Factors associated with default among new sputum positive tuberculosis treated with directly observed treatment short course (DOTS) under revised national tuberculosis control programme (RNTCP) of Thoubal district, Manipur, India, 2008

By

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CERTIFICATION

This is to certify that this dissertation, entitled "Factors associated with default among new sputum positive tuberculosis treated with directly observed treatment short course (DOTS) under revised national tuberculosis control programme (RNTCP) of Thoubal district, Manipur, India, 2008" submitted by **Mairembam Dinesh Singh,** in partial fulfillment of the requirements for the degree of Master of Applied Epidemiology.

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Abbreviation

CHC: Community health centre

CI: Confidence interval

CMO: Chief Medical Officer

DALY: Disability adjusted life year

DMC: Designated microscopic centre

DOTS: Directly observed therapy short course

DTO: District Tuberculosis Officer

GOI: Government of India

MLR: Multiple Logistic Regressions

NIE: National Institute of Epidemiology

NSN: New sputum negative

NSP: New sputum positive

OR: Odds ratio

PHC: Primary health centre

RNTCP: Revised national tuberculosis control programme

TB: Tuberculosis

TU: Tuberculosis unit

WHO: World Health Organization

X^2: Chi-square trend

Section I

Dissertation

ABSTRACT

Setting: Revised national tuberculosis control programme (RNTCP) emphasizing on DOTS in Thoubal district, Manipur, India.

Objective: To identify the risk factors associated with default among the new sputum smear positive pulmonary tuberculosis treated with DOTS under RNTCP.

Design: An unmatched case control analysis, obtained from the study of 308 persons of which 77 defaults were cases and 231 cured persons were controls, registered under the programme during the last quarter of 2006 and third quarter of 2007. Data collection was through interviewed by using pre-tested structured questionnaire. Then we calculated, odds ratio (OR) 95% confidence interval (CI) and multiple logistic regression (MLR) analysis to identify the factors associated with default.

Results: Treatment default was higher among males alcoholic (Adjusted Odds Ratio [AOR] =2.8, 95% CI: 1.0-7.9), (AOR=2.7, 95% CI: 1.1-6.5) and who had side effects to medication during treatment (AOR=7.7, 95% CI: 3.4-32.9) respectively. Other factors found to be significantly higher among with defaulter were knowledge about treatment duration (AOR=7.1, 95% CI: 2.1-24.4), those who said the DOTS timing was inconvenient (AOR=5.9, 95% CI: 2.3-15.3); and among those who were not satisfied with the interaction with DOTS providers (AOR=10.5, 95% CI: 4.1-31.4)

Conclusion: Our study identified determinants of defaulting among new smear positive patients in Thoubal district of Manipur. On the basis of our findings, we recommend (1) increasing working hours of DOTS centers and involving a neighborhood or family member as DOTS providers and (2) improving interpersonal communication skills of DOTS providers to create awareness about duration and frequency of treatment and possible side effects. It is also necessary that DOTS providers provide individual counseling to patients to clarify their doubts at the beginning of treatment.

Keywords: TB default, DOTS, Case Control Study.

Factors associated with default among new sputum positive tuberculosis treated with directly observed treatment short course (DOTS) under revised national tuberculosis control programme (RNTCP) of Thoubal district, Manipur, India, 2008

Introduction

Globally, there were an estimated 9.2 million new cases of pulmonary tuberculosis (TB) in 2006,[1] of which 4-5 million were new sputum smear positive cases.[2] More than 44% of the cases reported in 2006 were from Asia and Sub-Saharan Africa.[1] World Health Organization (WHO) introduced the Revised National Tuberculosis Control Programme (RNTCP) based on DOTS (Directly Observed Treatment, Short-Course) strategy worldwide in 1993.[1] The major thrust of RNTCP was achieving a cure rate of more than 85% among new smear-positive patients and detecting at least 70% of such cases.[3] Approximately 187 countries with population coverage of 89% adopted this strategy by 2005.[4] Although more than 26 million TB patients have been treated under WHO strategy, the world's TB control programme narrowly missed their 2005 targets for case detection (reaching 60%

compared to the target of 70%) and cure (84% compared to the target of 85%).[3] Inability to complete the prescribed regimens among patients is common in self-administered treatment. The adoption of DOTS has given impressive results with higher treatment success being reported from developing countries.[8] However, an efficient network of health infrastructure with committed treatment organization is key for the success of DOTS.[10]

India accounts for one third of the global TB burden.[5] Approximately 1.8 million people develop TB in India every year, of which about 0.8 million are new sputum smear positive cases. Despite being completely curable, TB kills more than 400,000 people in India every year.[5]Since 1993, the Government of India (GOI) had been implementing the WHO-recommended DOTS strategy through the RNTCP. The revised strategy which was pilot-tested in 1993 in five sites in different states (Delhi, Kerala, West Bengal, Maharashtra, and Gujarat)[5] was launched as a national programme in 1997. By March 2006, the programme was implemented nationwide in 633 districts, covering 1114 million (100%) population.[5] In India, in 2006[6] the cure rate among new sputum smear-positive cases registered under DOTS was 84% with a default rate of 6.2%.

Defaulting from treatment has been one of the major obstacles to treatment management and an important challenge for tuberculosis control.[5,7] Defaulting is often associated with serious consequences like relapse and drug resistance. A successful TB control programme therefore needs to have a

minimal default rate. According to RNTCP guidelines, the default rate should be <5%.[5]

Manipur, one of the northeastern states of India, implemented RNTCP in Imphal district in 1998 and in all nine districts by January 2003. In 2007, the state had a cure rate of 85% and 10.5% were defaulters.[7]Since implementation of RNTCP in Thoubal District of Manipur in April 2002; the default rate has been more than 5%. An evaluation of the programme in the district indicated that the default rate among new sputum smear-positive cases was 12% in 2007. The district had the second highest default rate in the state. In view of this, we conducted a study to identify the risk factors associated with default among new sputum smear positive pulmonary tuberculosis treated with DOTS under RNTCP in Thoubal district, Manipur.

Methods

Study population: The study was conducted in Thoubal District, Manipur, covering all the 689 new sputum smear positive pulmonary TB cases registered under the programme during the last quarter of 2006 and third quarter of 2007.

Study Design: We conducted an unmatched case control study. We used RNTCP definition to define cases and controls. We defined a defaulter (case) as a patient who, at any time after registration, has not taken anti-tuberculosis drugs for two months or more consecutively. We defined a cured patient (control) as smear positive TB patients who has taken the treatment and had

negative sputum smear, on at least two occasions, one of which was at completion of treatment.

Data collection: Using a pre-tested, structured questionnaire, trained health workers chosen from Thoubal district health administration interviewed cases and controls and collected information regarding (1) socio-demographic details including age, gender, literacy, marital status, alcohol consumption and per capita income (2) treatment related factors like mode of transportation, time taken to reach DOTS centre and take medicine under supervision, distance of DOTS centre from home, convenience of DOTS timing, interaction with DOTs providers, side effects to drugs and (3) knowledge about treatment duration, and mode of transmission of TB. The study was conducted during 1st June 2008 to 30th August 2008. To minimize bias, the interviewers were blinded about the status of TB patients (defaulters/cured patients). All the data were collected under the direct supervision of the principal investigator.

Sample size and sampling procedure: Assuming an exposure among controls as 10% (not satisfied with the interaction with DOTS providers), odds ratio worth detecting 3, three controls per case, confidence level of 95% and power as 80%, the required sample size was 70 cases and 210 controls. We inflated the sample size by 10% to account for non-response. So the final sample size was 77 cases and 231 controls.

There are two Tuberculosis units (TUs) and five designated microscopic centres (DMCs) in Thoubal district. We prepared the list of defaulter and treatment-completed individuals from both the TUs and DMCs during second

quarter of 2007 and first quarter of 2008. Using a random number table, we randomly selected 77 cases and 231 controls from these lists.

Data analysis: We analyzed the data using Epi-info software (version 3.5.1, CDC, Atlanta). We calculated odds ratios (OR) and their 95% confidence interval (CI) to identify the factors associated with default. We also measured the dose response by using chi-square (x^2) for trend of the variables found significant in univariate analysis. All the variables with p value of 0.2 or less on univariate analysis were included in multiple logistic regression analysis.

Human subject protection: We obtained written informed consent from participants or parents/guardians in case of minor. The study protocol was approved by the ethical committee of the National Institute of Epidemiology, Chennai. We also took the permission to carry out the study from The Director Health, Govt. of Manipur, Chief medical officer (CMO) Thoubal, and District tuberculosis officer (DTO) Thoubal.

Results

The analysis pertains to the study group of 308 persons of which 77 default persons were cases and 231 cured persons were controls.

Univarate analysis

Socio-demographic factors: Treatment default was significantly higher in males. [Odds Ratio (OR) =2.7, 95% confidence Interval (CI) =1.5-2.7] Compared to those who consumed alcohol occasionally, TB patients who

consumed alcohol daily were more likely to default. (OR=2.0, 95% CI=1.2-3.4) (Table1).

Treatment related factors: Treatment default was higher among those who used to visit DOTS centers by bus or two wheelers (OR=3.3, 95% CI: 1.9-5.6), traveled more than 2 Km (OR=2.8, 95% CI: 1.6-4.7), and took more than 60 minutes to reach DOTS centre and take medicine under supervision (OR=2.9, 95% CI: 1.7-5.2). The default was higher among those who said the DOTS timing was inconvenient (OR=2.8, 95% CI: 1.6-4.7), and whose work was affected by attending DOTS centre (OR=2.5, 95% CI: 1.5-4.3). TB patients who were not satisfied with the interaction with DOTS providers (OR=7.0, 95% CI: 3.6-14.3) and who felt that sufficient time was not given by DOTS providers (OR=7.0, 95% CI: 3.0-13.0) to clarify doubts were more likely to default. The default was also higher among those who faced side effects to anti-TB medication (OR=4.9, 95% CI: 2.8-9.0) (Table 2). The commonest side effects reported by TB patients were skin rashes (42%), nausea (28%).

Knowledge related factors: Treatment default was higher among those who said TB was not curable (OR=4.3, 95% CI: 2.5-7.7), did not know about treatment duration (OR=7.0, 95% CI: 4.0-13.0), and those who were not aware of mode of transmission of TB (OR=7.0, 95% CI: 4.0-13.0). (Table 3)

Dose response analysis: In dose response analysis, we found that the odds of default among male TB patients increased with consumption of alcohol. (Table 4)

Multivariate analysis

On multivariate analysis, we found that the treatment default was significantly higher among those TB patients who were males [Adjusted Odds Ratio (AOR) =2.8, 95% CI: 1.0-7.9], alcoholics (AOR=2.7, 95% CI: 1.1-6.5), had side effects to medication during treatment (AOR=7.7, 95% CI: 3.4-32.9) and those who had lack of knowledge about treatment duration (AOR=7.1, 95% CI: 2.1-24.4). Patients who said that DOTS timing was inconvenient (AOR=5.9, 95% CI: 2.3-15.3), and who were not satisfied with the interaction with DOTS providers (AOR=10.5, 95% CI: 4.1-31.4) were also more likely to be defaulters. (Table 5)

Discussion

Thoubal district reported high default rate in last seven years. The major factors influencing treatment default in Thoubal district were related to patients' interaction with DOTS provider, timings of the DOTS, side effects of drug and their knowledge about duration of treatment. Default was also high among male alcoholics. Knowledge of these factors would help the district programme managers in planning strategies for increasing treatment compliance and thereby reducing the default.

DOTS providers play an important role in administering the supervised treatment and counseling the TB patients about treatment including its duration, frequency and possible side effects. Several studies reported that not providing adequate information to TB patient about the disease and

treatment was associated with default .[8] Patients' knowledge about duration of treatment was also found to be an important factor associated with defaulting.[9] Symptoms of TB often disappear within few months of starting the anti-Tuberculosis treatment. TB patients, if not counseled about the duration of the treatment and the need for taking medicine for entire duration, are likely to equate the disappearance of tuberculosis symptoms with cure of the disease. Counseling during the initial contact is thus a key for ensuring proper compliance to treatment and thereby reducing the default.[10,11] In Thoubal district, patients who were not satisfied with the interactions with DOTS providers and those not knowing the duration of treatment were more likely to default.[11] Improving the interpersonal communication skills of DOTS providers addressing the need for taking drugs for complete duration would increasing the treatment compliance of TB patients in the district.

Minor side effects to medication like loss of sleep, nausea, vomiting, yellow discoloration of urine and skin rashes was associated with treatment default in Thoubal. Similar findings were also reported from other studies conducted in India, and Malaysia.[8, 12] Adequate health education of patients before starting the treatment, reassuring patients about the transient nature of these side effects and their symptomatic treatment would go a long way in treatment success and reducing default rate.

In Thoubal district, 45 of the 60 DOTS providers were health workers working in various public health facilities while 15 were neighborhood DOTS providers. Health workers administered TB drugs during OPD hours. Inconvenient DOTS

district as well as in several other studies. [13] The default was also higher among males, who are the earning members of the family in the district. Treatment default would have been lower if the timings of the DOTS centers in public health facilities are increased. Considering the remoteness of the district, use of family or neighborhood based DOTS providers could also be considered as option for increasing treatment compliance. Similar strategy was used in Ethiopia study and Bangalore city study.[9, 13]

Alcoholism was identified as independent risk factor for non-compliance in our study. Male alcoholic TB patients are more likely to default as compared to those who do not consumed. Similar findings have been reported from studies conducted elsewhere in India[15] and also in different parts of the world viz., New York City, England, Ireland, Denmark and Chile.[14] Improving compliance among alcoholic patients continues to be a challenge. Health personnel should be sensitive to this issue and evolve suitable motivation strategies. Sustained efforts should be made to counsel and motivate this group with their family members to ensure family support throughout the treatment period.[12, 16]

Our study had certain limitations. First, recall bias could have occurred while assessing knowledge of TB patients regarding the duration of treatment and its cure. This was because those who completed the treatment were more likely to recall this information than defaulters. We tried to minimize this bias by blinding the investigator about the outcome of TB patients. Second, all the

female TB patients reported that they did not consume alcohol; however consumption of alcohol is common practice in rural area of Manipur. On restricted analysis, alcohol consumption was a significant predictor of treatment default. Lastly, we included only the cured/defaulter TB patients of new sputum positive (NSP) cases and did not include sputum negative cases (NSN). However factors associated with default in NSP cases are likely to be similar to NSN cases.

In conclusion, our study identified determinants of defaulting among new smear positive patients in Thoubal district of Manipur. On the basis of our findings, we recommend (1) increasing working hours of DOTS centers and involving a neighborhood or family member as DOTS providers and (2) improving interpersonal communication skills of DOTS providers to create awareness about duration and frequency of treatment and possible side effects. It is also necessary that DOTS providers provide individual counseling to patients to clarify their doubts at the beginning of treatment.

Table 1: Socio-Demographic related factors associated with default with DOTS under RNTCP, Thoubal District, Manipur, India, 2008

	Frequency of exposure				Odds ratio	95% confidence interval
	Cases (n=77)		Controls (n=231)			
	#	%	#	%		
Male sex	63	82	144	62	2.7	1.5-5.3
Age between 10-40 years	35	46	93	40	1.2	0.7-2.1
General caste	38	49	108	47	1.1	0.7-1.9
Hindu	48	63	155	67	0.8	0.5-2.3
Married	67	87	200	87	1.0	0.5-2.3
Illiterate	45	58	112	49	1.5	0.9-2.5
Household size >5	50	65	126	55	1.5	0.9-2.7
Monthly family income >Rs. 5000	44	57	165	71	0.4	0.3-0.9
Alcoholic	36	47	70	30	2.0	1.2-3.4

Table 2: Treatment related factors associated with default with DOTS under RNTCP, Thoubal District, Manipur, India, 2008

	Frequency of exposure				Odds ratio	95% confidence interval
	Cases (n=77)		Controls (n=231)			
	#	%	#	%		
Mode of transportation by bus/two wheelers, compared to walking	45	58	69	30	3.3	1.9-5.6
Time taken > 60 minutes to reach DOT centre and collect medicine	31	40	43	19	2.9	1.7-5.2
Distance of > 2Km to DOT centre from home	41	53	67	29	2.8	1.6-4.7
DOT timing inconvenient	40	52	65	28	2.8	1.6-4.7
Work affected by attending DOT centre	37	48	62	27	2.5	1.5-4.3
Not satisfied with the interaction with DOT providers	28	36	17	7	7.0	3.6-14.3
Side effects to drugs	58	7	88	38	4.9	2.8-9.0

Table 3: Knowledge related factors associated with default with DOTS under RNTCP, Thoubal District, Manipur, India, 2008

	Frequency of exposure					
	Cases (n=77)		Controls (n=231)		Odds ratio	95% confidence interval
	#	%	#	%		
TB is not curable	55	71	59	26	7.0	4.0-13.0
Does not know about treatment duration	35	46	37	16	4.3	2.5-7.7
Fear of Stigmatization	56	73	180	78	0.8	0.4-1.4
Not aware of mode of transmission	42	55	87	38	2.0	1.2-3.4

Table 4: Default among male TB patients according to increase gradients of alcohol consumption, with DOTS under RNTCP, Thoubal District, Manipur, India, 2008

	Frequency of exposure					
	Cases (n=63)		Controls (n=144)		Odds ratio	95% confidence interval
	#	%	#	%		
No alcohol consumption	27	42	74	51	Reference	
<7 drinks per week	6	9	35	24	0.5	0.2-1.3
7-13 drinks per week	12	19	17	11	1.9	0.8-4.9
>13 drinks per week	18	29	18	12	2.7	1.2-6.5

Chi-square for linear trend = 25

P value = < 0.00

Table 5: In multiple logistic regression risk Factors associated with default with DOTS under RNTCP, Thoubal District, Manipur, India, 2008

	Crude Odds Ratio	Adjusted Odds Ratio	95% Confidence Interval
Male sex	2.7	2.8	1.0-7.9
DOTS timing inconvenient	2.8	5.9	2.3-15.3
Not satisfied with the interaction with DOTS providers	7.0	10.5	4.1-31.4
Alcoholic	2.0	2.7	1.1-6.5
Side effects to drugs	4.9	7.7	3.4-32.9
Does not know about treatment duration	4.3	7.1	2.1-24.4

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ANNEXURE I

INFORMED CONSENT FORM

Greetings,

I am Dr M Dinesh Singh and working as a Medical Officer in Manipur Health Services, now undergoing MAE, FETP, in National Institute of Epidemiology, Chennai. We are now working with the health officials of the district. Tuberculosis is one of the public health problems in our district. The tuberculosis is tested in Govt. hospitals by examining sputum. All tuberculosis patients receive free medicines when treated in Govt. hospitals. However some patients do not finish the full course of treatment. This is found very high among new bacteriological positive tuberculosis patients, than expected in our district. So we are doing a study. The National Institute of Epidemiology, Chennai, is also working with us in the study. We would like your help on this study. We would like to ask you some questions. There will be a few questions that we will be asking to you on a one to one basis. The whole process should take about a one hour or less. Once this is over, we will be done and will not bother you again. There is no special benefit for you to take part in this. There is no risk to you. All elements of the discussion that we will have together will be kept between you and me. We will not write your name on the paper and will use a code instead. If you do not like any of the

questions, feel free not to answer. If you are tired with the questions, you can also feel free to stop the whole thing at any time. It must be your decision to take part in the study. You can refuse to take part without giving any reason or without loosing any sort of benefit you receive. However, taking part in the study may help us to know the reasons why the patients do not take full treatment. If you wish to know more about the study, I will be happy to answer any questions, you may have. You may also contact Dr M Dinesh Singh, MAE, FETP, Scholar, NIE, Chennai. (Mobile No: 09436031609).

I have read the above information, or the information has been read to me in my own language. I have had an opportunity to ask questions any questions I have asked, have been answered to my satisfaction. I consent voluntarily to participate in study.

Signature / Thumb impression of the

Participant/Guardian in case of minor Name of the interviewer

Date:

Signature of witness

ANNEXURE II

Individual questionnaire

TB DEFAULT QUESTIONNAIRE

The questions ask about factors associated with default among new sputum positive pulmonary tuberculosis cases treated with DOTS under RNTCP, as your age, whether you are a male or female, and so on. Your answer will be looked at by people who are trying to learn more about why you became default and will be compared with other studies in other parts of the world.

If this study is to be helpful, it is important that you should answer each question as carefully as possible. All your answers will be kept strictly confidential and we are not asking you your name. Most people enjoy filling in this questionnaire, and we hope that you will too. Be sure to read the instructions before you begin to answer.

INSTRUCTIONS

This is not a test: there is no right or wrong answers, but please answer carefully.

For each question pick the answer that fits you the best and circle the choice as shown below. Pick only one answer for each question. Look at the example below.

Have you drunk any water during the last 30 days?

A No

B Yes, on 1-5 days

C Yes, on 6-9 days

D Yes, on 20 or more days

The answer chosen was "D", indicating that the person who answered the question had drunk water on 20 or more days during the previous 30 days.

Patient ID number:

Case status	1. Case	2. Control	
A. I would like to you a few question about yourself and household			
Questionnaire items	**Options**		**Coding**
1. Sex	1. Male	2. Female	
2. What is your age (In years)?			
3. What is your religion?	1. Hindu	2. Muslim	
	3. Christian		
4. What is your Caste?	1. ST	2. SC	
	3. OBC	4. General	
5. How many people are in your household?	1. <5	2. >5	
6. What is your family income (Rupees per month)?	1. <5000	2. >5000	
7. What is your marital status?	1. Married	2. Unmarried	
	3.Divorce/Separated	4. Widow	
8. What is your literacy level?	1. Illiterate	2. Primary	
	3. Middle	4. Higher secondary	
	5. Graduate or above		
9. What is your occupation?	1. Agriculture	2. Laborer	
	3. Government service	4. Student	
	5. Housewife	6. Private service	
	7. Unemployed	8. Others/Business	
B. I would like to ask you a few questions related to			

treatment of tuberculosis			
10. Did you find timing of DOTS convenient?	1. Yes	2. No	
11. Finding the location of DOT center convenient?	1. Yes	2. No	
12. To attend the DOT center, affected your working hours?	1. Yes	2. No	
13. What is your mode of travel?	1. By foot/walk	2. By bicycle	
	3. By two wheeler	4. By bus/four wheeler	
	5. others		
14. Time taken to reach the treatment centers and collect DOT (in minutes)?	1. <60	2. 60-120	
	3. 121-180		
15. Distance of DOTS center from your home (in Km)	1. <2	2. 2.1 to 4	
	3. 4.1 to 6	4. 6.1 to 8	
	5. 8.1 to 10	6. >10	
16. Were you satisfied with the interaction with DOT provider?	1. Yes	2. No	
17. Is sufficient time given to clarify the doubts during the treatment?	1. Yes	2. No	
18. Did you face any side effect of drugs during treatment?	1. Yes	2. No	
19. If yes, what type of side effect?	1. Nausea/Vomiting	2. Itching/Rashes	
	3. Discoloration of urine	4. Loss of sleep	
	5. Worsening of symptoms		
20. Did you consume	1. Yes	2. No	

alcohol during the treatment?			
21. If yes, how many alcoholic drinks did you consumed in an average per week?	1. >14	2. 7 - 13	
	3. <7		
22. For defaulter, did you take treatment elsewhere after stopping the treatment from Govt. hospital?	1. Yes	2. No	
23. If yes. Where did you take the treatment?	1. Private doctors	2. Other Govt. Hospitals	
	3. Quacks		
C. I would like to ask you a few question related to knowledge, and attitude about tuberculosis			
24. Did you know about tuberculosis prior to acquiring it	1. Yes	2. No	
25. If yes through what?	1. Media	2. Print	
	3. TV	4. Radio	
	5. Others		
26. Knowledge about the name of the disease?	1. Yes	2. No	
27. Knowledge about the causation of tuberculosis?	1. Infectious agent	2. Curse of God	
	3. Unhygienic condition	4. Hereditary	
	5. do not know		
28. Knowledge about the mode of tuberculosis transmission?	1. Droplets (coughing)	2. Water	
	3. Food	4. Do not know	
29. Is the tuberculosis curable with proper treatment?	1. Yes	2. No	
30. For how many months, are required to cure TB with treatment?	1. <1 month	2. 1-3 month	
	3. 4-5 months	4. 6-7 months	
	5. Do not know		

31. Did you hide the disease from family and society?	1. Yes	2. No	
32. If yes, why did you hide the disease	1. afraid of rejection from society	2. Feeling shy	
	3. Others	4. Do not know	

Section II

Literature Review

Review of Literature:

We reviewed different literature using manual and computerized methods to identify a set of potentially useful articles and books from National Institute of Epidemiology, Chennai; we developed questions of the research and for further research. We searched Pub Med (www.pubmed.gov), MEDLINE[1] important sources. After reviewing all relevant literature available and studied, we constructed the outline of the review of literature.

Background: Tuberculosis is a specific Infectious disease caused by tubercle bacilli of Mycobacteriaceae family - Mycobacterium tuberculosis (MTB). The disease primarily affects the lungs and causes pulmonary tuberculosis. It can also affects intestine, meninges, bones and joints, lymph glands, skin and other tissues of the body. The disease is usually chronic with varying clinical manifestations. Tuberculosis remains the primary killer of adults in developing countries despite the existence of cost – effective tools that can cure the disease.[2]

PROBLEM STATEMENT

World: Globally, there were an estimated 9.2 million new cases of pulmonary tuberculosis (TB) in 2006, of which 4-5 million were new sputum smear positive cases.[2] More than 44% of the cases reported in 2006 were from Asia and Sub-Saharan Africa.[2] TB accounted for a loss of 46.5 million DALYs globally. It was 3.4% of the total DALYs loss in the world. 95 % of TB cases and 98 % of TB deaths are in developing countries. 75 % of TB cases in

developing countries are in the economically productive age group (15-50 Years).[3]

World Health Organization (WHO) introduced the Revised National Tuberculosis Control Programme (RNTCP) based on DOTS (Directly Observed Treatment, Short-Course) strategy worldwide in 1993.[3] The major thrust of RNTCP was achieving a cure rate of more than 85% among new smear-positive patients and detecting at least 70% of such cases.[4] Approximately 187 countries with population coverage of 89% adopted this strategy by 2005.[5] Although more than 26 million TB patients have been treated under WHO strategy, the world's TB control programme narrowly missed their 2005 targets for case detection (reaching 60% compared to the target of 70%) and cure (84% compared to the target of 85%).[4] Inability to complete the prescribed regimens among patients is common in self-administered treatment. The adoption of DOTS has given impressive results with higher treatment success being reported from developing countries.[9] However, an efficient network of health infrastructure with committed treatment organization is key for the success of DOTS. (REF of RNTCP manual)

India: India accounts for one third of the global TB burden.[6] Approximately 1.8 million people develop TB in India every year, of which about 0.8 million are new sputum smear positive cases. Despite being completely curable, TB kills more than 400,000 people in India every year.[6] Over 600,000 Indians are unaware that they suffer from TB. India saw TB case detection rates increased by 10%-12% in 2001-2005. It fell to 5% in 2006. It is estimated that

about 6-8% of all new TB cases are in the paediatric age group,[2, 6, 7] 5% of all new cases are MDR in India. TB can be expected to develop in more than 50% of those who encounter HIV.[4] Spread of TB is deeply connected with poverty in India.[4] More than 100,000 women with TB are abandoned by their families every year, making it a major deterrent to women's empowerment. More than 300,000 children are forced to leave school every year; because their parents have TB.[4] Every year TB costs India more than $ 3 billion. India alone accounted for 23.3% (10.8 million) DALYs.[6] Since 1993, the Government of India (GOI) had been implementing the WHO-recommended DOTS strategy through the RNTCP. The revised strategy which was pilot-tested in 1993 in five sites in different states (Delhi, Kerala, West Bengal, Maharashtra, and Gujarat), [6] was launched as a national programme in 1997. By March 2006, the programme was implemented nationwide in 633 districts, covering 1114 million (100%) population.[6] In India, in 2006[7] the cure rate among new sputum smear-positive cases registered under DOTS was 84% with a default rate of 6.2%.

THE CONTROL OF TUBERCULOSIS: The history of tuberculosis (TB) control provides a fine example of the role of understanding basic public health principles in controlling a devastating communicable disease. The lessons learnt from the triumphs and failures of TB control over the last 50 years illustrate the importance of a multi disciplinary approach to disease control, encompassing epidemiology, health service management, social and behavioral sciences, pharmacology, clinical medicine, microbiology, and political science. The remarkable strides made in the last 50 years owe much

to this co-coordinated approach, and have culminated in the development of the DOTS strategy.[6]

PRINCIPLES OF TB CONTROL: The basic principle of TB control is extremely simple; prevent transmission of the infectious agent causing disease. The infectious agent causing TB is the tuberculosis bacillus; Mycobacterium tuberculosis, and the commonest route for getting from one person to the other is from lung to lung through the air. Other routes (for example, in cow's milk) ore much less important, and contribute only a small proportion to the global TB epidemic. People with TB of the lungs produce tiny droplets of TB bacteria into the air, whenever they cough, sneeze, talk or even breathe. These droplets can infect other people and give them TB. A person with infectious TB of the lungs cans infect10- 15 people a year. There are therefore, three opportunities for interrupting trans. mission of the TB bacillus; at the source, in the air, and at destination .All current strategies to control TB work at one of these points. [7]

National Tuberculosis Programme (NTP): During the 1950s and 1960s, significant research on tuberculosis was undertaken in India, and in 1962 the National Tuberculosis Programme has been in operation. It is essentially a permanent countrywide programme, integrated with the general health services at both the rural and urban levels. The District Tuberculosis Programme (DTP) is the backbone of the National Tuberculosis Programme. It was evolved by the National Tuberculosis Institute, Bangalore, and was accepted by the Government of India for implementation, which started in

1962.[7]

The long-term goal of the NTP is "to reduce the problem of tuberculosis in the community sufficiently quickly to the level where it ceases to be a public health problem". [7]

The short-term objectives were

1. To detect maximum number of TB cases among the outpatients attending any health institutions with symptoms suggestive of tuberculosis and treat them effectively.
2. To vaccinate newborns and infants with BCG
3. To undertake t6he above objectives in an integrated manner through all the existing health institutions in the country.

There was overdependence on X-rays for diagnosis. Incomplete treatment was the norm rather than the exception. The 1992 review revealed that only 30% of existing TB cases was being diagnosed, and these only 30% were completing treatment.

The Revised National Tuberculosis Control Programme (RNTCP): The Government of India, WHO and World Bank together reviewed the NTP in the year 1992. Based on the findings of that review a revised strategy for NTP was evolved. The programme was expanded in a phased manner to cover the entire country in 2005. By June 2005, over one billion of the population was covered under RNTCP.

Structure of the RNTCP: The RNTCP is lead by Central TB division (CTD) in the Ministry of Health and Family Welfare, Govt. of India in Delhi. The state,

district and sub-district levels and peripheral health institution implemented the programme.

Central TB division: At the Ministry of health and family welfare, the control TB division is responsible for TB control in the entire country. The Deputy Director General (DDG-TB) is the national programme manager. The main functions of the CTD are to formulate technical policy, plan, implement, monitor and coordinate the programme at the national level.

State level: At the State level, a State TB Officer (STO) is responsible for planning, training, implementing, monitoring and coordinating the programme. A State Tuberculosis Control Society (STCS) has been established for increased state ownership and accountability and also for the smooth transfer of funds from CTD to the state and to districts.

District Level: The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district and also functions as a specialized referral centre. There is a District TB Control Society (DTCS) in every RNTCP district. It is responsible for budgeting and providing financial resources and also for monitoring the programme implementation. It also arranges necessary logistics such as transport, hiring of contractual staff and procurement of materials including laboratory consumables. The District Collector is the Chairman and the District Tuberculosis Officer (DTO) is the Member Secretary. The DTCS has representatives from government and non-government sectors. The DTO has the overall responsibility to implement the programme at the district level and is assisted by a Medical Officer and other technical and administrative staffs.

Sub-district level: A team comprising of a designated Medical Officer-Tuberculosis (MO-TC), a senior Treatment Supervisor (STS) and a Senior TB Laboratory Supervisor (STLS) is based at the Tuberculosis Unit (TU). This is the sub-district unit of TB control activities and is usually based in health institution such as Community Health Centres (CHC), Public Health Centres (PHCs). The sub-district covers a population of approximately 500,000 (250,000in hilly, tribal and difficult areas) and is responsible for TB control activities at this level. The TU is also responsible for accurate maintenance of TB register and for preparing quarterly reports.

Designated Microscopy Centre: Designated Microscopy Centres (DMC) is usually situated at tertiary and secondary level health care institutions and PHCs or other equivalent institutions including private and NGO facilities. DMC will have doctors and laboratory technicians trained in RNTCP. The laboratory of the DMC will have adequate facilities such as an ESI hospital, a private nursing home, an NGO hospital, etc. However, certain criteria should be followed while designating laboratories as RNTCP DMCs. In addition, all DMCs should be included in the standard RNTCP External Quality Assessment (EQA) system.

The laboratories must have sufficient workload to justify being a DMC. The DMC either must be covering a population of 100,000, or having 60-100 new adult outpatient attendance per day. The laboratory technicians must be examining an average of at least 3-5 smears and not more than 20-25 smears per day. This will ensure an optimum workload in the lab to maintain proficiency of the laboratory technicians. Hence a limited number of the

laboratories could be DMCs and there would be either a referral system to these laboratories by the private practitioners for sputum smears examination, and a referral between the labs either of TB suspects or samples.

Peripheral Health Institutions: For the purpose of RNTCP, a PHI is a health facility which is manned by at least a medical officer. At this level are the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics/ hospitals/ TB hospitals/ Medical colleges within the district. All health facilities in the private/NGO sector participating in RNTCP are also considered as PHIs under the programme. Some of these PHIs will also be DMCs. All PHIs with/without DMCs should submit a monthly PHI level report to the respective TUs and the district.

Public Private Mix (PPM): India has one of the largest private health care sectors in the world. This sector is often the first point of contact for significant number of TB suspect and patients. Other sector like non-governmental organization (NGO), corporate sector, etc, also cater to a considerable percentage of TB patients. Because of their flexibility and easy accessibility, these service providers have gained credibility and are popular among patients.

Goal of RNTCP: The goal of RNTCP is to decrease mortality and morbidity due to TB and cut transmission of infection until TB cases to be a major public health problem. It aims to control TB by detecting and curing sputum smear-positive patients thereby interrupting the chain of transmission. The objectives of RNTCP are to achieve and maintain a cure rate of at least 85% among new sputum smear positive cases and to achieve and maintain detection of at

least 70% of such cases in the population. The only effective means to achieve means to achieve the goal of RNTCP is the application of DOTS strategy.

The five major components of DOTS are:

1. Administrative and political commitment to sustained TB control activities
2. Case detection by quality sputum smears microscopy among symptomatic patients self-reporting to health services.
3. Standardized regimens of six to eight months treatment at least for all confirmed sputum smear positive cases, with directly observed treatment (DOT) for the initial two months
4. A regular, uninterrupted supply of all essential anti-TB drugs
5. A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control programme overall

The revised strategy has been introduced in the country as a Pilot Project since 1993. During Phase I it has covered 2.35 million people, phase II 13.85 million people, and now in Phase III, it is envisaged to extend the project area covering a total of 271.21 million people. The objective of RNTCP is (1) achieve & maintain 85% cure rate of newly detected sputum positive cases and (2) to achieve & maintain detection of at least 70% of new smear positive cases. Presently the programme has entered in its second phase and the aims are 1) to consolidate the gain of 1st phase 2) widen the services in respect of activity and accessibility and 3) to sustain the effects.[8]

Case detection: Under the RNTCP, active case finding will not be pursued. Case findings will be passive. Patients presenting themselves with symptoms

suspicious of tuberculosis will be screened through sputum smear examinations. Supervision and monitoring were strengthened under the project. Supervisory teams per 500,000 populations in urban areas and per 300,000 populations in rural areas were constituted each consisting of a senior TB supervisor and senior laboratory technician.

Standard 1: All persons with otherwise unexplained productive cough lasting two-three weeks or more should be evaluated for tuberculosis.

Standard 2: All patients (adults, adolescents, and children who are capable of producing sputum) suspected of having pulmonary tuberculosis have at least two and preferably three, sputum specimens obtained for microscopic examination. When possible, at least one early morning specimen should be obtained.

Standard 3: For all patients (adults, adolescents, and children) suspected of having extra pulmonary TB, appropriate specimens from the suspected sites of involvement should be obtained for microscopy and, where facilities are available, for culture and histopathological examination.

Standard 4: All persons with chest radiographic findings suggestive of tuberculosis should have sputum specimens submitted for microbiological examination.

Standard 5: The diagnosis of sputum smear-negative pulmonary tuberculosis should be based on the following criteria: at least three negative sputum smears (including at least one early morning specimen); chest radiography findings consistent with tuberculosis; and lack of response to a trial of broad-spectrum antimicrobial agents. For such patients, if facilities for culture are

available, sputum culture should be obtained. In persons with known or suspected HIV infection, the diagnostic evaluation should be expedited.

Treatment part: All patients will be provided short-course chemotherapy free charge. During the intensive phase of chemotherapy all the drugs will be administered under direct supervision called Directly Observed Therapy Short-course (DOTS). DOTS are a community-base tuberculosis treatment and care strategy, which combines the benefit of supervised treatment, and the benefits of community-based care and support. It ensures high cure rates through its three components, appropriate medical treatment, supervision and motivation by health or non-health worker, and monitoring of disease status by health services. DOTS will be given by peripheral health staff such as MPWs, or through voluntary workers such as teachers, anganwadi workers, Dais, ex-patients, social workers etc.[8] Categories of Treatment

Categories of Treatment: (RNTCP)

Category of treatment	Type of Patient	Regimen*
Category I	New sputum smear- positive	2H3R3Z3E3 + 4H3R3
	Seriously ill** new sputum smear-negative	
	Seriously ill** new extra-pulmonary	
	All HIV/TB patients	2H3R3Z3E3S3+ 1H3R3Z3E3+
Category II	Sputum smear-positive Relapse	5H3R3E3
	Sputum smear-positive Failure	
	Sputum smear-positive Treatment After Default	
	Others***	
Category III	New sputum smear- negative, not seriously ill	2H3R3Z3+ 4H3R3
	New Extra-pulmonary, not seriously ill	

**The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh more than 60 kg receive additional rifampicin 150 mg. Patients more than 50 years old receive streptomycin 500 mg. Patients in categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.*

***Examples of seriously ill extra-pulmonary TB cases are meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications and intestinal and genitor-urinary TB.*

****In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active tuberculosis. In these cases, the patient should be categorized as 'Other' and given Category II treatment.*

Treatment outcome: (RNTCP definition)

Cured: Initially sputum smear-positive patients who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at the end of treatment.

Treatment completed: A sputum smear-positive patient who has completed treatment with negative smears at the end of IP but none at the end of treatment.

Died: Patient who died during the course of treatment, regardless of the cause of death.

Failure: Any TB patient who is smear-positive at five months or more after starting treatment.

Transferred out: A patient who has been transferred to another TB unit or district and for whom the treatment result (outcome) is not known.

Defaulted: A patient who has not taken anti-TB drugs for two months or more consecutively after starting treatment.

Defaulting from treatment has been one of the major obstacles to treatment management and an important challenge for tuberculosis control.[8] Inabilities to complete the prescribed regimens among patients are common in self-administered treatment.[8] Over the years there has been increasing emphasis on DOTS to ensure treatment adherence, where in each dose of treatment is given under the observation of a health worker. The adoption of DOTS has given impressive results with higher treatment success being reported from developing contries.[8] An efficient network of health infrastructure with committed treatment organization is most essential for the success of DOTS. The challenges encountered while implementing DOT vary from place to place depending on the geographic terrain, demographic structure and socio-cultural milieu.

Actions for patients who interrupt treatment (Defaulter): One of the principles of RNTCP is that the responsibility of curing the patient lies with the programme and not with the patient. Providers may be too far from where the patient reside or may have inconvenient timings. Patients also tend to discontinue treatment when they improve symptomatically thinking that they are cured of the disease. There can be also socio-demographic and economic causes for discontinuation of treatment. Proper counseling is essential to motivate patients to take the prescribed medications regularly and as per the treatment schedule. The treating practitioner should take the necessary steps to prevent and help retrieve patients who interrupt treatment. The concerned supervisory staff at the sub-district level (TU) should be informed immediately, if efforts by the DOT provider prove to be futile.[13, 14]

If a patient interrupts treatment at any stage during the course of treatment, visits to his/her home should be made to bring them under treatment. This should be done by the concerned DOT provider, or health staffs, no later than the day after the patient was due to come for treatment in the IP and within a week of the missed dose in the CP.

Importance of having low default rate: Compliance with the drug regimen is crucial. Mycobacterium tuberculosis has shown a propensity to mutate towards drug resistance, and defaulting patients almost invariably relapse, often with a drug resistant strain. Retreatment requires more expensive drugs, producing a greater financial burden for either the patient or public health care system. More ever, defaulting patients remain infectious and constitute a danger to their families and the community; this situation is exacerbated

because the infectious organism is then resistant to first-line drugs. Many TB epidemiologists regard obtaining high compliance levels in the population under treatment as even more important to a community's welfare than finding new cases.[14]

Reasons: The reason for conducting the study was, Thoubal district reported high default rate in last seven years. The major factors influencing treatment default in Thoubal district were related to patients' interaction with DOTS provider, timings of the DOTS, side effects of drug and their knowledge about duration of treatment. Default was also high among male alcoholics. Knowledge of these factors would help the district programme managers in planning strategies for increasing treatment compliance and thereby reducing the default. In this study multivariate analysis was performed to identify independent risk factors for default by means of logistic regression.

Many studies conducted in different countries were referred, during my study. The studies were discussed with my findings as given below.

DOTS providers play an important role in administering the supervised treatment and counseling the TB patients about treatment including its duration, frequency and possible side effects. Several studies reported that not providing adequate information to TB patient about the disease and treatment was associated with default (S. J.O'Boyle).[9] Patients' knowledge about duration of treatment was also found to be an important factor associated with defaulting (Arsi Zone in Ethiopia study).[10]

Factors affecting patient compliance with anti-tuberculosis chemotherapy using the directly observed treatment, short-course strategy (DOTS) Sabah, Malaysia.[9]

S. J. O'Boyle,* conducted this study in Kota Kinabalu the state capital of Sabah and its surrounding communities ,Malaysia in the year 2000,to establish factors affecting compliance of patients with anti-tuberculosis chemotherapy, their knowledge of the disease, and views on improving the DOTS strategy.

Tuberculosis is a significant cause of morbidity and mortality in Kota Kinabalu, the State Capital of Sabah, and in 1999 there were 550 new reported cases; giving an incidence of tuberculosis amongst the general population of 175 per 100000 population. There were a total of 142 deaths due to tuberculosis in Sabah: 80% of those affected were Malaysian and 20% were non-Malaysian, and most individuals were aged over 60 years.

Tuberculosis in Malaysia is treated using a combination of four drugs, administered by directly observed therapy at a clinic, in either daily or twice weekly treatment regimens. At the time of this study there were 76 dispensaries and 134 rural health clinics, providing DOTS. Patients are deemed to be non-compliant when they have missed more than 7 consecutive days of treatment. If patients are identified as non-compliant, a specialist defaulter tracing team visits their home address to establish why they have not attended the clinic for treatment. If a patient is not at home messages are left with friends or relatives. If patients subsequently fail to attend they are revisited. Approximately 10% of patients become noncompliant, and the

retrieval rate for such patients is 59%.The aims of this study were to compare compliant and non-compliant patients being treated for tuberculosis in Kota Kinabalu, Sabah, Malaysia, to determine factors that may influence compliance, to establish reasons why non-compliant patients were not attending health facilities, and to seek patients' views on how they thought the system could be improved. This may allow improvements to be made to the administration of the directly observed treatment, short course (DOTS) strategy.

Design: Interviews with compliant patients attending clinics for DOTS treatment and with non-compliant patients in their homes, in August and September 2000. A total of 63 compliant and 23 non-compliant patients were interviewed.

Statistical analysis: The link between compliance status and native origin, hospitalization, sex, having family members who had had the disease, age, occupation, education and the presence of side effects, was assessed using Yates corrected X^2 tests Differences between the compliant and non-compliant groups with respect to income, cost of travel to the centre, amount of time spent traveling to the. Centre and the opportunity cost of traveling to receive treatment compared using the Mann- Whitney test. Logistic regression was used to identify which factors were independently associated with compliance status. Calculations were performed using SPSS version 10.1 for regression and Mann Whitney tests.

Results: For non-compliant patients, reaching the treatment centre entailed greater cost ('$P < 0.005$) and travel time ($P < 0.005$) compared to compliant

patients. Cost of transport was the reason most frequently given for non-attendance. Non-compliant patients were more likely to have completed secondary education ($P < 0.05$), and to be working ($P < 0.01$). More non-compliant patients had family members who had had the disease ($P < 0.01$). There was no difference between the groups for overall tuberculosis knowledge scores; however, non-compliant patients were more likely to think that treatment could be stopped once they were symptom free ($P < 0.01$). Most patients (73%) felt that the DOTS system could be improved by provision of more information about tuberculosis.

Compliance with DOTS in the Kota Kinabalu area is affected by travel expenses, time spent traveling to treatment centres, and having family members who have had the disease. Patients would like more information on tuberculosis.

Limitation in this study: The patients in the compliant group were at various stages in their treatment, and it is possible that some may become noncompliant later. This would have reduced the differences found between the groups. Further, the study included only the patients whom they could trace among non-compliant patients this might have produced the selection bias in this study.

Defaulting from DOTS and its determinants in three district of Arsi Zone in Ethiopia.[10]

B Tekle, DH Mariam, and A Ali studied with the objective to determine the rate of defaulting from DOTS for tuberculosis and identify associated factors. The design of the study was a case control study. Records of 1367 New TB

patients put on DOTS during a period of 30 months (1 July 1997-31 December 1999) were reviewed to determine the defaulting rate. Cases were defaulter and controls were selected by paired matching of sex and age using the lottery method. The results were that the defaulting was highest (81%) during the continuation phase of treatment. Medication side effects were significantly associated with defaulting (OR=4.20, 95%CI=1.51-11.66), while adequate knowledge and support were found to be possible protective factors (OR=004, 95%CI=0.02-0.1) and (OR=0.19, 95%CI=0.08-0.46 respectively). The conclusion of the study was that the major factors contributing to high rates of defaulting were found to be lack of family support, inadequate knowledge about treatment duration and medication side effects.

Symptoms of TB often disappear within few months of starting the anti-Tuberculosis treatment. TB patients, if not counseled about the duration of the treatment and the need for taking medicine for entire duration, is likely to equate the disappearance of tuberculosis symptoms with cure of the disease. Counseling during the initial contact is thus a key for ensuring proper compliance to treatment and thereby reducing the default. (Ref of RNTCP manual, Madagascar study).[10, 11]

Factors determining compliance with tuberculosis treatment in an urban environment, Tamatave, Madagascar[11]

The study (T. M. Comolet,* et al) was a retrospective case-control study conducted in Madagascar (Country lying off the southeastern coast of Africa) in the year 1995 to have a better understanding of the various factors

accounting for treatment default. The study had two aims: 1) to identify the risk factors associated with default inherent in their system, in order to propose suitable, effective operational changes within that system; and 2) to identify predictive factors associated with patient default (i.e., personal risk factors for defaulting from treatment' detectable in the patients themselves), in order to be able to devote particular attention to those subjects at risk and thus reduce the number *of* patients who interrupt their treatment in an untimely fashion. Active tracing of all patients who defaulted from treatment in 1993 was undertaken in two cities in Madagascar, using a standardized questionnaire, in order to perform a retrospective study of factors that could explain their action. In order to check whether the factors are truly explanatory, the same questions were asked of matched controls, who were patients treated at the same time in the same centers, but who had followed their treatment for the full duration (there were three 'treatment completed' controls per 'treatment not completed' defaulter). Thus, Risk factors for default were assessed by a retrospective case-control study in a sample of 38 patients who had not completed treatment for pulmonary tuberculosis, compared with 111 controls that had completed treatment under comparable conditions. In this case-control study, 'lost to follow-up / treatment not completed' patients were defined as those cases with smear-positive pulmonary tuberculosis that had interrupted their treatment for more than a month before the end of the prescribed regimen (12 months, according to the national guidelines). 'Control' patients also had smear-positive pulmonary tuberculosis' but had completed the whole of their treatment without

interruption. The controls had begun their treatment during the same year as the previous group, and had followed the same I2-month regimen; even those individuals who did not have the final smear test to prove cure were included in the study. A list of possible determining factors was drawn up, based on the views of the health personnel and public health administrators involved in tuberculosis control. Using the list as a base, a series of questions that were designed in order to identify each potentially determining factor. Different kinds of determinants were studied: objective socio-demographic factors, subjective psychological factors, attitudes and behavior of patients in relation to chemotherapy, quality of relationships with the medical\ staff, knowledge and attitudes regarding tuberculosis. The results obtained were analyzed using Epi Info version 5.3.1 (CDC, Atlanta) in order to identify any significant differences between the two groups. Correlations were analyzed using the uncorrected *X2* test; wherever numbers were below 5, Fisher's exact test is used. No multivariate analysis was performed to study the correlation between the determinants themselves. Results shows that, default appears to be significantly linked to transportation time, the sex of the patient, patient information and the quality of communication between patients and health workers. False addresses given by patients are both a methodological bias and a risk factor for future default.

Limitation in this study: In analysis, the odds ratio, and 95%CI were given only for factors which were significant .It could have been more useful, if they had given OR the odds ratio, and 95%CI for all the factors. Further they have used uncorrected x^2 which could give an over estimation of significant results.

In Thoubal district, 45 of the 60 DOTS providers were health workers working in various public health facilities while 15 were neighborhood DOTS providers. Health workers administered TB drugs during OPD hours. Inconvenient DOTS timing was found to be an important risk factor for treatment default in the district as well as in several other studies (Bangalore city study).12

Default among Tuberculosis patient treated under DOTS in Bangalore City" A search for solution.[12]

Sophia Vijay, VH Balasangameswara, PS Jagannatha, VN Saroja and P Kumar conducted the study with an objective to identify socio-demographic and treatment related risk factors predictive of default with DOTS. The design was a retrospective case control analysis of the data obtained from the cohort study of 264 new (CAT1) and 219 retreatment (CAT2) bacteriological positive patients treated under DOTS from March 1999 to September 2000 and followed up till treatment outcome, The results were that the predictive factors associated with default identified through multivariate logistic regression were males (AOR: 2.99; 95%CI: 1.1.-6.18)- CAT-1, 2.78 (1.15-6.7)- CAT-2, and alcoholism (AOR=6.38(3.25-12.5)-CAT-1, 3.93(2.1-7.3)-CAT-2, and in addition, patients having poor knowledge of tuberculosis (AOR=3.06(1.24-7.54)-CAT-2. The conclusion of the study was that males and alcoholics are predictive risk factors of default with DOTS in an urban setting, and having poor knowledge of disease are additional risk factors.

Alcoholism, which was identified as independent risk factor for non-compliance in our study. Sustained efforts should be made to counsel and

motivate this group with their family members to ensure family support throughout the treatment period. [15]*(Pakistan study)*

A randomized trial of the impact of counseling on treatment adherence of tuberculosis patients in Sialkot Pakistan.[15]

Here R Leifooghe, C Suetens, H Meulemans, MB Moran, and A De Muynck conducted the study with an objective to determine whether intensive counseling can improve treatment adherence. The design of the study was a randomized controlled intervention trial of 1019 adult tuberculosis patients, 49% were assigned to the intervention group and 51% to the control group. Patients were followed until the end of treatment. The intervention included counseling at the start of treatment and at each subsequent visit for ambulatory patients, or weekly for hospitalized patients. Here they found that the default rate was 54% in the control group and 47% in the intervention group. The default risk ratio was 0.87. The impact was stronger in women, ambulatory patients, re-treatment patients, women who worked in the home, and patients who were not the main provider, those with a poor knowledge of the disease or those with a short treatment delay.

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