Chapter -2

2.1 BACKGROUND

2.1.1 Health impact

Tuberculosis is an infectious disease caused by *bacillus-Mycobacterium tuberculosis*. It spread through the air, when untreated tuberculosis (TB) patient cough. A single person with active tuberculosis can infect 10-15 others each year, if left untreated. (WHO 2000)

Globally in 1997, New cases of TB ware estimated 7.96 millions (range 6.3- 11.1 millions), including 3.52 millions (range 2.8-4.9 millions) cases (44%) of infectious pulmonary disease. There were 16.2 millions existing TB cases globally. (Dye at el 1999)

An estimated 1.87 millions people died of TB and the global case fatality rate was 23% but exceeded 50% in countries with high Human Immunodeficiency Virus (HIV) rates.

Tuberculosis has existed in India since the earliest days. In 1500 BC, The *"Rig-Veda"* described the illness as *"Raja-yaksa"* a King disease. Today, India accounts for nearly 30% all tuberculosis cases in world, a figure that is likely to increase as India's population grows and the HIV epidemic progresses. (WHO 1997)

In June 2000, a consultation was held at the National TB Institute Bangalore (NTI), on analysis of available epidemiological data to arrive at an estimate of current TB burden in the country. They conclude that the prevalence of bacteriologically positive cases is 4.48 per thousand and radiological positive but bacillary negative are 12.35 per thousand. Based on above rate, an estimate of existing burden of TB in India adds up to about 15.32millions (Lalitkant2000).

This is highest in the world. The prevalence rate of bacteriological positive pulmonary TB in previously reported studies according to various criteria is shown in table 2.1.

TABLE 2.1

Prevalence rate of bacteriological positive pulmonary TB in previously reported studies according to various criteria

Study (Ref.)	Rural/ Urban	Period of study	Age (Years)	Screening method used	Prevalence rate (*) Per 1000
New Delhi (Pamra73)	Urban	1962	5+	X-ray	4.0
(Goyal 73)	Urban	1973	5+	X-ray	3.2
Tumkur	Rural	1961	10+	X-ray	4.1
(Gothi 1979)		1973	10+	X-ray	4.4
Bangalore (Gothi 1976)	Rural	1975	5+	Symptom+Xrays	3.2
				Symptom	2.1
Chingalput (TRC 1980)	Rural	1968-71	10+	X-rays	10.8
Madanapalle (Moller 1981)	Semi-urban	1961	15+	X-rays	9.3
		1968	15+	X-rays	9.8
Bangalore (Chakraborty 1982)	Rural	1961	5+	X-rays	4.0
		1977	5+	X-rays	4.9
Wardha (Narang 1992)	Rural	1982-88	5+	Symptom	1.8
Bangalore (Chakraborty 1997)	Rural	1984-86	10+	Tuberculin Test	4.4
Raichur (Gopi 1997)	Rural	1988-89	15+	Symptom	10.9
North acort (Datta 2000)	Rural	1989-90	15+	Symptom	4.3
			15+	Symptom+Xrays	7.9

(*)-Smear and or culture

According to the 1999 world health report, the burden of Tuberculosis in India is 36 times more then Leprosy, 12 times more then Malaria, 2.5 times more then Tropical diseases, and 3.5 times more then acquired immunodeficiency syndrome (AIDS) /HIV (WHO 1999).

TB is a leading cause of death in India. As per an estimate there are approximately 4.5 lakh people die of TB (WHO 2000).

The prevalence of the disease is 3 times more then the incidence, indicating a failure of current treatment programme and a pooling up of previous cases. This calls for a prompt & efficient treatment programme, otherwise these patients will infect succeeding generation and the cycle of infection, disease, and death of TB will continue.

2.1.2 Economic Impact

TB is one of India biggest public health problem- a problem that India can't ill afford. Tuberculosis and its spread remind us that the air connects us all, we breathe.

Although some times considered a disease of slums and ghettos, affecting only the socially disadvantaged, Tuberculosis can in fact affect any one from remote village to bursting urban centres. Those infected are disproportionately young adults in the most productive years of lives; often the primary wages earners of their families (ICMR 1999). The direct and indirect economic cost of tuberculosis cost India at least Rs.13000 crore each year (Dholakia 1996).

A study conducted at Tuberculosis Research Centre Chennai (TRC) found that an average patient suffering of tuberculosis incurs a total loss of Rs. 3469 while shopping for diagnosis and treatment (Rajeshweri at el 1999). In another study Pathania 1997 found that an average rural TB patient spent Rs.1000 per month on TB diagnosis and treatment, while urban patient spent Rs.500 per month. The WHO estimates that TB patients in India together spent more then Rs.645 crore on private TB care in 1997.

Indian worker with tuberculosis lost an average of 83 workdays because of the disease, 48 of which lost while shopping for diagnosis. Considering the 2 million new cases are reported annually in India, the national loss per year workout to be 166 million lost workdays, at a cost of about Rs.694 crore. In addition the debts incurred by patients because of tuberculosis amounted to Rs.416 crore (Dholakia 1999).

TB kills more women of reproductive age then all causes of maternal mortality combined (WHO 1999) and may create more orphans then any other infectious disease. Indian women, who suffer from TB face special constrains. They tend to be neglecting their illness due to household responsibilities until they become sick to attend the normal duties. They are often dependent on others to get necessary medical attention. The triple burden of housework, childcare, and employment leaves very little time for women to get proper treatment for tuberculosis

2.1.3 Age and Tuberculosis

There is large difference in tuberculosis incidence by age. Theoretically, these discrepancies may be attributed to difference in risk or prevalence of infection, difference in disease risk once infected, or both. The trend of commonly observed higher incidence of disease with increasing age could be partly explained by the cumulative increasing prevalence of tuberculosis infection. Adolescents and young adults appear to especially prone to progression from latent infection to disease (Comstock et al 1974), while the children around the age 10 years appear to be least prone. The variation with stage of maturity is not likely an explanation of steady increases in incidence rates among adults up to the age

years. However, there are indications that the risk of tuberculosis following infection increases beyond the age 60 years. The prevalence of active disease observed in various surveys (Tumkur, Madanapalle, New Delhi, ICMR) shows that rising prevalence by age. (Rao 1981)

The new smear positive patients registered during the period of 1993-1999 in Revised National Tuberculosis Control Programme (RNTCP) in India shows the ratio of male to female increases markedly with age (Khatri 1999)

2.1.4 Sex and TB

There appears to be a difference between male and female in tuberculosis incidence rate following infection. Among tuberculin positive participants in the BCG vaccination trial in *Puerto Rico*, incidence was 18% higher among female then among male (Comstock at el 1974). In the Danish National survey (Groth at el 1959) the risk of tuberculosis among infected female was also greater then among male beyond 44 years of age (Rieder 1999).

In virtually all countries notification rate among male are more then among female (Holmes 1998). Disease notification is the result of multiple steps in a process, which incorporates the following components:

- Prevalence of infection
- Risk of disease given that infection has occurred
- Access of the patient to diagnosis
- Notification discipline in the health care system

The tuberculosis is less prevalent among women then man in all age group in Madanapalle (Moller 1981) and Tumkur (Gothi 1979), where as in Delhi (Pamra 1973) the disease does not draw any distinction between men and women up to 35 years but there after raises steeply amongst men. The

difference is probably because Delhi survey covers an urban population, while the other two were carried out in the rural area. Bangalore study has reported the rate of bacteriological confirmed disease and this rate was 5.8/1000 male and 2.1/1000 female with an over all rate 4.06/1000 in 1961 (Chakraborty 1982).

The observation of difference is further complicated by gender issue i.e. unequal access to diagnostic services for male and female with tuberculosis, which makes it difficult to disentangle the underlying epidemiological difference. In another study, a negative reaction to diagnosis of tuberculosis such as fear, shock, and despair were expressed by 88% of the female respondents (Thomas et al 2000). The triple burden of household works, childcare, and employment leaves very little time for woman to get proper treatment for tuberculosis, apart from the fear and stigma for the illness.

It is easier to determine the epidemiological component in countries where males and female have presumably equal accessibility to health care. Thus, the 2:1 male: female ratio in tuberculosis incidence rates observed in many industrialized countries, such as United States (CDC 1997), appears best explained by the generally higher prevalence of infection observes among male then among female. The male to female rate ratio may also differ over time as the age structure of tuberculosis changes, and may differ within sub-population in the same country (Groth at el 1959).

2.1.5 Socio economic status:

Poverty has been strongly associated with the incidence of tuberculosis (Enarson at el 1989). The low socio-economic indicators tend to result in crowded living condition. The condition that is conducive to increase transmission of

tubercle bacilli, resulting in a higher prevalence of tuberculosis infection with subsequent increase incidence of disease.

Poverty may also reduce access to health care services (Berger 1968). Thus prolonging the period of infectiousness of tuberculosis patient, and further increasing the risk of infection among the contacts of such patient.

2.1.6 Substance abuse

Smoking- Lowe (1956) and Edwards (1957) studied in England and examined the relationship between cigarette smoking and the risk of tuberculosis. From these case control studies, there was evidence that the odds of tuberculosis increased with an increasing number of cigarette smoked. In a study at Shanghai, Tuberculosis incidence was shown to higher among smoker then among non-smoker (YuG at el 1988). The effect remained after adjustment for age, sex, type of work, and history of contact and area of housing.

Alcohol Abuse- Despite the long-standing notion of association, between alcohol consumption and tuberculosis incidence, epiodemiologic evidence of a causal association is not convincing. The proportion of patients with alcoholism in Canada was strongly associated with incidence of TB, but was most likely confounded by socioeconomic group, the larger the proportion of alcoholic, both inversely associated with incidence of tuberculosis. Screening of substance abuse (alcohol and other drugs) has repeatedly shown the excess risk of tuberculosis in these population compared with the general population (Friedman et al 1907).

2.1.7 HIV/ AIDS and TB

The Human Immunodeficiency Virus (HIV) had spread across India since the cases of HIV infection were diagnosed in Bombay and Madras in 1986. WHO estimated that by 1999, at least 3 million, and possible as many as 5 million people in India are infected with HIV, which is the highest number in a single country (WHO 1999). HIV breaks down the immune system. It makes patient highly susceptible to TB and thus have a major impact on the TB epidemic in India.

Infection with HIV is the most potent known risk factor for progression to active tuberculosis among adults (Selwynpa et al 1989). Conversely, tuberculosis hastens the development of AIDS in HIV infected person (Leroy et al 1997, Whalen et al 1995). Individual who were not HIV infected and also who became infected with *Mycobacterium tuberculosis* had approximately a 10% lifetime risk of developing active tuberculosis, compared with a risk of 60% or more in person infected with both HIV and *Mycobacterium tuberculosis* (Telzak 1997). The risk of tuberculosis infection progressing to active positive person, as opposed to a lifetime risk of 10% in an immune potent person. This is particularly important in India where it is estimated that more than half of the adult population harbors *Mycobacterium tuberculosis* infection (WHO 2000).

The incidence of HIV sero positive among patients admitted to the TB wards of a large hospital in Bombay increased from 2% in 1988 to 16% in 1998 (Mohanty et al 1998). In another study shows that out of 243 HIV sero positive patients, 60.2% were diagnosed to be suffering from TB, where as out of 350 TB patients 4% reviled HIV infection (Jaswal 1998).

2.1.8 Tuberculosis and other associated diseases:

Diabetes- *Diabetes Mellitus* exerts the most adverse influence on the course of pulmonary tuberculosis (Rao 1981). The notion that diabetes mellitus and TB were associated was so old and prevalent that it had long been taken for granted as more than a coincidence. Symptom of one condition often mask those of the other because of the common symptoms such as lassitude, loss of appetite, loss of weight, etc. There were, however few large surveys that permit a quantitative assessment of the incidence of TB among diabetes in comparison with appropriate controls. In a large survey of Philadelphia in the mid 1940's, the incidence of TB was 8.4% in diabetes patients, compared with 4.3% in non-diabetic patients among industrial employee (Boucot et al 1952).

Silicosis- The Tuberculosis is common among miners, and patients with silicosis have long been recognized (Snider 1978). Paul has estimated that the incidence of tuberculosis among miner with silicosis was 26 times higher than among miner without silicosis (Pual 1961). In long-term follow-up study gold miners in South Africa the relative risk for tuberculosis was 2.8 for men with silicosis compared with that in men without silicosis (Cowice 1994). In the study carried out by Saiyad (1987) found that 30% of agate industries worker were having radiological abnormality consistent with tuberculosis in Khambhat (Anand).

Renal disease-Patients with end stage renal failure and those on heamo-dialylsis were at increased risk of tuberculosis (Andrew et al 1980). The incidence among such patients was estimated to be 10-15 times greater than that of general population (Rieder 1999).

2.2 Tuberculosis Death

Death from tuberculosis was the longest recorded indicator for tuberculosis epidemic in industrialized countries. In contrast information of death was rarely or never systematically collected in low-income countries. The risk of dying from tuberculosis is dependent on the site and type of the disease and the timeliness of diagnosis (Rieder HL1999).

Three major factors determine the characteristics of mortality. These include:

(1) Age specific difference in mortality.

(2) Difference in mortality in each cohort.

(3) Difference at particular period or events, such as during war.

The case fatality was so closely linked to the availability of timely and curative chemotherapy of clinically manifest, particularly among sputum smear positive TB patient. The magnitude of tuberculosis mortality in the future will not so much depend on the epidemiology of tuberculosis as on the availability of effective treatment. In India, TB mortality was estimated by National TB Institute Bangalore (NTI) to be 69 to 95 per lakh in 1961-68 and 41 per lakh in 1977-81. Data from the survey of census of deaths yield a more recent parameter by which to estimate current mortality, resulting in 4 lakh death in India. Among the 4 lakhs death 62.5% of death were in the age group of 25-44 years.

Using the number of cases of tuberculosis notified by NTI Bangalore, the reported treatment completion rate 30%, a case fatality rate of 10% among those who had completed treatment, 48% among smear positive patients who did not completed treatment, and 24% among smear negative patients. It was estimated that about 3.46 lakh TB patients reported to

NTI were died in India in each year. Almost all of these deaths were preventable. Increasing the treatment completion rate to 85% would be prevented to 2 lakhs death annually approximately i.e. 57% decrease in mortality (GOI 1992).

The reduction in TB mortality expected on the basis of treatment completion rate of TB was calculated by GOI (Table 2.3). This calculation was based on the cases officially reported in 1991. Following table shows the estimated probable tuberculosis mortality in India.

Table No.2.2
Estimated tuberculosis mortality in India

Source (Year)	Estimated mortality Per lakh	Annual death (Lakh)
NTI (1977-81)	41.0	3.46
Cause of death survey (1992)	50.0	4.22
Sample survey incidence estimation (1955-58)	77.8	6.57
Styblo model of incidence with 1.5% ARI (1992)	50.1	4.32

Source: GOI (1992)

Table No.2.3
No. of TB death, which could be expected among cases reported in 1991 at deferent rate of treatment completion and potential reduction in mortality in India

Treatment completion rate	Expected death		Reduction in mortality	
	Smear positive	Total cases	Lives saved	% Reduction
30%(current)	1,21,000	3,46,000	Base line	-
40%	1,09,000	3,05,000	36,000	10%
70%	71,000	2,02,000	1,43,000	41%
85%	52,000	1,48,000	1,97,000	57%

Source: GOI 1992

2.3 Tuberculosis diagnosis and treatment:

The national tuberculosis sample survey (ICMR 1957) reviewed the urgent need of a nation wide TB control programme in our country. The new information was that, a bulk of tuberculosis patients in the country stayed in rural area and tuberculosis was widely scattered made it imperative that the programme in the country should be one that reaches every nook and corner. Therefore in the year 1959, Govt. of India established the NTI Bangalore to develop a comprehensive, realistic and economically feasible TB control programme for the entire country. By 1962, the NTI could evolve a programme for the country based on scientific data obtained from the studies undertaken at NTI, Tuberculosis Research Centre (TRC) Madras and other valuable studies and the experience gained from within the country and all over the world (Shivram 1981).

National Tuberculosis Programme (NTP) as defined by GOI (1962) is **"An organized effort to bring the problem of tuberculosis under control in the country. It comprise of well-known anti-tuberculosis measures, knit into a comprehensive programme, which is acceptable, practical, and economically feasible".**

Some of the consideration contributing to the formulation of NTP was as follows:

A: **Epidemiological consideration:**

(1) The tuberculosis control programme should receive **appropriate priority**, as tuberculosis is a major killer, apart from causing considerable morbidity.

(2) The programme should have **a long time frame,** as tuberculosis is a long-term disease with a large

proportion of the population infected. The risk of infection is among the highest in world.

(3) The programme should be **uniform** as the prevalence rate of cases and the distribution are more or less similar throughout the country.

(4) The programme should be **integrated** to achieve wide coverage keeping in view the geographical distribution of the problem.

(B) Socio-economic considerations:

The problem of tuberculosis in the community in essence is the problem of human suffering. TB patients suffer physically, followed occasionally by disability or death. The patients, their family and the community as a result undergo considerable psychological and socio-economic setback. The TB being a chronic infectious disease, the cycle of suffering get perpetuated. Moreover, nearly 40% of the total TB patients in the community were found in age group 20-40 year (NTI 1994). This is economically the most productive group. The continuous and sizable amount of suffering cause in the above age group constitute the main reason why TB should be accorded due priority.

The studies conducted at NTI have revealed that bacteriologically confirmed TB patients (95%) are aware of their symptoms and as many as 52% of the patients contact government health institution for the relief of their suffering (Banerji 1963). So the facilities for diagnosis and treatment of TB should better be provided at these institutions.

The distance, which the TB patients have to travel for diagnosis or treatment, is also crucial importance. A

large number of sputum TB patients can be found and treated only if facilities are provided as nearer to their homes as possible in order to meet the felt need of community.

(C) **Resources considerations:**

The term resources cover trained personnel, equipment, material and money. The requirement for the country wide specialized programme would be so enormous that on no account such a programme can be justified. Therefore, National TB Programme was conceived as integral part of existing general health set-up, in order to improve the delivery of health services in general, and anti-tubercular services in particular.

(D) **Operational considerations:**

The enormity of operation problem in organizing efficient case finding and treatment services for TB in rural areas with scattered population and poor means of communication may not be generally appreciated. Opening TB clinic at taluka and block level is un-economic, impracticable and unnecessary. Also it was found in an operation research that the mobile mass case finding methodology, case yield was no better than that among self reporting chest symptomatics at Govt. health institution (NTI 1994). As regards treatment, it was again found that domiciliary chemotherapy was as effective as institutional therapy (TRC 1964). The domiciliary treatment was more acceptable to TB patients. It was because their domestic life was not disturbed. The above research finding has provided the basis for adopting the most practical means to organize a tuberculosis programme for rural areas.

Based on the above considerations, the following principles of NTP were enunciated:

1. Permanent TB services nearer to people to satisfy their felt-need.
2. Priority to smear AFB positive TB patient.
3. A complete functional integration of tuberculosis services with the general health services mainly through introduction of simple and standardized technique and procedures.

The NTP is in operation since 1962 and is integrated with general health service. This programme aims to detect TB cases early and treat them efficiently till they are cured. In the district, the programme is implemented through the District Tuberculosis Centre (DTC) and a number of peripheral health institution (PHI). AT present 446 (89.9%) DTC out of 496 districts have been established, out of which 292 DTC are shorts course chemotherapy district (SCC district). There are 47000 TB beds in the country and 330 TB clinics are functioning in urban area. In addition, there are 17 State TB Training and Demonstration Centres (GOI 2000). The summary of guidelines of the NTP and RNTCP are given in appendix (1).

Targets and achievements:

Target for detection of new TB cases and sputum examination and achievements for year 1994 to 1998 are shown in table No 2.4.

The treatment outcome of TB patients registered under NTP during year 1992 to 1997 was about 52 % to 59% for SCC regimen and 28% to 35% for standard regimen (SR) (WHO 2000). The treatment outcome, NTP year 1992 to 1997 is shown in table 2.5.

Table 2.4

Target and achievement of new case detection in NTP during 1994 to 1998

Sr. No	Year	Targets and achievement			
		Sputum examination		New cases detection	
		Number	%	Number	%
1	1994-95	22,41,379/35,18,000	63.7	12,49,139/19,00,000	65.74
2	1995-96	24,02,969/39,99,301	60.1	13,89,695/12,70,000	109.0
3	1996-97	33,60,000/41,40,801	81.2	14,60,000/13,64,000	107.0
4	1997-98	43,59,457/1,41,89,175	30.7	13,09,681/12,77,026	102.0

Source- Annual report Govt. of India year 2000

Table 2.5

Treatment outcomes, NTP, 1992-1997

Year	Reported Smear Positive Cases.	SCC			SR			Total
		Eval-uated	Completed Treatment	%	Eval-uated	Completed Treatment	%	% Completed of total registered
1992	235,998	48,384	25,372	52	75,910	26,699	35	22
1993	225,507	43,918	23,944	55	66,990	22,674	34	21
1994	226,604	65,375	34,644	53	64,673	20,749	32	24
1995	261,795	72,729	42,364	58	55,598	15,528	28	22
1996	284,589	75,812	44,566	59	43,253	12,496	29	20
1997	267,181	79,221	45,221	57	47,029	14,061	30	22

Source- Joint Tuberculosis Programme review, India, (WHO 2000)

2.4 Health institutions & manpower at Mehsana and Anand District:

On 2nd October 1997, The Kheda district was divided in two districts namely- Anand & Nadiad. Similarly Mehsana was also divided in Mehsana & Patan. The demographic information of these newly created districts are as follows.

Demographic information

Particular	Population in lakh	
	Anand	Mehsana
Population (Male + Female)	16.47 (8.61 + 7.86)	15.97 (8.18 + 7.79)
Rural population	12.34 (74.91%)	12.65 (79.9%)
Density of population	4.78 Sq. Km.	3.25 Sq. Km.
Literacy rate	65.83%	65.13%
Female literacy rate	49.93%	51.60%
Growth rate	14.12%	15.26%
Sex ratio (Female / 1000 male)	919	950

Health institutions

DTC	1	1
Referral hospital	8	8
PHC	43	38
TB clinic	1	0
NGO run TB hospital	2	2

Health Man Power

Medical officers	74	74
LT (DMC)	18	15
MPHW / MPHS	384	310
Pharmacists	43	33

2.5 Review of National TB Control Programme of India:

The Ministry of Health and Family welfare and The Director General Health Services (DGHS) for appropriate action periodically review the National TB Control Programme. Following table shows the review reports are available in medical literature.

Table 2.6
Review of NTP in India

Sr. No.	Title	Review authority	Year
1	A review of NTP	ICMR New Delhi	1995
2	In depth study of study on NTP of India	ICORCI Bangalore	1988
3	Tuberculosis Control Programme review, India	GOI, WHO, SIDA	1992
4	Joint TB Programme review, India.	WHO	2000

All the above said review revealed almost similar observations and determined that the NTP has not had the desired impact on TB in India. These review noted:

- Inadequate budgets.
- Lack of coverage in some part of country.
- Shortage of essential drugs.
- Poor administrative support.
- Unmotivated and unevenly trained staff.
- Lack of equipment.
- Poor quality of sputum microscopy.
- Over reliance of X-rays as a tool of diagnosis.
- Focus on case detection without an accompanying emphasis on treatment outcome.
- Low priority as compared to other disease.
- Patients experience indifferent programme delivery.

2.6 Revised National Tuberculosis Control Programme of India.

In 1992, a review committee highlighted the reasons for the failure of NTP in India and suggested a revised strategy to combat the disease (WHO 92). The recommendations were as follows:

1. Strengthen structure of NTP by -(A) Establishing an apex policy-making authority and an executive task force with managerial functions to implement programme reorganization. (B) Upgrading central TB unit to provide strong leadership and enhance the efficiency and effectiveness of NTP.
2. Strengthen sputum microscopy facilities and ensure good equipment, well-trained laboratory technicians in PHIs. and with quality control.
3. Ensure an uninterrupted supply of SCC good quality drugs even in remote districts.
4. Revised in current NTP system of registration and notification by giving emphasis on the cohort analysis of treatment results (i.e. completion, cure, transfer, defaulter, death, and treatment failure rates as the main indicator for programme effectiveness).
5. Decentralization of treatment services closer to patient home.
6. Pilot project should be implemented at block level to test feasibility and results of different technique and organizational strategies to be adopted by the TB programme.
7. Establishment of sub-district TB unit to facilitate decentralization of supervision.

8. Improve training of all person.
9. Encourage operational research that would enhance the efficiency of the programme.

On the basis of the recommendations of the review committee and endorsed by central council of health, a revised strategy for National Tuberculosis Control Programme has been evolved. The objective and strategies has been adopted are as follows. (GOI 1995)

OBJECTIVES:

1. Emphasis on the cure of infectious and seriously ill patient of TB, through administration of SCC, to achieve a cure rate of at least 85%.
2. Augmentation of the case finding activities to detect 70% of estimated cases, only after achieved the desired cure rate.

STRATEGIES:

1. Use of sputum testing as the primary method of diagnosis among the self-reporting patients.
2. Standardize treatment regimens.
3. Augmentation of the PHI supervision through the creation of sub-district supervisory unit.
4. Ensuring a regular, un-interrupted supply of drugs up to the most peripheral level.
5. Augmentation of organizational support at central and state level for meaningful co-ordination.
6. Emphasis on training, IEC, operational research and NGO involvement in the programme.
7 Increase budgetary outlay.

In 1993, this strategy was pilot tested in a population of 2.35 million and later extended to cover 13.85 millions in 13 states throughout the country. In the initial areas of implementation, cure rates of 80% have been obtained, with some areas consistently achieving cure rate above 90% (Khatri 1999).

A joint TB Control Programme Review (WHO 2000) found that 19% of patient examined were smear positive, with male having higher positively rates than female (22% versus 15%, P <0.001). The correct numbers of smear were recoded in 95% of patients. Of the smear positive patients, 64% had three positive smears, 26% had two positive smears and 10% had only one positive smear (WHO 2000).

A review committee analyzed the treatment outcome of patients treated under RNTCP since 1993- 1998. The results are shown in table 2.7.

Table 2.7
Treatment outcomes, RNTCP, 1993-1998

Year	TB Pt. Evaluated	Cured (%)	Copt. (%)	Success (cure Copt)	Died (%)	Failure (%)	Default (%)	Transfer out (%)
NSS +ve	29926	80.2%	1.7%	81.9%	4.0%	3.2%	8.4%	2.4%
NSS-ve	26123	NA	82.7%	82.7%	3.3%	1.5%	10.7%	1.8%
EP	8468		89.6%	89.6%	1.8%	0.2%	6.8%	1.5%
Relapse	4635	68 5%	3.0%	71.5%	6.0%	6.5%	11 9%	4 1%
Other retreatment	8734	58 2%	11.7%	69.9%	6 5%	5 5%	14.7%	3.4%

Source-Joint TB Programme review, India 2000

There was a general consensus that, in RNTCP, the patient would have to be a starting point of the focus. So it is therefore essential to understand the pattern of diagnosis and treatment from the patient perspectives.

2.7 Health seeking behavior of chest symptomatics

The health seeking behavior of chest symptomatics is described in the following stages:

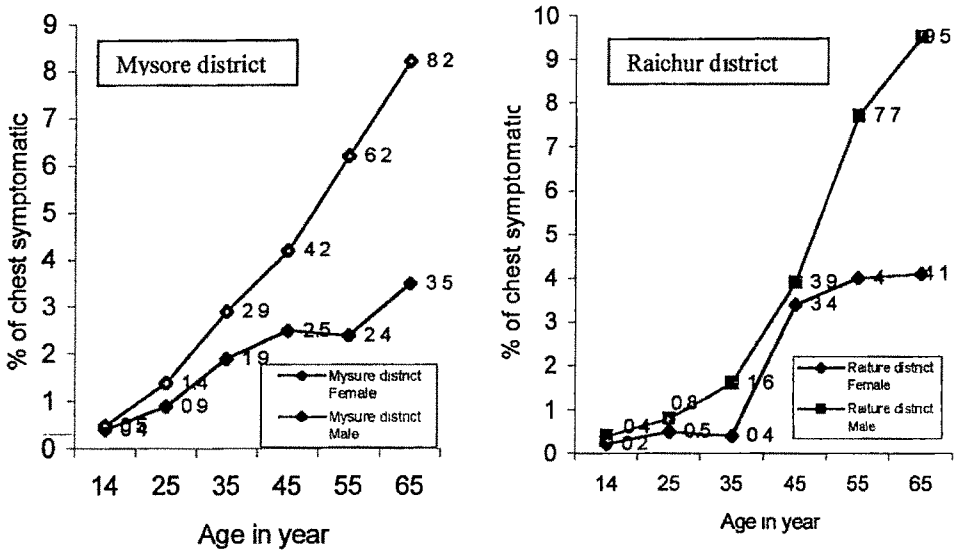
(1) **On set of symptoms**- The initial symptoms of TB are cough, chest pain and fever; makes it virtually indistinguishable from other respiratory illness, consequently it is reasonable to expect that the initial response to the onset of symptoms closely parallels to the case seeking behavior of chest symptomatics in general.

(2) **Prevalence of chest symptoms**- Chest symptomatics were defined differently by different researcher as discussed bellows, various studies indicated that the prevalence of chest symptoms in the general population range from 5-10% (Narayan et al 1976, Narayan et al 1979, Krishnaswamy et al 1977). A population-based survey in 55 villages at Bangalore district found that 12.1% of the surveyed population had chest symptoms: cough, chest pain, fever, or heamoptysis, of seven days duration or more (Narayan el al 1976).

A sample surveys in rural area of Tamil-nadu revealed that 5.6% of population had chest symptoms: Cough for two weeks or more, fever, or chest pain for one month or more, or heamoptysis (Subramaniam 1990). Cough appears to be the most common symptom followed by chest pain and fever. (Narayan at al 1976, Narayan at al 1979, Krishnaswamy et al 1977)

In a community – based symptomatic survey by Nair (1999), cough for 3 weeks or more was present in 1.4% of people of Karnataka. The rates increase with age and were higher in male than females (Figure 2.1).

Figure 2.1
% of adults with report of cough for 3 weeks or more in previous 6 months, by age and sex, Karnataka, 1997



Source- Research for action – Understanding TB in India (WHO 2000)

(3) Factor influencing patient's behavior

The case seeking behavior of patients are complicated and dynamic – continuous learning takes place during the process. Several factors seem to shape this behavior.

(a) <u>The knowledge and attitude towards the community:</u>

A household survey at Pune, Upleker (1996) found that there was reasonable awareness of disease, the main symptoms of TB ware enumerated by 55% of rural and 73% of urban respondents. However widespread misconception on the source of the disease continues to persist. In rural area of Pune 7-21% of house holds were found to attribute TB due to behavioral causes such as physical stress, drinking alcohol, smoking, sexual activities, food and water (Upleker 1996). The Pune surveys revealed that a majority of household (70%) believed that TB was curable. Yet the disease remains stigmatized. The researcher found people reluctant to talk about the disease. The TB patient was often considered

"impure" and stigmatized by the community. 16% of Patients attending TB clinic were found to give wrong home address to keep their identity confidential (Prajapati 1996)

The information for household comes from personal experience and the community, more then the media and health services. Stigmatization of patients has obvious consequences for the success of treatment. Patients would be reluctant to come forward for medical help and reveal their condition.

(b) Socio-economic status of patient: The socio-economic status of the patient determines their access to information about the disease and the diagnostic and treatment facilities available. It influences their choice of the health care provider and their ability to meet the demand involved in regular treatment.

A study in Jaipur (Purohit 1988) on the awareness about TB in the general population found significant difference in the knowledge about the disease among different socio-economic groups. More than 70% of illiterate respondents were either unaware or had misconception about different aspects of TB. In contrast more than 70% of the literate respondents gave correct answers to the most of the question about the disease.

The poor patient who lives in harsh conditions, tempted to discontinue chemotherapy when symptomatic relief is obtained. It is especially difficult to justify expenditure on medicine when there are other pressing demands on meager finances in absence of knowledge for importance of completion of treatment.

(c) Gander as a special case of social status influencing patient behavior: The women of India were described as

reluctant patients (Murthy 1982). Women, because of household responsibility and out of ignorance, tend to neglect their illness until they became too sick to move around and attend to their normal duties. They were often dependent on others to gets their medical attention (Murthy 1982).

(d) **Patient perceptions of various healths care provider and patient provider interactions**. Patient perception influences their choice of health care providers. The choice of health care provider involves numerous trades-off, e.g.

- Monitory **costs**
- Perceived **quality** of care
- **Attitude** of health care provider
- Time costs & Need for **privacy**

The preference for health care provider for ambulatory curative care was an indication that people in general perceive private health care provider as better at meeting their needs. The study (Upleker 1996) had found the following perceptions about private health care provider:

- Private health care provider was perceived to play the healer role and patient expressed faith in them.
- Conveniently located
- Affordable, allowing credit for payments
- Respectful, understanding and sympathetic
- Offered privacy which was considered an important aspect of treatment especially in slums
- Provider instant relief.

Government run service were faulted on:

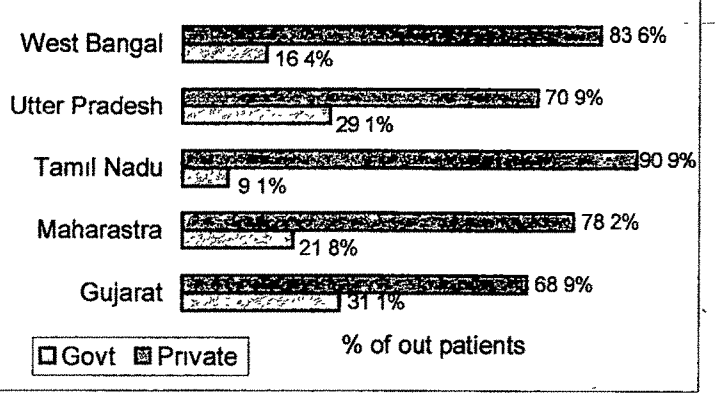
- Doctors being negligent, condescending, and inattentive to patient
- Duplicate and substandard drugs
- Unavailability of drugs

- Unhelpful attitude of Para-medical staff
- Long waiting time

(4) **Choice of health care provider**: The patient perception of the various health care provider and patient provider interaction as well as patient knowledge regarding availability of service play a predominant role on choice of provider.
A National Sample Survey 42 round in India shows that 9-31% of house hold in rural area first approached to govt. health institution and rest approaches to private health care provider (World Bank 1996).

For minor illness rural household in Pune used a private health care provider in 78% of cases, followed by government run services19%, Chemist 13%, and self half 12% (Multiple response). In the same study the household in Pune who reported chest symptoms, over 60% of the symptomatic first reported to private health care provider (Upleker 1996).
The health seeking behavior of chest symptomatics in rural area of Karnataka, Tamil Nadu, and Delhi found that 64% first sought help from private health care provider (Table 2.8). 29% went to govt. facilities for first visit (WHO 2000).

Figure 2.2
Proportion of out patients choosing Health care Providers



Source: World Bank Report No. 13042-IN, 1996

Table 2.8
First action taken by chest symptomatic in various studies in India

Health care Provider	First action taken by chest symptomatics							
	Mysore district		Raichur district		Tamil Nadu		Delhi	Average
	Rural %	Urban %	Rural %	Urban %	Rural %	Urban %	%	%
Private Provider	48	76	93	74	48	57	55	64
Govt. Facility	51	22	5	25	46	32	21	29
Self-Medication	-	-	-	-	4	8	10	3
Home remedies	-	-	-	-	1	2	6	1
Other	1	2	2	1	1	1	8	2
Total taking action	**83**	**85**	**90**	**85**	**63**	**80**	**82**	**81**
No action prior to interview	17	15	10	15	37	20	18	19

Source: WHO 2000

2.8 Disease awareness and perception in TB patient:

Tuberculosis is not an easy topic to discuss with people and elicit view on. It is still view by them as a serious problem leaving behind death and devastation in affected family. The process of health seeking for TB patient is often complex and will loose several years. The response of people when asked *"Have you heard about TB?"* followed by series of question to understand their knowledge about various aspect of the disease as discussed below.

(a) Knowledge of symptom of TB: What do people do when they developed persistent cough and other symptoms suggestive of TB? Do they suspect TB and seek help in conformity with their help seeking behavior? In a study

carried out at Pune suggested that 70-79% of patients recognized the disease when cough as a TB were enumerated (Upleker 1996). The cough appear to be the most common symptom followed by chest pain and fever in TB (Rao 1972)

(b) Choice of health care provider: The initial help seeking behavior of TB patients would parallel to general response to illness. About 43% (21/49) of rural patients seeking help form Govt. services for a major illness like TB (Upleker 1996).

(c) Shopping for diagnosis: Quality of diagnosis was generally poor, as suggested partly by the need to "shop" for diagnosis. This was confirmed by a study at Bangalore district, which found that of 21 sputum culture positive TB cases, who had gone to a modern medical facility (Private allopathic or government run services). Only 9 could be confirmed as having received anti TB treatment (Narayan 1976). The survey also reports that a large proportion of bacteriologically positive cases were not received anti TB treatment (Narayan 1979).

Table 2.9

Source and nature of past treatment among sputum positive chest symptomatics found in a population based survey

Source	No. of Pt. seeking professional help	% of Pt. received TB treatment
Indigenous practitioner	10	10%(1/10)
Private doctor	22	22.7%(5/22)
Govt. Hospital	26	42.3%(11/26)
TB Hospital	5	80%(4/5)

Source: Narayan at el (1997)

Only a 20% of rural patients with care private provider in the Pune based study were subjected to sputum examination (Upleker 1996). 96% of Pune patients with Govt. run service reported X-ray test while 79% reported sputum test.

(d) Shopping for treatment: Patient shop for effective private treatment and later switch to government services. A survey of patients registered at government run clinic (Saxena et al 1997) revealed 60% of the patients registered at New Delhi govt. run clinic had first sought professional help from two or more sources without adequate relief, before ending up at the TB clinic.

(e) Treatment adherence: Case holding has long been recognized as the weakest component of services (both in private and public). Among private sector patients in Pune and Bombay, adherence was reported 70% in the first two months and than declined to 54% by the end of 6^{th} months (Upleker 1996). Radhakrishna (1983) estimated that only 35% of the cases started on treatment in govt. run services remain under treatment for adequate length of time. The treatment completion rate average 58% for short course chemotherapy (SCC) and 27.9% for standard regimen (SR) regimen were observed in the cohort period of 1-1-95 to 31-12-95 (NTI 1997). Several studies (Table 2.10) had attempted to investigate the factor responsible for non-adherence.

Adherence behavior is also shaped by medication knowledge though there was evidence that the patients were generally aware of required duration. Nearly half of the non-complainant patient in the Wardha study knew the correct treatment duration (Bourhoor 1992).

Survey in Pune and Bombay found patients to be knowledgeable about duration of treatment. About 2/3 could gave right answer (Upleker 1996). The health care provider is often a key source of information for patients. Patients appear to understand the need for regularity. Over 86% in Pune survey indicate that irregular treatment could lead to worsening of disease and possible death. Knowledge did not insure adherence (Upleker 1996).

The socio-economic status probably influence adherence through the financial means available to the patients and perceived importance of regular treatment versus other tasks. Social support appears to help and facilitate regular treatment. Patient health care provider interaction seems to be yet another important factor. Those who complete treatment or take treatment as prescribed are more likely to express faith in the doctors than those who do not. (WHO 1987)

Table 2.10
Summary of key finding from studies of factors influencing patient adherence to TB treatment

Sample	Key factors
60 Patients at a NGO TB clinic in west Bengal (Geetakrinan 1990)	• Patient-provider interaction • Change of residence • Adverse reaction
400 patients at a govt. TB clinic in Lokhnow (Khanna et al 1977)	• Careless and forgetful personality • Failure to accept diagnosis • Unsuitable clinic timings • Long distance to clinic • Symptomatic relief
60 defaulter in controlled SCC trails in Madras (Suhadev et al 1995)	• Unwilling for treatment • Adverse reaction to drugs • Pressure of work • Out station trips due to family • Social and business obligations
150 defaulters and 150 adherents at govt. TB clinic in Agra (Singh et al1976)	• Socio-economic factors like caste, literacy, occupation, income • Family affairs like births, marriages, functions • Financial difficulties • Transportation problems
50 non adherent and 52 adherent patient at govt. clinics in Wardha district (Barnhoon et al 1992)	• Socio-economic factor • Health beliefs • Social support • Patient-provider relationship
299 patients on treatment in govt. clinic in Pune and Bombay (Upleker et al 1996)	• Feeling better • Economic constraints • Unforeseen problems • Health services related problems • Adverse effects of drugs

Source: WHO 1997/TB/. 223 page 20

2.9 Health care provider perspectives:

In order to have better understanding of health care provider perspective, it was necessary to review the historical background of the integration of health services and National TB Programme. Since its inception, it was first vertical programme to be integrated with general health services. About a decade later, National Institute of Health Administration and Education New Delhi (NIHAE) carried out an experimental project where worker engaged under Malaria, Smallpox, and Family Planning had been group together (MHFW 1973).

In 1973, the committee on multi-purpose worker under health and family planning programme recommended by Kartarsingh committee that multipurpose worker for the delivery of health and family planning and nutrition services to the rural communities were both feasible and desirable (MHFW 1973), but neither the NIHAE and nor Kartarsingh committee considered any functions relating to NTP which had been integrated with the general health services for more than 10 years. Consequently, the job responsibilities suggested by the Kartarsingh committee for health worker and their supervisors did not include any function relating to NTP.

In 1986, job responsibilities in relation to NTP were fixed for Medical Officer Primary Health Centre (MO PHC). The job responsibilities of health assistant male and female and health worker (HW) male and female were modified (GOI 1986), to incorporate duties related to NTP. The duties assigned to health personnel were as follows:

Medical Officer (PHC)

- He will provide the facilities for early detection of cases of TB, confirmation of their diagnosis and treatment.
- He will ensure that all cases of TB take regular and complete treatment.

Health Assistant (male & Female)

- Check whither all cases under treatment for TB take regular treatment.
- Motivate defaulter to take regular treatment and bring them to the notice of MO PHC.

Health Worker (Male)

- Identified chest symptomatic in community and referred them to MO PHC for investigation.
- Insure that all TB patients should take regular treatment.
- Motivate defaulter to take treatment. Bring them in notice of health assistant.
- Assist the village health guide in understanding the activities under TB control programme.

Health worker (Female)

- Assist the health worker (male) in maintaining record of cases in her area, which were under treatment for TB.
- Check whether TB patients taking regular treatment.
- Motivate defaulter to take regular treatment and bring them in notice of health assistant male.

It is evident from the above discussion that, even though NTP was formulated in 1962 as an integral part of general health service and DTP manual and NTI training enunciated job responsibilities in relation to TB work. The job

responsibilities for case finding alone was actually prescribed for the general health services staff below PHC levelin1982 only and that too not for MO PHC. The job responsibilities for primary health centre level and below covering both case finding and treatment were prescribed as late as in 1986 only. Further the job responsibilities and the definition of chest symptomatic were not the same in NTP and Multi-Purpose Worker (MPW) manuals. NTP modules defined role of MPW were comprehensive in action. (For full text – Please refer to Appendix 2)

(A) Priority to TB Control Programme: The health functionary in the community – The health workers is the first level of health care providers for the public services for community. A variety of health programme were implemented at the gross-root level through them, but their priorities, as admitted by themselves were family planning, MCH, UIP, (Upleker 1996). In a study at Pune 7% of HWs reported as priority to TB Programme rest 93% could not. In 1988 ICORCI Bangalore observed that 26% of medical officer agreed to equal importance to all health programme. (ICORCI 1988)

(A) Knowledge, Attitude and Practice of health care provider: The actual contribution of the health worker to the programme was minimum, yet their knowledge about case finding was satisfactory (Upleker 1996). About ¾ knew how to recognize a chest symptomatic and about 90% knew the correct technique of sputum collection. Further ½ of them knew the names of the drugs used in SCC regimen. The main weakness in their knowledge was about the defaulter retrieval action, which was unclear to them. It did not confirm to the programme guidelines (Upleker 1996).

2.10 Programme Management, Supervision and Monitoring

The programme management was one of the weakest aspects of District Tuberculosis Programme(DTP). This was not surprising against the background of the low priority accorded to it (Upleker 1996). According to NTP policy, the district tuberculosis officer (DTO) and his teams were responsible for supervision of all personnel within district involved in TB activities. The team was expected to visit each of their PHC on a quarterly basis (WHO 1992). They were expected to do following evaluative activities:

- Diagnostic and treatment procedures,
- Validate laboratory results,
- Monitor record keeping activities,
- Check the defaulter action taken,
- Monitor the anti-TB drugs supplies and
- Support the equipments maintenance.

There has been steady decline in the proportion of Peripheral health institution (PHI) supervised by DTC teams, from 51% in 1988 to 41% in 1991. In 1987 only 84% of functioning DTC sent quarterly reports. Of these 72%(60% of functioning DTP) gave information on supervisory visits. Of the 60% of DTP gave information, they had supervised only 45% of their PHIs. Thus 27% of the PHI had been reported supervised, while the quality of the supervisions was not known (ICORCI 1988).

The supervision of TB work by MO PHC was also very poor. Only 35.3% of MO PHC mentioned that they supervised microscopic centre and 29.4% mentioned that they check the entries on treatment cards, only 11.7% of MO mentioned about defaulter action in the study (ICORCI 1988).

2.11 Impact of TB Control Activities:

Evaluation of the epidemiological impact of NTP is difficult due to following reasons:

(1) TB is an age-old disease so the substantial reduction of prevalence / incidence of TB cannot be expected in a short period.

(2) There are no reliable statistics on morbidity and mortality due to TB. Surveys, which can depict change in TB prevalence, need very large sample size and are prohibitive in cost and difficult to organize.

(3) Change due to socio-economic development also influence TB prevalence and incidence. Hence the changes observed over time, particularly over long period, can't be attributed to NTP alone.

Attempts have been made to solve this problems by making use of epidemetric models but the models evolved so for cannot quantify adequate changes due to socio-economic development and their influences on TB prevalence and incidence.

In the view of above, the various indicators can be used to review the process of implementation and it's out come in TB control activities. These indicators in turn indirectly reflect the future change in epidemiology of TB morbidity and mortality. The possible indicators propose based on our experience and other National Health Programme is:

(1) **Process indicator**:

Training-

(a) Proportion of Para-medical health personnel trained or retrained for TB control programme in previous 3 years

(b) Proportion of health workers responsible for BCG vaccination, who were trained or retrained in BCG vaccination technique in previous three years.

(c) Proportion of medical personnel, who were trained or retrained for TB control programme in previous three years.

Supervision

(a) Proportion of HW, who report that one or more visit by their immediate supervisor (MO) in previous 3 months for TB control activities.

(b) Proportion of medical officer, report that one or more supervisory visit of DTO in previous one year for TB control programme.

Health information systems

(a) Proportion of health institution submitted monthly monitoring reports during last one year

(b) Proportion of medical officer, who report that they received feedback of monthly monitoring report within three months of their submission.

Drugs-supply

(a) Proportion of medical officer, who report that the supply of anti -TB drugs was in sufficient quantities during last one-year period.

Health-education

(a) Proportion of TB patients, who report that they know govt. Facilities located nearer to their house (PHC), where the diagnosis and treatment of TB available free of cost.

(b) Proportion of chest symptomatic patients, who report that they know govt. Facilities located nearer to their house (PHC), where the diagnosis and treatment of TB available free of cost.

(c) Proportion of health worker who know correctly the nearest govt. health facilities where the diagnosis of TB is available.

(d) Proportion of health worker who know correctly the nearest govt. health facilities where the treatment of TB is available.

(e) Proportion of medical health care provider (MO), who received the TB training,
report correctly about national TB regimen

(f) Proportion of medical health care provider (MO), who did not received the TB training, report correctly about national TB regimen

(2) <u>Out come indicators</u>

Case finding activities

(a) Proportion of chest symptomatic suggestive of TB, seeking medical advice for early detection out of total symptomatic in community.

(b) Proportion of chest symptomatic suggestive of TB seeking medical advice from govt. facilities for early detection, out of total who seek the medical advice.

(c) Proportion of chest symptomatic, seeking medical advice from health care provider, who reports that, his health care provider advice for sputum AFB examination.

(d) Proportion of chest symptomatic, seeking medical advice from health care provider, who reports that, his health care provider advice for X-ray chest after the sputum AFB examination.

(e) Proportion of TB patients, who report that they had first visited to govt. facilities for their symptoms.

(f) Proportion of smear AFB positive TB patient out of total chest symptomatic patient in community

Treatment activities

(a) Proportion of TB patients, who report that they received TB treatment from Govt. facilities out of total TB patients in community.

(b) Proportion of TB patients, who report that they received TB treatment from Govt. facilities and prescribed the National TB drug regimen.

(c) Proportion of TB patients, who report that they received RNTCP drugs regimen from govt. facilities, in presence of DOTS worker.

Treatment outcome

(a) Sputum smear conversion rate at the end of three months in new smear AFB positive TB patients treated at govt. facilities

(b) Cure rate in new smear AFB positive TB patients treated at govt. facilities.

(c) Treatment completion rate in new smear AFB positive TB patients treated at govt. facilities

(d) Default rate in new smear AFB positive TB patients treated at govt. facilities

(e) Failure rate in new smear AFB positive TB patients treated at govt. facilities

(f) Death rate in new smear AFB positive TB patients treated at govt. facilities

(g) Migration/ Transfer out rate in new smear AFB positive TB patients treated at govt. facilities.

Mortality

(a) Crude Death Rate /Thousand/ year

(b) TB mortality/ lakh/year

(c) Proportionate death due to TB (in relation to CDR)

Prevention & prophylaxis

(a) Proportion of children age 1-2 year of age BCG vaccinated as per their mother in community.

(b) Proportion of TB patient disposed their sputum hygienically.

In a view of above review of literature the study was designed with aim & objectives given in chapter 3.