic problems with devaluation of the rupee in the 1960s, meant political leaders were involved with crisis management, and support to TB policy diminished. Increased dependence on external aid including food aid in the 1960s led to conditionalities concerning family planning, with strong support from the local elite. This affected the Ministry of Health leading to its bifurcation, creating divisions and strong competing interests, adversely affecting the NTP at every level by diverting resources and attention. Peripheral institutions and field staff (auxiliary nurse midwives now called health assistants) were funded by the family planning/welfare budget, all staff had to meet targets and increasingly coercive methods were used till 1977. Oil price shocks, unemployment and political instability in the 1970s aggravated the situation. Though State government expenditure on TB control in Karnataka is higher than central government, it is spent on large urban institutions and as such does not support the philosophy of the NTP. With inadequate financial and political support at State level for the right strategy, the quality and credibility of the NTP suffered. The context during the 1990s with structural adjustment and the growth of coalition politics has created further complexities, uncertainty and some instability and appears unconducive to effective implementation. Growing corruption at high levels in the Ministry and Directorate of Health referred to in Chapter 6, destroys morale and diminishes gains that have been made. Policy leadership was not always strong enough to steer the policy through these crises over the decades and ensure implementation.

9.4 Policy Process and Implementation Factors

Political processes strongly influenced the policy. During the early phase, central government supported TB control, with the first Prime Minister and Health Minister both taking an active interest in it. Starting from the 1950s a state dominated framework generated research that was different to disease oriented research, which is more often driven by purely scientific, professional, or pharmaceutical and corporate interests and funding. The research-based evolution of policy content of the NTP in India was mandated politically as part of a broader post-independence national policy process, which used the instrument of planning (five year plans). Research was directed to be socially relevant, nationally applicable, to function within financial constraints and to be scientifically sound. Thus policy content, sometimes assumed to be the rational, scientific component of policy in the health sector, was determined by a political process which influenced the type of research questions asked, research methodology employed, and the institutional mechanisms set up to translate research into policy. However, this research base did not ensure success in implementation, which took place in different circumstances, encountering several difficulties.

Political support to the NTP at the centre was inconsistent, being fairly high till 1962, declining till 1982, and then receiving some attention through the Twenty Point Programme. It rose in the agenda in the early 1990s receiving substantially greater funding with the revised NTP. Although political support at national level is considered important, this does not necessarily translate into good implementation practices, as is evident from experience of the government's Twenty Point Programme and the pilot phases of the RNTP. Strong authoritarian central political pressure could be counter-productive as the use of targets in TB and forms of coercion in other programmes (family planning) have shown.

At state level in Karnataka, the NTP was supported in the 1960s when a physician cum political freedom fighter was state health minister, followed by relatively low support, until the current period of renewed interest. The state government invests more money

than the centre in TB but unwisely, in larger institutions, and not at primary care level where it is most necessary, effective and accessible. Political priority can be gauged by resource allocations of finances, personnel, and drugs for TB. Inspite of political rhetoric resources have been low and insufficient both at central and state levels. Being under-resourced provides an immediate and important reason for poor performance.

Inter-dependence of political and *policy leadership* and the role of personalities in leadership positions were found to be important in this study. During the early phase, national policy leadership in TB was dynamic, with the ability to negotiate with political leadership at central and state levels, with international agencies, to commission and learn from research and experience and to change policy when necessary. It created influence and position for the TB programme, generated resources and built institutions. Evolution and implementation of the TB programme was best when good national policy leadership promoted leadership at other organisational levels. In the 1970s state and district leadership weakened, with a low sense of policy ownership. Team leadership for the NTP at peripheral health institutions never developed and continues to be a major weakness.

The NTP's *power* or level of influence is weak and fragmented. This accentuates the ineffectiveness of a thinly spread intervention strategy (through general health services) for a problem diffusely spread across a large population. The central TB unit in the Ministry of Health is small, a legacy from the past when it depended on national institutes (which are advisory) and state centres. It currently functions in some competition with the National TB Institute, which has greater technical expertise and experience and was designed and mandated to be the enginehouse and watchdog of the NTP. In the absence of strong policy leadership each group tends to be relatively isolated, promoting their institutional interests. Power at State and district levels is weaker. As shown in Chapter 6 the medical lobby within government reduced the power of District TB Officers in an internal conflict with public health professionals. Power for the NTP is non-existent at the crucial implementation level through the 21,800 primary health centres and 4,432 public sector hospitals. Consequently, these peripheral institutions are characterised by apathy

towards the NTP. Poorly functioning weak peripheral institutions serving the majority rural population, reflect power relations in society and is an important reason for poor implementation.

Not only was leadership in TB declining in the 1970-80s, but there was increasing politicisation and corruption at different levels. Later the *institutional base* at national level was further eroded in the 1990s, with frequent change of top leadership, the devaluing of existing institutions in policy making with adoption of international policy packages and increasing use of short term contracts. Further, weak *institutional structures* at state and district level (state and district TB centres) could not provide the technical or administrative direction or support, especially with the disjunction between planners, programme managers and implementors. Due to a lack of infrastructure and authority, the DTC's, with incomplete or partly untrained teams are almost non-functional in the execution of their key role of training, providing supportive supervision to peripheral teams, organising supplies, and managing the recording and reporting system.

Peripheral primary health centres are the weakest link in the NTP, with vacancies (particularly of laboratory technicians), non-performance (particularly of health assistants), and apathy characterising the crucial point of contact between patient and provider. Accommodation between personal and programme interests and goals, and extensive use of discretion and re-interpretation completely alter the NTP. Negative attitudes and rude behaviour towards poor patients also reflects social relations. Payments made for free NTP services and prescriptions given for drugs make regular treatment difficult in addition to closure/absence of staff at peripheral health institutions. The credibility and performance of these centres is low.

At all levels TB programme managers and staff tend to work within the constraints of the system, rather than question it or attempt actively to change it. This role has been left to the NGO's. However inspite of its many problems, the public sector (especially

government district general/TB hospitals and *taluk* hospitals, funded entirely by State governments), play a large role in TB care in the district[10].

Support to the growth of an unregulated *private for profit sector,* including the pharmaceutical sector, undermined the NTP and public sector. Direct and indirect policies, promoted the private sector, such as subsidies to medical education producing graduates for the private sector, support to capitation fee medical colleges, allowing or turning a blind eye to private practice by government medical officers etc. More powerful sections of society with ability to pay accessed private services, reducing pressure on the public sector to perform. The pharmaceutical policy had ensured availability of TB drugs at reasonable prices on the market, though shortages were consistently reported in the public sector. A weakened public sector further promoted growth of private services particularly from the 1980's. At local level, private sector practices in the district (and in other studies specifically looking at TB treatment practices) are irrational, unregulated and not always in the interests of patients. With mixed training backgrounds, competencies, interests and commitments, in rural areas private practitioners usually referred patients after a time when TB was suspected, (especially the poor), to government hospitals and were uninterested in follow-up. As one of them bluntly said 'TB control is not our business'. Their role in the NTP seems limited.

Different groups in the *voluntary sector* (sometimes called the non-profit private sector) played an important policy role in TB by placing it on the agenda, taking responsibility and supporting policy formulation in the early phases. Contributions to policy discourse from the critical and analytic, advocacy role of NGO's, deriving from grassroots work and upholding the interests of the poor are important. Marginalising voluntary sector participation in policy to just alternative service provision limits their role, though innovative approaches may be evolved.

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[10] The sample of patients were derived from lists of those attending government and NGO institutions, though they had all used the private sector as well. Patients using only the private sector would not be represented. However, given the relatively small number of private practitioners in the *taluks* and the fact that say that they refer TB patients, it is unlikely that a significant proportion of patients particularly the poor, would be completely treated by them. Hence this would give a fairly true picture for this region.

Voluntary sector efforts at the district with a community based TB programme demonstrated that achievements are possible, with low programme costs and positive health workers contributions, within supportive programmes[11]. The role of committed community health workers in improving TB programmes, especially treatment completion, has been reported from Ghana, South Africa, Korea (Grange 1993) and Bangladesh (Chowdhury 1997). The integration of TB work not only with health, but with development and education/awareness raising at village/family level are new approaches, in which *panchayats* could participate. However NGO's are sparsely and unevenly distributed and cannot be viewed as a policy alternative for TB control. The NGO's in this study, and their involvement in TB work, were also unrepresentative of NGO's in general.

Thus a policy analysis approach to understanding the implementation gap in the NTP has revealed that it is essential to include the underlying societal forces and the political and economic stakes operating at national, international, state and local levels that influence policy process and implementation. These factors cannot be adequately grasped by techno-managerial frameworks and methodologies, though they do provide supporting evidence.

9.5 Policy Implications from this Study

- TB policy should address not only what needs to be done (policy content), but how it is to be achieved at various levels. While considerable work has been done regarding technical aspects at an operational level, more detail is required to actualise them in different states and districts. More importantly, strategic policy level planning is required which specifically focuses on implementation issues. Suggestions arising from this study are discussed below.
- *Leadership* has emerged as a crucial element, and leaders need to be carefully chosen at national and state level. Expertise in the technical and administrative aspects of TB

[11] Though case detection was lower than expected (at incidence levels), treatment completion or cure was 72.5%, which was higher than the NTP achievements in the district.

control, need to be supplemented by abilities to create political support and adequate authority for the TB programme, to mobilise resources, interact with a variety of agencies, foster growth of important institutions, and nurture leadership at district level. This requires commitment, vision, imagination, flexibility and human relation skills in addition to competence. Current trends of leadership choice on the basis of seniority, a rapid turnover and lack of actual decision making power will hinder this process. District leadership by the district TB officers form the backbone of the programme in the 506 districts. Mandatory professional training requirements with regular continuing education inputs, adequate authority to take action at peripheral institutions in relation to the TB programme, sufficient resources so that their credibility is not undermined, and a complete team including an additional medical officer are all necessary components. If these are compromised, successful implementation is unlikely to result. Human resource development thus far underestimated, comprises a foremost component of policy implementation. A programme of this complexity need the best personnel, who will then require adequate recognition and compensation.

Institutional actors, particularly the National TB Institute, the TB Research Centre, other research and educational centres, and State TB Centres are important in giving technical direction, in monitoring and evaluation and providing an information base, in maintaining quality and providing training/continuing education. While several of the institutions have a rich tradition in research and training, their role has been undermined in the 1990s. They too require the necessary status, authority and resources.

Thus leadership at about 550 nodal points[12] throughout the country, covering over 950 million people is essential for the TB policy.

- Structural changes giving greater autonomy, responsibility and resources to states for the TB policy would make it more responsive to local conditions.

[12] Central TB unit, national institutes, 25 states, Union Territories and 506 districts.

- Policy makers and programme managers at national, state and district levels (the leadership) need to recognise the extent to which societal disparities, political processes and competing interests within the health sector influence the implementation of the NTP. They can then build strategies to identify areas of need; negotiate with organisations of medical professionals, the pharmaceutical industry, federating agencies of NGO's; promote the philosophy of the NTP more assertively and effectively and counter resistance. For instance, districts in greatest need (those more economically disadvantaged as measured by the development index, with more difficult terrain's, with less developed health services, and poor performance in the NTP according to monitoring reports) could be identified and preferential support to the NTP provided by the centre, including the National TB Institute, through channelling of resources and development of local expertise and human resources. Currently, disbursement of financial resources/supplies to DTP's based on performance, results in the better states getting a larger share.

Further the incomplete coverage and urban bias in the NTP needs to be corrected by developing the remaining District TB Centres and extending implementation to all peripheral institutions, particularly Primary Health Centres. The strategy needs to build from bottom upwards strengthening the base, particularly Primary Health Centres with capacity building, provision of means and resources (staff, diagnostics, drugs, transport) and adequate supervision and encouragement. Medical officers need more regular professional training inputs, perhaps with a system of being accredited by the NTP through State TB Centres. They need to be accountable to District TB Officers for the performance of the NTP in their areas. Links with *Gram Panchayats,* district TB Associations and local NGO's could help ensure that adequate financial and social support reaches poor TB patients. This may cause problems, including some misuse, which could be handled locally. The role of health assistants in the NTP needs to be be reconsidered and readopted by the policy, though with the current target-free approach. Flexibility and use of discretion is required at this critical level of implementation and while the policy can provide guidelines, it has to build on trust. TB patients require

skilled attention for associated medical problems and side-effects, besides support in coping with the psychological effects of the disease. Building up the self confidence and self-worth of peripheral health teams, and showing that their contributions are valued, can enhance their performance rather than using the present hierarchical, top-down, prescriptive approaches, that may not suit the circumstances.

- The historical review suggests that the policy environment and political processes are never going to be easy or optimal. Therefore a strong policy leadership is required to be able to respond to contextual changes and steer policy implementation. The idea of compact and knowledgeable task forces at national and state levels comprising government and NGO representatives to monitor implementation and support the programme has been made and merits consideration. Mechanisms providing backing to and developing linkages with poverty alleviation and housing programmes need to be established.

- In the context of social disparities, the public sector plays an important role in TB treatment and control, to counterbalance these forces. It is the only sector which is organised, which is paid for by the tax-payer and mandated to provide services, and which can be held accountable. The private sector, with profit making interests, have never been consistently involved with TB or with issues concerning poverty. However their potential needs to be recognised by the NTP, and educational strategies evolved through the Indian Medical Association and its branches. Regulation of private sector practices is another important though difficult issue.

- Active measures are needed to provide financial and social support to materially deprived patients through *panchayats* utilising existing local development schemes to ensure employment for affected families and improved housing. Local voluntary agencies/ philanthropists could also assist. The inclusion of patients with advanced disease (the criteria for which would need to be developed), as suffering from a disability, would entitle them to rehabilitation and some disability benefit.

- Local government (*zilla parishad, gram panchayats)* could increase local participation, accountability and link with development, housing besides specific support to affected families.
- Other actors, particularly NGO's[13], have played policy roles as watchdogs, issue raisers and researchers. If programme managers took greater cognisance of critical issues raised by NGO's, the media and legislators, they would find an additional source of information regarding field realities.
- It is frequently reiterated that the *policy content* is technically sound. However, as seen from the district data and from various evaluations, the implementation of the NTP alters and distorts policy content in the field. The technical component forms the essential core of the policy. Focus on the policy process dimensions will enable the proper implementation of policy content namely early diagnosis especially at primary health centres, maintaining the quality of sputum microscopy, and completion of treatment. Additional technical elements such as notification, action oriented analysis of data at district and state level, regulation of TB treatment practices of the private sector, monitoring drug resistance at state level, policies for chemoprophylaxis (used by the private practitioners), treatment of TB patients who are HIV positive or have AIDS or are dually infected with Kala-azar etc, and safeguarding health personnel working with TB, are in need of policy attention and action.

In conclusion, by taking a policy analysis approach this study demonstrates that several factors, other than technical issues, affect the success of implementation. It highlights conflicts and dilemmas at different levels. The interests of patients, of medical professionals (public and private), of allied health professionals and workers, of the pharmaceutical and diagnostic industries and of the state in TB control are interdependent. Though apparently working towards a common goal, they represent inherently strong conflicting interests, needing mediation and resolution, so that the well-being of the majority of patients is safeguarded.

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[13] The TB Association of India, Voluntary Health Association of India, Medico Friend Circle, Foundation for Research in Community Health, ICORCI, Nucleus for Health Policy and Planning, Community Health Cell.

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ANNEXE 1

TECHNICAL ASPECTS OF TUBERCULOSIS RELEVANT TO CONTROL POLICIES/PROGRAMMES

Historical, epidemiological, sociological and technical knowledge concerning tuberculosis relevant to public health policy is briefly reviewed in this appendix. Socio-political dimensions are included as they form an integral part of the knowledge base required for control strategies.

1.1 History, Scientific Understanding and Societal Factors

1.1.1 History: Tuberculosis is an ancient infectious disease (Stead and Dutt 1994). Comments on its history (*ibid,* Snider 1994, Daniel *et al* 1994) cite work by Pierry and Roshem,1931; Buickstra,1931; Perzigian and Widmer, 1979; Morse *et al*, 1964; and Manchester 1984. Key points that emerge are: tuberculosis has been found in skeletal remains dated around 8000 BC in Germany; and around 2500-1000 BC in Egypt; was mentioned in ancient Chinese writings; was written about in the Sanskrit Vedas suggesting that pulmonary tuberculosis was known in 1500 BC (Metcalf 1991); was recognised by Hippocrates (c.460- 377 BC); by Sushruta in India around 500 AD; and was found in an Inca mummy of about 700 AD. It is mentioned in classical Indian texts including the Ayurvedic Samhitas (Gothi 1982). These findings suggest that the tubercle bacillus co-existed with human beings in various regions of the world since early times. Like other organisms, in the process of evolution it developed complex ecological relationships with its host, indicated by its ability to survive in a dormant state within host cells for years (Smith 1994), by varying strains and virulence of the bacillus and the presence of non-pathogenic environmental bacteria. Tuberculosis probably occurred sporadically during this time (Daniel 1994). Two important periods in the *epidemic spread* of the disease among major population groups, that have been identified, appear to have been:

a) the period of *agriculture and cattle domestication* when people started living in larger communities with increased population density during the sixth and seventh millennia BC (*ibid*); and

b) the second period, which has been recorded, is of *industrialisation* and urbanisation, starting in England in the sixteenth century. The substantial increase in TB mortality in the latter half of the 1700's, accounting for nearly 20% of all deaths in England in the 16-17th century, was 'undoubtedly linked to the overcrowding and deplorable socio-economic conditions that prevailed during the early years of the industrial revolution. Similar increases in tuberculosis mortality were observed in several countries during their periods of industrialisation.'(Murray 1989;1789). Epidemic waves occurred in different regions of the world (Grigg 1958). It is suggested that the epidemic 'spread world-wide as a result of infected Europeans traveling to and colonising distant sites' (Daniel 1994;14). Theories linking susceptibility to tuberculosis with genetic factors, race and creative genius were made at various times. These gave way to recognition of the association of socio-economic and environmental factors such as poverty, overcrowding and poor living conditions with the disease (Dubos and Dubos 1952, McKeown 1979). Besides migration, colonialism and war led to increased tuberculosis in populations (Metcalf 1991). Tuberculosis death rates increased in all countries at war, during the first World War, from 1915 to 1919 and in England the decline was halted for 10 years from 1939 during the Second World War (Dubos and Dubos 1952). War related social disruptions, displacement and deprivations were responsible for the changes (Snider 1994). Its close links to the social history of humankind are further evident in contemporary times (1.2.5).

1.1.2 Scientific Understanding: Tuberculosis, the dreaded `white plague' or `consumption' in the terminology of the last century, has been the subject of extensive scientific study. Important biomedical/ technological milestones cited in reviews (Snider 1994, Daniel *et al* 1994, Stead and Duet, 1994) are: recognition of the infectious nature of tuberculosis by Girolamo Fracastoro in 1546; autopsies recognising the formation of lung nodules termed `tubercles' by Dutch physician Franciscus Sylvius in 1679; recognition credited to Laennec that TB in its various forms and sites is a single disease in 1819; experiments by French

surgeon Jean-Antoinne Villemin published in 1868 about its transmissible nature; Pasteur's experiments in 1862 suggesting airborne transmission; Robert Koch's isolation *of* *Mycobacterium tuberculosis* in 1882 as the causative agent of tuberculosis; development of an acid fast stain by Ehrlich in 1885; its subsequent refinement by Ziehl and Neelson; and the discovery of X-rays by Roentgen in 1895, the latter three of key importance for diagnosis. Subsequent discoveries of tuberculin testing (intradermal skin test) to identify the presence of infection by Von Pirquet (1902) developed further by Mantoux (1910), the first human trials of BCG vaccine by Albert Calmette and Alphonse Guerin in France in 1921 and of specific anti-TB chemotherapy since 1944 (streptomycin by Waksman and co-workers), 1952 (isoniazid), and 1966 (rifampicin) lead to improved treatment for individuals and better control measures at public health levels.

The enquiry into tuberculosis was at the core of the development of modern, scientific medicine, of microbiology, pathology, immunology, chemotherapeutics, and thoracic surgery (Banerji 1993). Koch's postulates helped establish a powerful medical philosophy, a new paradigm (*ibid*), the germ theory of disease causation over the prevailing miasmatic theory, leading to an underestimation of the socio-economic character of TB and the role of living conditions in its spread (Ratledge *et al* 1989, Grange 1993).

Scientific understanding lead to efforts towards disease control. Establishment of the infectious airborne nature of TB led to a public health movement in the USA and spitting in public became socially unacceptable and regulated (Daniel 1994). BCG is the oldest and most widely used prophylactic vaccine even today (Fine 1994). Strengthening of the medical armamentarium raised hopes of controlling the disease in society to levels such that it would cease to be a major public health problem (WHO 1964). However the 1960's debate about eradicating/eliminating tuberculosis was critiqued by MacLeod (1963).

With a substantial decline of the disease in Western Europe/the established economies in the 1950-60's, scientific interest, research priorities and funding shifted away from tuberculosis (WHO 1993). TB control became primarily a matter of implementing known, universally applicable interventions/strategies (Porter and McAdam 1994).

1.1.3 Societal Factors: Frost (1939) in the USA suggested that tuberculosis had been on the wane long before effective therapy was introduced. Dubos and Dubos (1952;210) wrote concerning the social nature of the disease, 'By 1900, it had become obvious that tuberculosis was most prevalent in the poorest elements of the population, and that healthy living could mitigate its harmful effects'. The Societies and Leagues from 1890 comprising the anti-tuberculosis movement represented 'a farsighted citizenry who saw in tuberculosis a social disease that was not likely to be solved by a conventional medical approach' (*ibid*;211).They suggested that the impact of social and economic factors be considered as much as the mechanisms by which tubercle bacilli cause damage to the human body (*ibid*). McKeown (1979) showed that decline in TB mortality rates in England and Wales preceded widespread use of BCG and development of chemotherapy. Highlighting a different perspective, Snider(1994) cites the work of Wilson (1990) and Newsholme (1924) attributing the decline of tuberculosis to reduced exposure to infection resulting from segregation of persons with infectious TB and to Poor Law Infirmaries in England.

Historical investigations into the spread of tuberculosis in South Africa and its high prevalence among miners, migrant labour, and black townships highlighted the societal dimensions (Packard 1989). Tuberculosis remained a problem in the developing world affecting about 80 % of the global population despite control programmes spanning three decades (WHO 1988).

From the late 1980's a resurgence of TB in developed countries and increasing rates in several developing countries is associated with HIV co-infection, increasing poverty, urban congestion, homelessness, social and political breakdown, migration and war and inadequate health services (WHO 1993, Iseman 1997). In East Europe and the former USSR TB was under control till 1989 with a decline over 40 years, but subsequently has experienced increased incidence and mortality even among the productive age groups (WHO 1994b). This has been attributed to political changes and breakdown in inter-regional dependence, disintegration of the economic and civil situation of many countries, population displacement, increasing poverty with growing overcrowding and under-nourishment in many countries (*ibid*).

1.2 Epidemiological Factors

1.2.1 Agent: Tuberculosis is a bacterial infectious/communicable disease most commonly caused by *Mycobacterium tuberculosis* and less frequently by *M. bovis*. In certain areas persons infected with Human Immunoeficiency Virus (HIV) develop infections due to *M. avium intracellulare* (Godfrey-Faussett 1994). There are other members of the *M.tuberculosis* complex (Manjunath 1991).

The virulence of *M. tuberculosis* varies, with the South Indian strain less virulent than British and Thai strains (WHO 1965). It is possible that the varying biology of the Mycobacterium is reflective of an adaptation of the bacteria to its host and environment (*ibid*). There is as yet imperfect knowledge about the organism, partly because of difficulties inherent in working with it in the laboratory till recently. Methods of molecular biology, such as DNA finger printing used in the Tuberculosis Genome Project, is furthering understanding of the biological processes of tuberculosis (Porter and McAdam 1994), and generating useful knowledge for the further development of diagnostics, chemotherapeutic agents and vaccines (Orme 1997).

Several atypical mycobacteria present in the environment resemble *M.tuberculosis* but are non-pathogenic. They prime protective immune pathways (Rook and Stanford 1994). Differential response to BCG in countries where they are present was thought to be due to their immuno-modulating effects. One such *Mycobacterium vaccae,* being experimented with as an immunotherapeutic supplement, is reported to accelerate cure (*ibid*). It is a fast growing mycobacteria found in Uganda. Other environmental mycobacteria are *M. parafortuitum, M. aurom, M. obvense* and the slow growing *M. scrofulaceum* (Stanford 1991).

1.2.2 Transmission: Tuberculosis is transmitted directly from *person to person* or mammalian host to host, with no intermediate carrier/vector (McNeill 1976).

a)Tuberculosis caused by *M.tuberculosis* is an *air borne* infection spread by droplet nuclei containing bacilli (Snider 1994). These are produced by patients with active pulmonary TB (with cavitation of the lung associated with productive cough), whose sputum tests are

positive for the bacilli. Coughing, sneezing and even speaking releases bacilli into the air and uninfected persons inhale them by just breathing. Experiments by Pasteur in 1862 suggested air borne transmission, which was conclusively proved by studies by William Wells in the 1930's (*ibid*). The method of spread was demonstrated by delivering untreated air from a TB ward to guinea pigs in an animal exposure chamber by Riley in 1957 (*ibid*). Close contacts of smear positive patients are at maximum risk (Stead and Dutt 1994) with infection rates of 25-50% in overcrowded conditions (Comstock 1982, Styblo 1984). Much transmission occurs in enclosed environments (Snider 1994). Most spread of infection from sputum positive cases of pulmonary TB occurs before case detection (Kamat *et al* 1966). Hospitalisation/segregation thus would not reduce transmission substantially. In some studies infection rates in contacts of smear negative, culture positive patients is not different to that in the community. Studies estimate that untreated smear positive patients infect 10-14 healthy persons annually and usually excrete bacilli for about two years, thus causing 20-28 new infections before dying or becoming sputum negative (WHO-SEARO 1994). Therefore priority in control programmes is given to diagnosis and treatment of sputum positive patients.

Newer techniques of DNA fingerprinting[1] found 30-40% of new TB cases in New York City and San Francisco resulted from recent transmission, challenging earlier views that 90% of new cases were from reactivation and 10% from recent infections (NIAID 1994). A retrospective re-evaluation of data from the French national survey (1962-70) on prevalence of primary resistance indicates that in 66% TB was recently transmitted (Marchal 1997). This and other similar findings suggest that TB is more easily transmitted than thought and development of disease occurs quicker than earlier anticipated (Upham 1994). Following contact with an infectious case about one in six (15%) become infected (Enarson and Rouillon 1994). There is increasing recognition that health care providers are at high risk of contracting tuberculosis, besides the socially deprived, homeless, drug addicts and HIV positive persons (Orme 1997). Occupational risks of physicians developing TB were observed as being high in the 1940-50's in the USA (Murray 1989).

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[1] specific strains of the organism are identified by their genetic factors (NIAID 1994)

b) Infection due to *M.bovis* caused by *consumption of milk* from infected cows was common in Europe and a Royal Commission in the early 20th century established the epidemiology, bacteriology and pathology of bovine TB (Grange 1996). Pasteurization of milk and elimination of diseased animals as part of effective bovine TB control measures, led to reduced spread of bovine tuberculosis in England and Europe (*ibid*). Bovine infection was considered uncommon in India. Ukil (1930) cites studies by Soporkar who found Indian breeds to be resistant to tubercular infection, and of Joshi who found no growth of tubercle bacilli from cultures of cows milk. Cultures from extrapulmonary foci of tuberculosis did not isolate bovine tuberculosis. Reports of bovine tuberculosis were however reported from Madras. A 1995 veterinary conference in Madras expressed concern about prevalence of TB in cattle in India.

1.2.3 Host Immune Response, Infection and Disease: An understanding of cell mediated immunity (CMI), the main immune mechanism in tuberculosis, grew in 1973 with recognition of the role of Thymus derived lymphocytes in CMI (Orme 1995). The complexities of the host immune response and the ability of the bacilli to reside within host mononuclear cells are such that precise mechanisms of killing/controlling the bacilli are still not fully understood, though there are several hypotheses (*ibid*).

A degree of Delayed Type Hypersensitivity (DTH) to tuberculin develops in most individuals within 6-8 weeks of infection with *M. tuberculosis* or related bacteria (Fine 1994). This response measured by tuberculin skin testing[2], indicates the status of infection in individuals, and since the 1950-60's was used to assess prevalence of infection in populations (WHO 1965). The shift from using two tests (strong and weak) to one (using a low dose) reduced the incorrect inclusion of non specific mycobacteria[3], altering existing ideas of prevalence of infection (*ibid,* NTI 1990). The average Annual Risk of Tuberculosis

[2] Skin reactivity to a small quantity of injected tuberculin, indicative of a past infection with the tubercle bacillus, was discovered by Von Pirquet in 1907 and is of epidemiological value (Grange 1996; 86). In the Mantoux test, commonly used for the purpose, tuberculin PPD (purified protein derivative) is injected intradermally and induration if any is measured 48-72 hours later (Narain 1992).

[3] At 16mm or more most reactions are tuberculous. Intermediate size reactions in India could be due to cross reactions from organisms that rarely cause disease (NTI 1990).

Infection (ARTI)[4] is considered a good epidemiological index to evaluate the TB situation and its trend, though there are limitations when the ARTI is less than 0.5% (Raviglione 1995). It has been estimated by Styblo that for every 1%ARTI 50 new smear positive cases of TB develop per 100,000 per year (*ibid*).

Cell mediated immunity evoked by the bacilli cause a nonspecific inflammatory response in the lung tissue and corresponding lymph nodes, termed the primary complex (Grange 1994). Depending on adequacy of the immune response, the bacilli become sequestered in dormant foci which in 90% do not progress to clinical illness (Murray 1989). These persons are infected with tubercle bacilli, but do not have tuberculous disease (*ibid*). Infection is followed by a 10% lifetime risk of progressing to clinical disease (WHO 1993), particularly if immunocompromised or under physical or emotional stress (Snider 1994). In India while 35% of the total population, is infected only 2% are diseased (NTI 1994c). In most the host's immune system overcomes the primary infection (Grange 1994). Two to six weeks after primary infection a certain level of CMI develops to *M. tuberculosis* antigens, with the formation of granulomas around bacilli. These may get calcified and are detectable on chest X-ray as a calcified primary complex. The presence of dormant foci of bacilli that can get endogenously reactivated later into post primary disease, slows the process of reduction/elimination of tuberculosis in a community (Styblo 1991, Murray *et al* 1993) as the risk of reactivation or breakdown cannot be entirely prevented. It has taken decades for infection rates to reduce substantially even in developed countries.

Prior to the onset of allergy and immunity, escape of bacilli into the blood stream from the primary lesion in the lung, can cause foci to develop in other parts of the body. This could occur in the kidneys, ends of long bones, spine or brain. In infants and young children serious forms of tuberculosis, such as miliary tuberculosis and tuberculous meningitis, may develop. These occur much less frequently in adolescents and adults.

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[4] The proportion of the population which will be primarily infected or reinfected (in those previously infected) with tubercle bacilli during a year, expressed as a percentage or rate (Styblo 1991,40). It is usually estimated from age specific prevalence of tuberculin skin sensitivity (Enarson and Rouillon 1994,20).

In young adults there is a female excess in disease, though there is a male excess in tuberculin positivity (Fine 1994 citing NTI 1974). It is suggested that this could be due to gender differences in manifesting Delayed Type Hypersensitivity or susceptibility to the disease or to additional physiological stresses of child bearing (*ibid*). In older adults tuberculosis occurs due to endogenous reactivation or by reinfection. The proportion varies according to the level of risk of infection in the population, with greater endogenous reactivation when transmission rates are low (Fine 1994 citing Sutherland 1976).

Atypical environmental mycobacteria present in some regions, including India, cause increased tuberculin positivity (WHO 1965), but with smaller indurations as infection due to atypical mycobacteriae produce an immune response in the host.

Concepts of TB control and eradication/elimination are linked to levels of infection and disease in a country. The Centers for Disease Control, USA, and Styblo define elimination in developed countries as occurring when '1) the incidence of the disease is less than 1 per million, or 2) the prevalence of TB infection in the general population is under 1% (Gonzalez 1994;191). The USA aims to reach this goal by 2010 while in The Netherlands it is accepted that it cannot be reached within the next three decades (*ibid*).

1.2.4 Natural History of Disease in Individuals and Populations: *In individuals*, of those infected, approximately 10% have lifetime risk of progressing to clinical disease, particularly if immunocompromised or under physical or emotional stress (Snider 1994). Five percent may develop "early" progressive disease within 5 years of exposure, and the remaining 5% may develop "late" recrudescent disease after several decades of infection (Stead and Dutt 1994, Snider 1994). In the latter the dormant bacilli get reactivated and cause disease at any time during the individuals life time, often precipitated by physical or psychological stress or an immuno-compromised condition. An untreated patient with pulmonary tuberculosis can infect 10-15 persons during their lifetime (WHO/TB/95).

The latent period between primary infection and clinical disease varies from weeks, months or years. In 1968, Sutherland estimated that about 80 % of disease occurs during the first

two years after infection. It appears that the risk of progressive disease soon after primary infection is a function of the age at which infection occurs. The risk is high in underfives, lower (less than 5%) between 5 and 12, and 10-20% in young adults (Fine 1994;56). Childhood tuberculosis is more frequently meningeal, miliary and extrapulmonary. Diagnosis of pulmonary tuberculosis in children is difficult leading to underestimation of its prevalence.

In populations, historian McNeill (1976), quoting Dubos specifically regarding tuberculosis, suggests that symptomatology of infectious diseases alters from the time a disease is first introduced to a population, to the third generation exposed, by when resistance develops in the host population. In TB acute fulminating disease patterns, high prevalence among children and high mortality rates give way over time to more fibrotic forms affecting older age groups (Grigg 1958, Enarson and Rouillon 1994). TB declined at about 4% per annum prior to introduction of chemotherapy and was subsequently accelerated up to 10% in certain groups (e.g. military recruits in The Netherlands) and by 5.3-5.5% in Europe and the USA till recently (Enarson and Rouillon 1994).

Indian data concerning natural history is discussed in Chapter 1 (1.2.6). Similar patterns occurred earlier in Europe and the USA. TB mortality rates of 190-200/100,000 for white Americans and 400/100,000 for black Americans at the turn of the century indicate the magnitude and social distribution of the problem in the USA (Guttmann Rosenkrantz 1987). Dubovsky (1991) cites hospital TB case fatality rates by William Farr in 1885 as being 62% in the first year, 85% in the second year and 95% in the fifth year after presentation. He cites hospital trials in the United States by Ferrebee and Palmer from 1947 covering over 10,000 patients. A year after non anti-microbial treatment patients had a mortality of 21%, 54% were sputum positive and 25% sputum negative. In the early 1950's combination treatment with streptomycin and PAS reduced mortality to 3%; while 32% remained sputum positive and 65% became non-infectious. By 1963, mainly through the impact of isoniazid and streptomycin, PAS and pyrazinamide mortality rates dropped to 1%, sputum negatives increased to 95% and only 4% remained sputum positive (*ibid*). The

declining incidence of tuberculosis in the USA and Europe was accelerated by the introduction of chemotherapy and modern methods of TB control (Murray 1989).

It was estimated in 1950, that since 1900 5 million people died prematurely due to tuberculosis. The mortality in 1950 was 34,000 or 22/100,000 (Dubos and Dubos 1952). However mortality rates have declined steadily in England and Europe since the nineteenth century i.e. before introduction of vaccines and chemotherapy, pointing to the powerful impact of improved housing, nutrition and living conditions (Mckeown 1979). WHO estimates currently that of 90 million new cases 30 million are expected to die between 1990-99 without improved world-wide control (Raviglione 1995). Others suggest that this is an overestimation (Enarson and Rouillon 1994). It also assumes a high 33.3% mortality rate.

Epidemiological evidence regarding disease patterns of TB in India over time suggest a declining trend in the epidemic. Infection rates among children 0-4 years decreased from 2.1% in 1961 to 1.2% in 1982; the relative distribution of cases among the 5-39 year age group and 40 plus age group was 1:1 in 1961 and 1:4 in 1985; sputum smear positive case rates declined from 189/100,000 in 1961 to 68/100,000 in 1985; and decline of serious forms of TB like miliary TB and meningitis (NTI 1994c). TB mortality rates decreased from 250/100,000 in 1949 (*ibid*) to 50/100,000 in the 1990's (Datta 1994).

1.2.5 Environment: The influence of the environment on TB engendered by poverty, through overcrowded housing, undernutrition, poor living/working conditions with associated psychological stresses has received wide acknowledgement. Evidence linking TB and socio-economic factors continues to be reported. In British Columbia, Canada, between 1980-82, annual notification rates were 242/100,000 in the lowest socio-economic groups and 2/100,000 in the highest groups, with similar patterns in Edmonton and Calgary (Enarson and Rouillon 1994). In South Africa TB is uncommon among well to do Whites and highly prevalent among Blacks who are poor, live in overcrowded tenements, are undernourished and have high unemployment rates (Thomas 1997). Higher TB notification rates among the homeless and poorer sections of society in Britain has been reported from

studies in the 1980-90's with a social class gradient in mortality from TB (Mangtani 1995). For instance of the 12% increased notifications between 1988-92 in England and Wales, there was a 35% increase in the poorest 10th of the population, 13% in the next two, while in the upper 70% there was no increase (Bhatti *et al* 1995). Part of the increased TB in the USA since the mid-1980's is attributed to inner city deprivation, homelessness and lack of access to care (Murray 1989). Besides HIV co-infection, household crowding was an important force in New York City's TB epidemic, strongly associated with poverty, dependence on public assistance income, larger household size, Hispanic ethnicity and greater social isolation (Drucker 1994). Among the homeless in the USA, TB infection rates were 32%, and prevalence rates of active disease 1.6-6.8% (higher in shelters with large numbers of HIV infected adults) (Tulsky and Long 1996). The TB situation in Eastern Europe since 1989, in the absence of HIV as an important factor, highlights linkages with deprivation and social dislocation. It is suggested that in China urban rural differences in TB rates (in 1987, 419.1/100,000 and 693.7/100,000 respectively) reflects the greater impoverishment in the countryside (Wallace 1996).

In the political environment, the gaps between rich and poor are increasing internationally. From the mid-1980's to 1994, the negative transfer of resources from developing countries increased through debt/capital/interest repayment (Benatar 1996) reaching up to US$8.4 billion, while structural adjustment programmes caused a net transfer of US$178 million from poor countries to Northern commercial banks from 1984-1990 (Balasubramaniam 1996;1410). Evidence from Africa suggests that Structural Adjustment Programmes have been associated with increased food insecurity, undernutrition, ill-health and decreased access to health care for the two-thirds of the population already living below the poverty line (Loewenson 1993). Underlying causes of poverty internationally and nationally need to be addressed as a deeper level of preventive action for TB control (Table 1.3) and for better health and well-being of a large proportion of the global population.

To sum up the effects of the environment 'TB remains the quintessential disease of socio-economic misery. Wherever there is poverty with its attendant crowding, malnutrition and poor hygiene, tuberculosis flourishes' (Murray 1989;1794). The perceived association

between social deprivation and TB and the high TB incidence in Europe in the nineteenth century was a factor leading to movements for improved living conditions (Grange 1993). Though 'elimination (of TB) will be impossible as long as poverty, overpopulation and malnutrition characterise large portions of the earth' (Stead and Dutt 1994;1), there is less clarity now of how to integrate societal factors into intervention strategies, with dominant medical and public health approaches focusing on biomedical and techno-managerial aspects.

1.3 [5]Diagnosis of Tuberculosis and Case Finding comprise key components of control strategies (Grange 1993).

1.3.1 Sputum microscopy (of specimens stained by the Ziehl-Nielsen method) has been accepted over the past four decades as being capable of detecting a substantial proportion of sputum positive infectious patients (Baily *et al* 1967, Toman 1979, Godfrey-Faussett 1994). Others suggest that microscopy on unconcentrated sputum specimens is a cheap but grossly insensitive tool (Iseman 1997, Hopewell 1995). Extrapulmonary and childhood TB cannot be diagnosed with sputum examinations (Hopewell 1995). The quality and quantity of the sputum specimen, quality of smear, staining technique, time spent on examination, the bacterial load etc. affect the sensitivity and specificity of the test (Rao 1970). Results depend on the skill, aptitude and experience of staff (Chadha 1995). The proportion of culture positives that are also smear positive varied in Indian studies from 40-48% to 73-87% (*ibid*). Sputum microscopy requires quality control and is an appropriate technology the infrastructure for which exists in India. Examination of three specimens, with two spot samples on consecutive days and one overnight sample, is advisable to reduce false negatives and false positives (TB Div.1995a). With fluorescence microscopy larger fields are examined through low power objectives, requiring a shorter time for examination and yielding marginally more true positives (Toman 1979). However its disadvantages include high cost, need for uninterrupted power supply with no voltage fluctuations, advanced

[5] Strategies for TB control include a) Early case detection and complete treatment. This is the most important. b) BCG has little role in preventing transmission. c) Chemoprophylaxis used for individuals exposed and at risk, and particularly for HIV positive persons. It is not part of National TB Programmes because of cost, compliance and organisational/logistic problems.

technical skills for handling and maintenance of optical equipment, frequent repairs and changes of bulbs (*ibid*).

1.3.2 Radiology: Observer error is widely reported in using chest X-rays to diagnose pulmonary TB with interpreters showing a high degree of inter and intra-reader variation (Chadha 1995). Only 30% of those diagnosed on single X-rays at State TB centres were culture positive, with estimations of the proportions declining to 10% in peripheral centres, resulting in considerable over-diagnosis (Nair 1974). 63% were cited as culture positive in another Indian study (Toman 1970). Very small proportions of culture negatives in both studies, 3-4%, became culture positive on follow-up *(ibid)*. Several studies in Europe and the USA found under-reading in 26-43% of films (Toman 1979). An IUAT international study found a high degree of disagreement concerning abnormalities in the respiratory system (*ibid*). A substantial proportion of patients are wrongly diagnosed as TB and unnecessarily treated (WHO 1974, ICORCI 1988). Thus it is not recommended to start treatment on radiographic findings alone (WHO 1974) as X-ray diagnosis of tuberculosis is unreliable (TB Div.1995a). Radiographic facilities are additionally expensive to set-up and maintain, being available only at district centres and in urban private diagnostic centres.

1.3.3 Culture is more sensitive, specific and reliable but is expensive, requiring specialised facilities and personnel and is slow, taking 4-6 weeks for results (Toman 1979). Greater use is suggested to facilitate earlier case-detection (Hopewell 1995).

Newer polymerase chain reaction (PCR) based tests[6] for rapid diagnosis of pulmonary TB maybe used in national reference laboratories and for research in the present Indian situation (Chadha 1995). Problems of diagnosis of paediatric and extrapulmonary tuberculosis and the need for rapid detection of drug resistant tuberculosis remain (Godfrey-Faussett 1994).

1.3.4 The objective of **case finding/detection** as an integral part of a public health oriented TB control strategy is to identify sources of infection in the community, treat them

[6] The method employs amplification of a segment of DNA and can detect a few bacterial cells in a sputum specimen within 4-5 hours (Chadha 1995). Blood based PCR assays are being tested for sensitivity and specificity with varying results (Condos 1996, Aguado 1996).

and reduce disease transmission (Toman 1979). Citing an early NTI definition, case finding is an 'organised and systematic effort to discover the largest possible number of cases in the community on a continuous basis with an acceptable, practicable and cost-effective methodology using simple standardised tools' (Chadha 1995). Emphasis was on early case detection and passive case-finding (Banerji & Andersen 1963). Case finding and treatment (case holding) have conceptually been a single functional entity under NTP's (WHO 1974). In practice there was greater emphasis on meeting targets for case detection with large proportions of patients taking irregular incomplete treatment (GOI/WHO/SIDA 1992).

1.4 Treatment of Tuberculosis

Prior to the discovery of anti-TB chemotherapy bed rest, a dry climate, fresh air and good food for those who could afford it, was the only option for patients with tuberculosis (Porter & McAdam 1994). From the mid-nineteenth century the sanatorium movement grew for about 100 years. An unintended effect of this treatment strategy was the spread of disease to unexposed populations, as has been documented in South Africa (Packard 1994, Metcalf 1991). Surgical procedures such as artificial pneumothorax and pulmonary resection were used from the late 19th century (Dubovsky 1991).

In 1946 the first trial of streptomycin against tuberculosis was reported initiating the era of chemotherapy. Problems of resistance led to the search for new antibiotics and to the use of multiple drugs (as new drugs were discovered). Effective drug regimens were developed through a series of clinical trials conducted by the British Medical Research Council starting in the 1940's with streptomycin, streptomycin and PAS, isoniazid alone, isoniazid+streptomycin+PAS for 18-24 months, later reduced to 12 months (Snider 1994, Porter and McAdam 1995a).

There are two categories of drugs: a) bactericidal and/or sterilising[7]- streptomycin, isoniazid, rifampicin and pyrazinamide; b) bacteriostatic- ethambutol and thiacetazone (Prabhakar 1996, Van Scoy and Wilkowske 1992). They have all passed the patent period

[7] With ability to kill the persistors, measured by relapse rates during a two year follow-up period (Prabhakar*1995).

(Weil 1994) with the last, rifampicin being introduced 30 years ago. Newer classes of broad spectrum antimicrobials such as the quinolones, macrolides, rifamycins and betalactans that could possibly play a role have not yet been adequately studied in animal models or in human clinical trials (*ibid*).

The development of low cost standardised regimens made mass chemotherapy possible through TB control programmes (WHO 1965). 'This more than the actual discovery of the drugs themselves, was the real breakthrough' (*ibid*;16). They included the demonstrated effectiveness of domiciliary treatment (Tuberculosis Chemotherapy Centre, Madras 1959) and intermittent therapy (Tuberculosis Chemotherapy Centre, Madras 1964). Money spent on the cheapest sanatorium bed was calculated to provide 1000 domiciliary cures, while the maintenance of a bed covered costs for 300 domiciliary courses (WHO 1965). The shift from prolonged 18 month to 6-9 month Short Course Chemotherapy (SCC) following the introduction of Rifampicin, pioneered by the British Medical Research Council under Fox and Mitchison in 1975 (Snider 1994) and 'demonstrated first in developing countries' was another advance (WHO 1982;21). Good response (98-100% sputum conversion) and low relapse rates (less than 5% disease reactivation during 2-5 year follow-up) were obtained in clinical trials (WHO 1993b). It reduced non-adherence, case fatality, relapses (Enarson and Rouillon 1994). SCC achieves good results under certain conditions but is less optimal in most others with difficulties in drug supplies, case holding and supervision (Grange 1993). The reasons for its success in developed countries 'include low rates of primary drug resistance, well developed health services and insurance schemes to cover the costs of treatment, good patient education, and supervision of treatment in hospital' (WHO 1993b;3). Because of immediate costs limited populations in developing countries were covered by short course treatment. Two regimens were recommended for 'programme conditions in developing countries': a) isoniazid plus thiacetazone often supplemented by streptomycin in the initial phase, and b) twice weekly supervised streptomycin plus isoniazid with an intensive daily phase when possible (WHO 1982;18). The WHO suggested joint pool procurement schemes for essential TB drugs and the possibility of

loans to national governments from the World Bank and regional development banks for TB drug procurement (*ibid*).

Patients' non-completion of treatment, non-compliance or non-adherence has been long recognised as a cause of treatment failure (Grange 1993). While technical strategies to overcome this include supervised therapy, combination tablets, blister packs, pill checks, urine tests and hospitalisation, physician attitudes, behaviour and relationships are important (*ibid*, 219).

The introduction of chemotherapy resulted in unintended consequences such as drug resistance and large numbers of incompletely treated chronic excretors who increase the sources of infection in a community (Enarson and Rouillon 1994). By reducing the dramatic consequences of the disease, political commitment to public health programmes and research efforts declined (Iseman 1997). Forty years following the introduction of chemotherapy more new cases occur annually than ever before (p1)[8], with low cure rates, high mortality and increased transmission from the enlarged reservoir of infection in developing countries, where 95% of the world's TB cases occur (WHO 1993b). It is suggested that 'chemotherapy has failed to have a significant impact on tuberculosis morbidity' (*ibid,* 1).

To minimise these public health programme dimensions of chemotherapy include: well organised drug procurement and distribution systems that ensure uninterrupted and adequate supply of good quality drugs, good infrastructure and management systems, training and continuing education of staff, supervision and patient education. It would also include community involvement in support of patients' completion of treatment.

1.5 Drug Resistance

Drug resistance[9] in TB has been observed since streptomycin was introduced (Toman 1979). Biologically drug resistance occurs with *Mycobacterium tuberculosis* because of its

[8] In India there were an estimated 5 million TB patients in 1959 (ICMR) and 13-14 million in 1994 (NTI 1994c).
[9] Bacilli continue to grow *in vitro* in the presence of high concentrations of the drug (Toman 1979)

ability to mutate and adapt. As newer TB drugs were discovered after streptomycin multiple drug regimens were developed to overcome the problem of resistance. Poor chemotherapeutic practices also cause drug resistance, leading to treatment failure, relapses, spread of resistant tuberculosis and development of multi-drug resistant TB (Nunn 1994). Drug resistance 'is a sensitive measure of the quality of a tuberculosis programme' (Enarson 1995;98).

During the 1950's it was common therapeutic practice (*ibid*) and WHO policy to use isoniazid monotherapy (interviews 1996). Primary drug resistance occurring in patients who have not received TB chemotherapy before, is caused by infection/transmission of resistant organisms from another patient (Toman 1979). It is a parameter to assess the amount of resistant bacillary transmission in the community. Secondary or acquired drug resistance is due to incorrect chemotherapy and develops while the patient is on treatment due to non-adherence or faulty prescribing (*ibid,* Snider *et al* 1994). When it is not possible to obtain a reliable history of previous TB chemotherapy the term initial drug resistance is used and includes true primary and undisclosed secondary resistance *(ibid*). Though a resistant strain does not return to sensitivity in clinical practice, single drug resistance, especially if primary, does not impede success of a triple drug regimen (*ibid*).

More recently, the emergence of Multi-Drug Resistant (MDR)TB[10] which does not respond to Short Course Chemotherapy is a cause of concern. Retreatment with ofloxacin and cycloserine costs 30-35 times more than SCC and requires hospitalisation (Portaels 1994). Though MDR is not yet a major world problem *(ibid*), the implications of its spread are serious.

Findings from New York City suggest that most drug resistant cases were due to person to person transmission and not due to poor treatment compliance or treatment failure (NIAID 1994). Of significance to the current policy debate is the WHO recommendation, 'We cannot afford to produce rifampicin resistant TB by introducing rifampicin in the continuation phase without supervision. Our recommendation is that when introducing

[10] A strain is considered multi-drug resistant when it is at least resistant to isoniazid and rifampicin (Portaels 1994 citing WHO definition).

rifampicin, mechanisms have to be in place to ensure patients take their drugs.' (Kochi 1994;7). The importance of well organized and functioning TB programmes with uninterrupted drug supplies in minimising drug resistance is widely recognised. Development of drug resistance is commonly ascribed to patients' non-adherence (WHO 1993), but physician and health system factors, and biological mechanisms of the bacteria also play a role.

Data from India on drug resistance is given in Chapter 1, 1.3.2

1.6 TB and HIV Co-Infection

It is established that people dually infected with the tubercle bacilli and human immunodeficiency virus are at increased risk of developing tuberculosis (WHO 1993). Immunosuppression (of cell mediated immunity measured by CD4 lymphocyte counts) by HIV makes it the most significant risk factor for progression of primary TB infection to disease or for reactivation of a dormant focus (Murray 1989, Narain 1992). TB increases progression to AIDS in HIV infected persons (WHO 1993). Globally in 1990, 305,000 cases of tuberculosis attributable to HIV were cited as occurring, of which 230,000 were from Africa (Porter & McAdam 1994a). In 1992, an estimated 4 million were dually infected worldwide since the onset of the HIV pandemic, 95% in developing countries (Narain 1992). The epidemiological impact of HIV on the TB situation depends on the prevalence of the two infections in the community, the annual risk and trend of TB infection, the breakdown rate of TB infection to disease and detection and cure rates of sputum positive cases (Styblo 1991). Increased TB incidence has been observed in countries where both infections are prevalent (*ibid,* Snider *et al* 1994). Studies are cited showing the risk of active TB in dually infected persons to be 3.8% per year with a lifetime risk of 50% or higher (Porter 1996). Persons with dual infection are 30 times more likely to get sick with TB than persons who are HIV negative (WHO 1996). WHO estimated that globally HIV contributed to about 4% of new TB cases in 1990 and was expected to rise to 14% by 2000 AD (Kochi 1994). In Africa, the proportion is higher with about 50-60% of TB due to HIV *(ibid)*. It is estimated that globally about 5 million

persons are infected with both HIV and TB with three-quarters of them in Africa (WHO 1994b). Because the occurrence of HIV and AIDS is greatest in the 15-45 year age group the excess of TB cases following HIV occurs in this age group (Enarson 1995). In Africa 20-44% of AIDS patients had clinical TB, while it was 25% in some Latin American countries (Narain *et al* 1992).

Conventional diagnosis of TB in HIV positive persons is complicated by increased frequencies of false negative tuberculin skin tests, sputum smear negative pulmonary and extra-pulmonary disease and atypical radiological manifestations (De Cock 1994;41). Studies are cited documenting increased drug side-effects, relapses and mortality following treatment (Porter and McAdam 1994a;306). Short Course Chemotherapy is as effective for TB among HIV positive as among HIV negative patients (Narain 1992). In IUATLD assisted programmes treatment results of TB patients with HIV are reasonably good suggesting that well organised TB control programmes might contain the excess TB caused by HIV (Enarson 1995). TB with HIV however increases the demand and pressures on general health services (WHO 1993b). In countries with a high prevalence of TB, WHO and UNICEF recommend BCG administration to non-symptomatic infants, even when the mother is HIV infected (Narain 1992). Preventive chemotherapy, commonly with isoniazid alone for 6 months or rifampicin and pyrazinamide for 2-3 months, in dually infected persons is considered important to reduce the increase in clinical TB due to HIV (*ibid*).

In India HIV prevalence is low but increasing. Till mid-1994, 15000 HIV positive persons (predominantly HIV-1), and 559 patients with AIDS were reported, probably an underestimate (Pais 1996). Ninety percent of HIV infected persons were 15-45 years, from socio-economically disadvantaged groups, with a male to female ratio of 5:1 (*ibid*). Several case studies report tuberculosis as a common clinical presentation. In Karnataka and other states prevalence was estimated to be 1% among patients with Sexually Transmitted Diseases (TB&HIV 1994). Data regarding TB among persons infected with HIV in India is given in Chapter 1.

Conclusion: Substantial scientific knowledge concerning TB has been gained during the past century. Though knowledge gaps continue and newer related problems have developed, effective interventions exist that are applicable at individual, community and country level. Inspite of adequate scientific knowledge and technology, TB takes a heavy toll worldwide particularly from economically poorer countries and people who comprise the majority of the global population. More cases of TB exist presently than before. Though partly due to demographic reasons, it points to the need to recognise other societal forces that result in persistent transmission, to the importance of implementation of public health oriented TB policies and to support alternate lines of inquiry and action. There need be no conflict between a societal and technological approach. The application of available, sound technical approaches is part of an egalitarian, politically committed, societal approach.

ANNEXE 2

INFORMATION SOURCES: DOCUMENTS AND INTERVIEWS

2.1 Sources for national documents/ reports:

A: a) The National Tuberculosis Institute, Bangalore; b) NTP Evaluation/Assessment Committees; c) The Directorate of Health Services, Ministry of Health, New Delhi; d) The Tuberculosis Research Centre, Madras; e) The Planning Commission, N.Delhi; f) The Tuberculosis Association of India, N.Delhi; g) The Voluntary Health Association of India, N.Delhi; h) Medico Friends Circle; i) All India Drug Action Network j) Professional journals and reports.

B: Review of - a) News reports on NTP/TB in select English language national newspapers in 1996 obtained from the documentation service of the Voluntary Health Association of India and a contracted news-service agency. b) Questions raised in Parliament about NTP/TB/ functioning of general health services with which NTP is integrated, through the Public Policy Division of the Voluntary Health Association of India and review of Lok Sabha Debates.

2.2 List of persons interviewed/met at national and international levels

For historical and current information this included professionals involved with the NTP from its early phases, those presently holding responsibility, those concerned with drug policy and NGO's.

1. Dr. DR Nagpaul, Rtd. Director, NTI currently Scientific and Technical Advisor, TB Association of India, New Delhi;
2. Dr. D Banerji, Rtd. Professor, Centre for Social Medicine, Jawaharlal Nehru University, currently Founder Director of Nucleus for Health Policies and Programmes, New Delhi;
3. Dr. GVJ Baily, Rtd. Director NTI, Bangalore;
4. Dr. SP Tripathy, previously Director TB Research Centre, Madras and Rtd. Director Indian Council for Medical Research;
5. Dr. Radhakrishna, Rtd. Director, Institute for Research in Medical Research, Madras;

6. Dr. Kul Bhushan, Rtd. Scientist, NTI, Bangalore;
7. Mr. SS Nair, Rtd Statistician/Director Evaluation Unit, Directorate General of Health Services, New Delhi, currently Director, Institute of Communication, Operations Research and Community Involvement, Bangalore;
8. Dr. P Chandrashekar, Rtd. Director NTI, Bangalore;
9. Ms. Seetha, Rtd. Sociologist, NTI, Bangalore;
10. Dr. AK Chakravarty, Rtd. Acting Director, NTI, Bangalore;
11. Dr. V Benjamin, Rtd. Professor of Community Medicine, Christian Medical College, Vellore, currently President, Society of Community Health Awareness, Research and Action, Bangalore;
12. Dr. KK Datta, Director, National Institute of Communicable Diseases, GOI, N Delhi, previously DDG(TB), DGHS;
13. Dr. Khatri, DDG(TB), Directorate General of Health Services (DGHS),GOI, N Delhi;
14. Mr. R Srinivasan, Rtd. Secretary Health, Ministry of Health, GOI, New Delhi;
15. Dr Mrs P Ramachandran, Member- Health, Secretariat, Planning Commission;
16. Mr. P Chopra, Joint Secretary Health (TB), Ministry of Health, New Delhi;
17. Dr. J Abraham, Dept. of Economics, Planning Commission, GOI, New Delhi;
18. Dr. B T Uke, Director, NTI, Bangalore;
19. Dr. R Prabhakar, Director, TB Research Centre;
20. Dr. Mrs. P Jagota, Dpty Director, NTI, Bangalore;
21. Dr. LBS Dey, TB Unit, DGHS, New Delhi;
22. Dr. D Das, TB Unit, DGHS, New Delhi;
23. Dr. P Biswal, TB Unit, DGHS, New Delhi;
24. Dr. Jadav, Regional Consultant, TB Unit, DGHS, New Delhi;
25. Dr.Dass-Sharma, Regional Consultant, TB Unit, DGHS, New Delhi;
26. Dr. Selvakumar, Dpty. Director, TB Research Centre, Madras;
27. Dr. Sowmya Swaminathan, Asst. Director, TB Research Centre, Madras;
28. Dr. L Suryanaryana, Chief Medical Officer, NTI, Bangalore;
29. Dr. Chadha, Epidemiologist, NTI, Bangalore;
30. Dr. S Chandrasekaran, Chief Medical Officer, NTI, Bangalore;

31/32. Mr. Vembu and Mr. Sathyanarayana, Monitoring Section, NTI, Bangalore;

33. Ms.R Rajalakshmi, Statistical Section, NTI, Bangalore;

34. Dr. Ralte, District TB Officer, Kohima, Nagaland (at NTI, Bangalore);

35. Dr. N Rama Rao, Director, State TB Centre, Hyderabad

36. Dr. BM Soni, Asst. Director (TB), Ahmedabad, Gujarat;

37. Dr. Parmar, Acting District TB Officer, Mehsana, Gujarat;

38. Dr. S Mishra, Asst. DG, National Malaria Eradication Programme, New Delhi;

39. Dr. M Issac, Professor of Psychiatry, National Institute of Mental Health & Neurosciences, Bangalore;

40. Mr. KM Kaul, Project Officer, Dept. of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, GOI, New Delhi;

41. Mr. MM Sharma, Technical Director, Indian Drugs and Pharmaceuticals Ltd.(IDPL), Corporate Headquarters, Gurgaon;

42. Mr. Rakesh Buddhiraju, Marketing Division, IDPL Corporate Headquarters, Gurgaon;

43. Mr. Jain, Director, IDPL Corporate Headquarters, Gurgaon;

44. Mr. S Chakrabarti, Indian Drugs and Pharmaceuticals Ltd., Bangalore;

45. Dr. I Quadeer, Professor, Centre for Social Medicine, JN University, New Delhi;

46. Dr. M Rao, Assoc. Professor, Centre for Social Medicine, JN University, New Delhi;

47. Dr. R Priya, Asst. Professor, Centre for Social Medicine, JN University, New Delhi;

48. Dr. Rajesh Kumar, Asst. Professor, Dept. of Community Medicine, Post Graduate Institute of Medical Education and Research, Chandigarh;

49. Dr. B Jhunjunwala, Economist, New Delhi;

50. Dr. R Narayan, Coordinator, Community Health Cell, Bangalore;

51. Dr. M Uplekar, Consultant, Foundation for Research in Community Health, Bombay;

52. Mr. A Mukhopadhya, Director, Voluntary Health Association of India, New Delhi;

53. Dr. PN Sehgal, Rtd. Director National Institute of Communicable Diseases, currently Consultant, VHAI, New Delhi;

54. Dr. M Shiva, Head, Public Policy Division, Voluntary Health Association of India, New Delhi and Secretary, All India Drug Action Network;

55. Dr. A Sengupta, Delhi Science Forum, New Delhi;
56. Mr. C Srinivasan, Director, LOCOST, Baroda;
57. Mr. BK Keayla, Convenor, National Working Group on Patent Laws, Centre for Study of GATT Issues, New Delhi;
58. Mr. Narula, Corporate Manager, Lupin Laboratories Ltd., New Delhi;
59. Mr. A Sachdeva, Secretary, TB Association of India, New Delhi;
60. Dr. P Rao, Secretary, Drug Action Forum, Karnataka;
61. Mr. Amitava Guha, Federation of Medical Representatives Associations of India, Patna
62. Dr. Almas Ali, Consultant, Voluntary Health Association of India, New Delhi
63. Dr. Manjunath, VGKK, Yelandur and Mysore

Respondents from International Organizations interviewed for the NTP or RNTP

1. Dr. MVH Gunaratne, WHO Advisor to SEARO, New Delhi on Communicable Diseases, working particularly on TB;
2. Dr. K Shein, Essential Drugs Programme, WHO-SEAROffice, New Delhi;
3. Mr. R Grose, India Desk, Dept. For International Development (UK), New Delhi;
4. Dr. J Porter, Senior Lecturer, Clinical Sciences, London School of Hygiene and Tropical Medicine, coordinator of DFID Aid to the RNTP in India and member of the WHO/World Bank assessment team for the RNTP;
5. Dr. R Fryatt, Health Division, DFID, New Delhi;
6. Ms. A Khalak-Dina, DFID, New Delhi;
7. Mrs. Anna-Kari Bill, Health Division, SIDA Office, Stockholm (was in SIDA Office, New Delhi in the 1980's when SIDA supported the NTP and 2 years in the WHO, TB Unit, Geneva);
8. Dr. Hans Rosling, Dept. for International Child Health, Uppsala University, Sweden;
9. Prof. G Dahlstrom (telephonically), University of Uppsala, Sweden, member of SIDA mission assessing SIDA funding to the NTP;
10. Mr. G Tiroler, Uppasala University, Consultant for SIDA on Disability and Rehabilitation to India;

11. Dr. G Holmgren, ICH, Uppsala University, Sweden;
12. Dr. G Kvale, Centre for International Health, Bergen, Norway and three MPhil. students working on TB;
13. Dr. W Fox (telephonically), Rtd. TB Research Unit, British Medical Research Unit (Founder Director, TB Research Centre, Madras), Surrey;
14. Prof. Patrick Vaughan, Health Policy Unit, London School of Hygiene & Tropical Medicine;
15. Mr. A Veliath, UNICEF office, New Delhi;
16. Dr. Pankaj Mehta, Bangalore, (worked with UNICEF in the USA);
17. Dr. P Kok, Asia Desk, MEMISA, The Netherlands;
18. Dr. R Baastian, Tubingen Institute, Wurtzberg, Germany;

Discussions with:

19. Mr. R Bumgarner, Global TB Unit, WHO, Geneva;
20. Dr. J Almeida, Global TB Unit, WHO, Geneva;
21. Dr. T Frieden, presently with WHO-SEARO, New Delhi;
22. Meeting with Dr. Paul Nunn, Global TB Unit, WHO and Health Policy Unit staff, LSHTM;
23. Mr. Srinivasan, Office of World Health Reporting, WHO, Geneva.

Several other officials/professionals were met during the course of the study.

2.3 State and District Level Interviews

1. Dr. HC Mahadevappa, Hon. Minister for Health, Governement of Karnataka;
2. Dr. Vishveshwaraiah, Joint Director (TB), DH&FW, Bangalore;
3. Dr. Nagraj, Rtd. Joint Director (TB), DH&FW, Bangalore;
4. Dr. Ranganath, Project Manager, RNTP Pilot Phase Project, Bangalore Municipal Corporation;
5. Dr. S Shekar, RNTP Pilot Phase Project, Bangalore Municipal Corporation;

6. Dr. Saraswathi Devi, MO Adugodi Bangalore Municipal Corporation Dispensary;
7. Dr. GN Srinivas, MO Neelasandra Bangalore Municipal Corporation Dispensary;
8. Other Staff at three Bangalore Municipal Corporation Dispensaries
9. Dr. SV Rama Rao, Rtd. Dean Government Bellary Medical College;
10. Mr. Sundareshwar, Hon.Sec., Karnataka State TB Association, Bangalore;
11. Dr. Kishore Murthy, Consultant, GOK- WB State Health Systems Development Project;
12. Senior Health Assistant, Lady Wellingdon State TB Centre, Bangalore;
13. Dr. Chandrashekar, Professor, Indian Institute of Management, Bangalore, previously Member of the State Legislative Council;
14. Mr. Jayaram, Registrar,Office of District Commissioner, Mysore;
15. Dr. Ambrose Pinto, Political Scientist, Principal, St. Joseph's Evening College, Bangalore;
16. Dr. G. Pais, Director OXFAM, Bangalore Office;
17. Dr. Paresh Kumar, Sociologist, Mysore University;
18. Dr. Gnaneshwar, District Tuberculosis Officer, Mysore, three repeat interviews;
19. Sri. Chikkaiah, Treatment Organiser, DTC, Mysore;
20. Observation of supervisory visit of Dr. Sathyanarayana to DTC;
21. Dr. H.P.Ramesh, Med. Suptd. PK TB & Chest Disease Hospital, Mysore;
22. Sri. Ramesh, X-ray Technician, DTC, Mysore;
23. Dr. Chinnaswamy, District Health & Family Welfare Officer, Mysore District;
24. Mr. A Sait, Deputy Commissioner, MysoreDistrict;
25. Junior Lab. Technician, District Tuberculosis Centre, Mysore;
26. Dr. H Sudarshan, Sec., Vivekananda Girijana Kalyana Kendra, BR Hills, Mysore District;
27/28. Dr. Sridhar and Dr. ShivKumar, Medical Officers, VGKK and Karuna Trust, Yelandur, Mysore District;
29. Dr. Jyothi, Medical Officer, VGKK, BR Hills, Mysore District;
30. Dr. S Ullal, VGKK, BR Hills;
31. Sri. Krishnan, VGKK, BR Hills, Mysore District;

32. Sri. Rajanna, Community Organiser, Karuna Trust, Yelandur, Mysore District; Health Workers, Karuna Trust, Vasu, Mahalakshmi, Nanjundaswamy; Laboratory Technician, Mallu; other workers, Bhagyalakshmi; Kumar; Kurien;
33. Dr. Sr. Acquinas, Medical Officer, Holy Cross Hospital, Kamagere, Mysore District;
34/35. Dr. Vivek & Dr. Prasad, MO's, Shankar Hospital, Kenchanahalli, Mysore District;
36. Mr. William D'Souza, Director, MYRADA-PLAN, Handpost, HDKote *Taluk;*
37. Mr. Vijay Kumar, Project Officer and other staff, MYRADA-PLAN, HD Kote *Taluk*
38. Dr. HS Shiva Kumar, HDKote General Hospital, HDKote;
39. Sri. BS Somanna, Laboratory Technician, HD Kote General Hospital;
40. Sri. V Thimma Shetty, Pharmacist, HD Kote General Hospital;
41. Sri. GT Devegowda, President, Mysore *Zilla Panchayat*
42. Smt. Rathnamma, Vice- President, Mysore *Zilla Panchayat*
43. Meetings with *Mahila Mandals* (Womens Groups) at villages Muruganahally, Ambedkar Nagar, Gulligatte, Mentihadi at HD Kote *Taluk*, Mysore District;
44. Meeting with Dr. Sukant Singh, and medical/health teams from CMAI, Holdsworth Memorial Mission Hospital, Mysore, and Tibetan Settlements, Mysore District;
45. Staff from the Organisation for the Development of People, Mysore;
46/47. Sr. Mariola and Sr. Philomena, *Shanti Grama Abhivriddhi Kendra*, HDKote *Taluk*
48. Sr Concepta, nurse, M&RF Hospital, Naganahalli, HD Kote *Taluk*;
49. Fr. Kiran Kamaliprasad, working with bonded labourers, Centre for Non-Formal and Continuing Education, Bangalore;
50. Fr. J D'souza, Centre for Non-Formal and Continuing Education, Bangalore;
51. Sri. Nanjundaiah, Development Worker, Fedina-Vikasa, HD Kote *Taluk*;
Staff from Holdsworth Memorial Mission Hospital, Mysore: Ms. S Balraj, Nursing Superintendant;
52. Sri. Devendra Heggade, *Dalit Sangharsh Samiti*, Bangalore;
53. Dr. Prabhakar, MO, Primary Health Unit, Beechanahally, HD Kote *Taluk*;
54. Dr. Lalitha P, LMO, Primary Health Centre Sargur, HD Kote *Taluk*;
55. Dr. SM Mahadevaiah, MO, Primary Health Centre, Sargur, HD Kote *Taluk*;
56. Dr. Basavaiah, MO, Primary Health Centre, N.Belathur, HD Kote *Taluk;*

57. Dr. B Mahesh, MO, Primary Health Centre, Hampapura, HD Kote *Taluk*;

58. Dr. Somashekar, MO, Primary Health Centre, Annur, HD Kote *Taluk*;

59. Dr. Ranga Nayaka, MO, Primary Health Centre, Madapura, HD Kote *Taluk*;

60. Sri. Venkatnarayanappa, Senior Health Assistant and other staff, Primary Health Centre, Sargur, HD Kote *Taluk;*

61. Smt. TA Nanjamma, Junior Health Assistant, N Belathur PHC, HD Kote *Taluk;*

62. Smt. AC Minnu, Junior Health Assistant, Hampapura PHC, HD Kote *Taluk;*

63. Sri. Zahir Yusuf, Laboratory Technician, Hampapura PHC, HD Kote *Taluk;*

64. Sri. PL Swamy, Junior Health Assistant, Hampapura PHC, HD Kote *Taluk;*

65. Smt. Komala, Group D Employee, Hampapura PHC, HD Kote *Taluk*;

66. Smt. S Jnanamitra, Senior Health Assistant, Annur PHC, HD Kote *Taluk;*

67. Smt. Renuka, Junior Health Assistant, Annur PHC, HD Kote *Taluk*;

68. Smt. Rathnamala, Junior Health Assistant, N.Begur PHC, HD Kote *Taluk;*

69. Smt. Devamma, Junior Health Assistant, N.Begur PHC, HD Kote *Taluk;*

70. Smt. Sudhamani, Junior Health Assistant, Madapura PHC, HD Kote *Taluk;*

71. Sri. Narasimha Murthy, Junior Health Assistant, Madapura PHC,

72. Smt. PA Shanti, Junior Health Assistant, HD Kote General Hospital,

73. Sri. KN Nagaraju, Community Health Volunteer, Kolagala, HD Kote *Taluk*;

74. Dr. Cariappa, private practitioner, Handpost, HD Kote *Taluk;*

75. Dr. Joshi, Private Practitioner, Hommarahalli, HD Kote *Taluk*;

76. Dr. Usha, Private Practitioner, Hommarahalli, HD Kote *Taluk*;

77. Dr. Mallappa, Private Practitioner, Hommarahalli, HD Kote *Taluk;*

Elected Representatives from HD Kote Taluk 78-88

78 Sri. Kullananjaiah, *Gram Panchayat* President, Kandahally

79. Smt. Ningamma, *Gram Panchayat* Vice- President, Hampapura

Ten *Gram Panchayat* members 80. Sri. Shivabasavagowda, Hampapura; 81. Smt. Nanjamanni, Kolagala; 82. D. Siddarajaiah, Chikkanayakanahally; 83. Maridas, Kalegowdanahally; 84. Mahadev, Thumbusoge Post; 85. Aslam Pasha, N Begur; 86. P Shanataraju, Saloor Hundi; 87. Puttachennamma, Mellahally; 88. Govindraj, HDKote; Bhaskar, HDKote;

89. Sri. Nagaraju, Bill Collector, Bidrahally; 90. Sri. Siddaraju, store keeper, Kenchanahally;

91. Dr. K Satish, MO, Gowdahalli Primary Health Centre, Yelandur *Taluk;*

92. Dr. M Nanjundaswamy, MO, Yelandur PHC, Yelandur *Taluk;*

93. Dr. Kantamani, LMO, Yelandur PHC, Yelandur *Taluk;*

94. Sri. GS Narayan Prasad, Senior Health Assistant, Yelandur PHC, Yelandur *Taluk;*

95. Sri. Lingaiah, Senior Health Assistant, Yelandur PHC, Yelandur *Taluk;*

96. Sri. Shivamallappa, Junior Health Assistant, Yelandur PHC, Yelandur *Taluk;*

97. Smt. S Vijayakumari, Junior Health Assistant, Yelandur PHC, Yelandur *Taluk;*

98. Smt. Rudramma, Junior Health Assistant, Yelandur PHC, Yelandur *Taluk;*

99. Smt. HS Kamalamma, Junior Health Assistant, Santhe Marhally PHC, CHNagar *Taluk;*

100. Sri. Channaju S, Junior Health Assistant, Gowdahally PHC, Yelandur *Taluk;*

101. Sri. Puttaswamy, Group D Employee, Gowdahally PHC, Yelandur *Taluk;*

102. Sri. Nanjundaiah, Junior Health Assistant, Honnur PHC, Yelandur *Taluk;*

103. Sri. Shivamalappa, Junior Health Assistant, Honnur PHC, Yelandur *Taluk;*

104. Sri. Puttamadu, Junior Health Assistant, AgaraMamballi PHC, Yelandur *Taluk;*

105. Sri. Basavanna, Community Health Guide, Kamagere, Mysore District;

Elected Representatives from Yelandur Taluk 106-113

106. Smt. Shakuntala, *Gram Panchayat* President, Mambally;

107. Sri. Srinivas, *Gram Panchayat* President, Yeriyur;

Gram Panchayat members: 108. K Mahadev, Yergambally; 109. Basavarajappa, Melhally;

110. Madamma, Kunagally; AP, Chinchahally;

111. Sri. PC Mahalingashetty, *Gram Panchayat* President, Chamarajanagar;

112. Sri. Neelaiah, PUC, Yeriyur; Sri. Manjunath, Lecturer, Malavalli;

113. Dr. Ramesh, Private Practitioner, Yelandur;

114. Dr. Shivaswamy, Private Practitioner, Yelandur;

115. Dr. Santosh, Private Practitioner, Yelandur;

116. Dr. Nagraj, Private Practitioner, Honnur;

117. Dr. Lakshman, Private Practitioner, Soorapura;

118. Dr. Mariyappa, Private Practitioner, Melhally;

119-125. Six staff from the Mysore *Zilla Parishad* Office

TB Patients from Mysore District- 75 (under the NTP)

TB Patients from Bangalore- 15 (under the Revised NTP)

2.4 Meetings Attended

1. 1994- National Consultation on the NTP/RNTP organised by VHAI in New Delhi.
2. September 1995- GOI/WHO/WB Meeting on Role of Private Practitioners and the Voluntary Sector in TB Control in New Delhi.
3. October 1995- National Meeting on the Role of the Voluntary Sector in the NTP organised by Action Aid and NTI, Bangalore.
4. December 1995- 50th National Conference on TB and Chest Diseases organised by the TB Association of India, Thiruvananthapuram, Kerala.
5. January 1996- Meeting organised by the Karnataka State TB Association for the Release of TB Seals, Bangalore.
6. February 1996- National Meeting on Primary Health Care organised by the Christian Medical Association of India, New Delhi.
7. March 1996- Public Meeting on TB and its Control organised by the Karnataka State TB Association, Bangalore.
8. May 1996- Meeting of TB experts on the RNTP organised by the Community Health Cell and Voluntary Health Association of India, Bangalore.
9. August 1996- Meeting on the Impact of the Structural Adjustment Programme on Health, Ahmedabad.
10. November 1996- 51st National Conference on TB and Chest Diseases, Bangalore.
11. Sept.-October 1997- Meeting on the Monitoring of Equity in Health, WHO, Geneva.
12. November 1997- Meeting on Globalisation and Sustainability of Health Systems, WHO at Helsinki.
13. December 1997- Meeting on Inequalities in Health, WHO in London.

ANNEXE 3

CHECKLISTS OF QUESTIONS

A cohort analysis conducted by the NTI in Mysore district had documented the implementation gap (NTI 1994b). Records from the District TB Centre concerning number of sputum positive and suspected cases detected and put on treatment revealed gaps between expectations and actual outcomes.

Semi-structured interviews were conducted at State and District level to a) understand processes/ mechanisms at State and District level for planning, communication, budgeting, training/ continuing education/ supervision, monitoring of the NTP in the public sector and of relationships if any with the private sector, and b) explore perceptions regarding the implementation gap and explanations for it.

Checklist of Questions for District Officials

Is TB a problem in the district? How would it rank in comparison to other health problems? Where do patients, particularly the poor, usually go for treatment? What is the role of the private for profit sector and the voluntary sector? What are your perceptions regarding the functioning of the NTP? What are its main components? What are its achievements? Based on your experience why have expectations not been met? What are the major areas of problem?

Staff

◊ Availability of part or full component of DTC team trained at NTI during past 5 years.

◊ Pattern of vacancies; transfers; private practice.

◊ Budget head for staff salaries (general pool/ specific programme), adequacy, delays.

◊ Number of PHI's in the district trained by the DTC team.

◊ Frequency of supervisory visits.

◊ Methods of communication from PHI to district level.

◊ Workload, job satisfaction related to NTP work.

Drugs

◊ Drug regimens in use - SR /SCC/ DOT.

◊ Drug supply: adequacy, regularity, delay, supply close to expiry dates.

◊ Reasons for problems- procedural, logistic, financial.

◊ Method of indenting, basis of estimation of need, source of supply.

◊ Availability/ price in the open market.

Equipment

Microscopes, stains, stationery - availability and condition.

Transport

Availability of vehicles and fuel for supervisory visits.

Patient Related Factors

◊ Perception of adherence, reasons for non-adherance.

Health Education

Health Education materials available, source, utilisation.

BCG Coverage

For the past 3 years.

Other

Role of Multi Purpose Health Workers and Community Health Guides in case detection and follow up.

◊ Impact of *Panchayati Raj* since 1988 on the health services, Role played by *Panchayati Raj* members.

Information Collected From PHI Records

1. Population, area and number of villages covered.
2. Type of PHI - referral/ microscopy/ X-ray centre.
3. Number of subcentres attached.
4. Recommended staffing pattern and actual staff in position.
5. Job responsibilities of male and female MO's, Health Supervisors, MPW's, and CHG's.
6. Staff turnover/ transfers/ absenteeism.
7. Data regarding TB patients as mentioned in 9.3.2

8. Nearest referral centre for TB.

9. Transport available in the centre.

Checklist of Questions for PHI MO's

◊ Period of service as a PHC/ PHI MO and at this PHI, number of transfers.

◊ Is TB a problem in the area.

◊ What activities are undertaken under the NTP (regarding case finding, treatment, follow up, referral).

◊ Explore issue regarding integration of health services

- what are the priority areas of work at the PHC, could these be ranked in importance.
- budget heads under which payment of staff is done.
- to whom do they report.
- difficulties and advantages experienced in NTP being integrated with general health services.
- impact of Family Planning/ Welfare programme and UIP.

◊ Explore activities concerning case detection

- what is done if tuberculosis is suspected.
- do TB patients come direct to the PHC's, are patterns shifting.
- who does the sputum smear, availability of microscopist with training in examining sputum specimens, availability/ condition of microscopes and stains, workload in terms of number of specimens to be examined per day/ for the past month/ year.
- What are their perceptions of the strengths and weaknesses of the MPW's work in NTP in sputum examination and possibly in follow up. Are only male MPW's involved or also female. What have been the consequences of involvement of MPW's for case detection and collection of

smears during home visits.

- in what way does the DTC support them.
- any formalised quality checks on microscopy.
- are repeat sputum tests done at 3/4 and 6/8 month, is it feasible.
- when is the report given, how is it communicated to the patient.

◊ Regarding Treatment

- availability of all necessary drugs regularly throughout the year. Are there regular periods when shortages occur eg at year end. Are any particular drugs more prone to shortages.
- what is the basis and method of indenting for TB drugs, is it done annually, from where are supplies made.
- if drugs are not available what is done, which is the nearest pharmacy.
- what is the cost of treatment by a private practitioner for consultation and for drugs.
- what is their explanation for drug shortages.

◊ What percentage of patients get cured.

- What are the reasons that patients do not continue treatment.

◊ Functioning of BCG vaccination work through the UIP programme.

◊ Knowledge regarding the budgeting of NTP

◊ Importance given to NTP by the State DHS.

◊ Role and scope for decision making and action by the STO, DTO.

◊ Perceptions of strengths and weaknesses of NTP. Do they perceive an implementation gap? What are the explanations based on their experience.

◊ Satisfaction with NTP related work.

◊ Problems faced in relation to NTP.

eg.a) organisational - staff position, regularity of salaries, transport availability, drug supplies, availability of diagnostic methods.

b) other factors - pressure to perform/ workload resulting from other programmes such as FP, UIP, malaria; excessive paperwork; transfers; political interference; lack of support from DTC/ STC/STO/State DHS regarding TB;

c) patient related factors - default, under-utilisation of services; explore explanations for the same.

◊ Do TB patients in the area prefer to use public or private sector services; their perceptions of reasons for the choice.

◊ Working conditions- salaries, housing, transfers, facilities for children's education.

Questions for Senior and Junior Health Assistants and other staff

a) What activities do you undertake in regard to tuberculosis control in your area?

b) What problems are faced in this work?

Observation of monthly meetings at the Primary Health Centre and District Health and Family Office regarding importance given to TB.

Questions for Patients with TB (Translated into Kannada)

◊ What were the initial symptoms you had? When did these start?

◊ What did you do to alleviate these symptoms: did you use home remedies; go to traditional healers; private practitioners of the modern system; the local pharmacist; the sub-centre MPW; the PHC; the Community Health Centre; the taluk hospital; the DTC; the medical college hospital; a private nursing home; any other?

◊ Did MPW's from the sub-centre visit you, what advice did they offer, did they take some phlegm for testing?

◊ What was the time period between onset of symptoms and first visit to a health care provider?

◊ Did you shift/ move from one health care provider to another? If so between whom, after what period and why?

◊ Was your sputum tested?. Did you have a chest Xray?

◊ What medicines did you take and for how long?

◊ What did the doctor tell you about the disease? What advice was given to you?

◊ At what intervals did you visit the health centre for collection of medicines?

◊ How frequently did you see the doctor?

◊ Did you have any problem related to the medicines?

◊ Were you satisfied with your experience of the public health system?

◊ If yes, did you complete treatment with the public sector?

◊ What were the costs involved?

◊ If not satisfied, what were the problems: distance, poor transport facilities, non-availability of staff during visit, attitude of doctor, attitude of other health staff, need to

meet different staff at each visit, irregular or non availability of drugs, payment for service, long waiting time.

◊ Did you go to private doctors? Were you satisfied? What were the total costs of treatment ie for consultation, investigations, drugs, transport, loss of wages.

Questions for Elected Representatives (Translated into Kannada)

◊ What is your opinion regarding services provided by the PHI?

◊ If found satisfactory, what are the reasons?

◊ If not satisfactory, what are the main problems ?

◊ Do you know anyone with prolonged cough, fever, and loss of weight/ tuberculosis?

◊ Do you have any specific comments regarding tuberculosis treatment at the PHI?

◊ What is your opinion regarding the services of private practitioners? Are such services available? Are people satisfied with their services? If yes, why and if not what are the main problems?

◊ Where do poor people from your area who have tuberculosis go for treatment?

◊ Did the introduction of Panchayati Raj in 1988 have any impact on the functioning of the general health services?

◊ What are the responsibilities of elected representatives towards health services? In what way could elected representatives help to improve the services?