Bridging Gaps in Revised National Tuberculosis Control Program at Bankura District, West Bengal State, India

Tapas Kumar Roy[1], Gautam Sarker[2*], Avishek Gupta[3], Shinjini Ghosh[2], Debabrata Sarbapalli[4], Ranabir Pal[5]

[1]Medical Officer, Blood Bank, Deben Mahata Sadar Hospital, Purulia, West Bengal, India
[2]Department of Community Medicine, MGM, Medical College & LSK Hospital, Kishanganj, Bihar, India
[3]Department of Community Medicine, Midnapur Medical College, West Bengal, India
[4]Pro Vice Chancellor, West Bengal University of Health Sciences, Kolkata, India
[5]Department of Community Medicine and Family Medicine, All India Institute of Medical Sciences, Jodhpur, Rajasthan, India
*Corresponding author: dr.gsarker@gmail.com

Abstract   **Background:** Tuberculosis distresses economically productive age groups and emerged as a noteworthy reason of global burden. **Objectives:** The study was undertaken to find the gaps at the level of patients, or health providers in implementing RNTCP and also find out the reasons therein. **Methods:** This study was carried out among all patients enrolled as pulmonary tuberculosis cases in DOTs register of Tuberculosis Unit (TU) of a tertiary care teaching institute in eastern India in the third quarter of the year 2011. **Results:** Majority of cases (56.61%) belonged to 35-54 years age group, male (75.47%), from rural areas (64.15%), literacy up to primary (47.18%). Sputum was examined in 75.47 percent cases within 2-3 weeks after onset of cough and 89.62 percent were found sputum positive. DOTs providers completed initial home visit up to 70.75 percent cases; 71.70 percent initiated treatment within seven days after diagnosis. Initial defaulter was in 28.30 percent of cases; Literacy status showed significant difference in timing of diagnosis, initiation of treatment. Significance of difference with and without BPL Card was noted in delay of diagnosis and initiation of treatment. Literacy status was significantly associated with both timing of diagnosis and initiation of treatment. Socio economic status was also found significantly associated with delay in diagnosis and initiation of treatment. First contact with unqualified local practitioner with delay in advising sputum examination in Government health facility, long distances from facility, non-availability of drugs and staffs with refusal to supply drug, inconvenient timing of clinic, fear from social stigma and fear of side effects of drugs with long duration of treatment were cited as negative issues in treatment. **Conclusion:** Initiation and continuation of treatment of TB is related with socio-demographic correlates that needs counselling & motivation for early intervention.

Keywords: defaulter, initiation, tuberculosis

1. Introduction

Across the world with transition of psycho-socio-economic milieu, there is re-emergence of *tuberculosis* (TB) hand-in-gloves with dual pandemic of HIV/AIDS and Diabetes Mellitus. Now TB is among the commonest global infectious diseases contributing huge morbidity and mortality with Pulmonary TB as its commonest form. Early and accurate diagnosis is vital for both the patient's well-being and for the community as undiagnosed patients spread the disease. As per World Health Organization, in 2009 there were 9.4 million new cases of TB globally killing nearly 1.7 million people, 85 percent from Asia and Africa. India accounted for 21 percent of all TB cases worldwide. [1, 2] Among the notified new and relapse cases, in 2009, new sputum positive pulmonary cases were 62 percent, Case Detection Rate was 83 percent,

Incidence Rate 2000/100,000 population, Prevalence Rate 3000/100,000 population, HIV positive cases 6.4 percent and Mortality Rate 280/100000population. [1] The Revised National Control Programme (RNTCP) was launched in 1997 in India based on a WHO recommended strategy of Directly Observed Treatment Short Course chemotherapy (DOTs). [2] Yet there are gaps in implementation of RNTCP especially regarding delay in diagnosis, initiation and completion of treatment. Different regions of this country have encountered several types of challenges while implementing RNTCP viz. inconvenient DOTs clinic timings, low case detection rates etc. [3]. Further, rapid and accurate diagnosis of active tuberculosis remains a challenge till date. [4] Researchers also reported that a contributory factor for the low case detection rate under DOTs especially in the metropolitan areas is that, many patients prefer to be treated in the health facilities other than DOTs clinics. Thereby RNTCP recently developed strategies to involve all relevant public health

care providers on RNTCP panel. [5] In this background the present study was undertaken with to determine the gaps at the level of patients, or health providers in implementing RNTCP and also find out the reasons for the lacunae in the ongoing RNTCP activities in the study area.

2. Materials and Methods

An observational descriptive cross-sectional study was carried out in the third quarter (July to September) of the year 2011 among 106 outpatients enrolled as pulmonary tuberculosis cases in *tuberculosis* (TB) register of Bankura Sammilani Medical College (BSMC) –Tuberculosis Unit (TU). This TU serves hinterlands of two rural areas (Bankura Block 1 and Block 2) and one urban area (Bankura Municipality) of Bankura district, West Bengal. Study variables were age, gender, literacy, occupation, residence, socio-economic status according to possession of BPL card, time interval between onset of chest symptoms and collection of sputum, sputum smear examination result, time interval between diagnosis and initiation of treatment, factors causing delay in diagnosis and initiation of treatment after diagnosis.

2.1. Study Tools

a) predesigned, pretested, semi structured questionnaire for patient, b) predesigned semi structured questionnaire for health staffs, c) TB Register, d) Treatment card, e) TB Laboratory Register, f) TB Register for outpatients, g) Directly observed therapy – short course (DOTs) Directory and h) Other Medical Records.

2.2. Data Collection Technique

Necessary ethical clearance was obtained from the institutional ethics committee and informed consent was obtained from each of the participants. Information was collected by interviewing patients, review of relevant records and key staff of the Tuberculosis Unit. All patients were registered by concerned health staff and treatment was started from this DOTS Centre; otherwise they were referred to the nearest Sub centre according to their residential address to initiate thrice weekly regimen. After being registered a DOTs directory was also available in DOTs Centre and a TB Register was kept in the District Tuberculosis Centre that was also reviewed to obtain essential information about registered patients. Participants were interviewed in DOTs Centre on every Wednesday & Friday using predesigned, pretested semi-structured questionnaire prepared in local language and were custom-made for the study by piloting to affirm validity, feasibility, applicability and practicability for the respondent to answer the questions that contained factors responsible for delay in diagnosis and initiation of treatment. The study tool was developed with assistance from Faculty members and Statistician of the department of Community Medicine, Bankura Sammilani Medical College. Information was collected from the DOTs providers of various sub centres under Bankura Block-I & Bankura Block-II BPHC every Monday using abovementioned questionnaire on the registered TB cases [using DOTs Directory] after being briefed by the investigators. The sub centres were also visited by the investigators on every Monday for obtaining information using same questionnaire. Information was also obtained from key health staffs like Senior TB Treatment Supervisor and Senior TB Laboratory Supervisor of BSMC-TU by interview about functioning of TU.

2.3. Operational Definitions

Smear-positive pulmonary TB: A patient with one or two smears positive for AFB out of the two sputum specimens subjected for smear examination by direct microscopy. [6]

New Cases: A TB patient who has never had treatment for TB or has taken anti-TB drugs for less than one month. [6].

Initial default: New diagnosed sputum smear positive TB patient who has been recorded in RNTCP Laboratory Register, but neither been placed on RNTCP regimen within seven days of diagnosis nor referred for treatment under the RNTCP outside the district. [7]

DOTs Centre: The place of provision of free anti-TB drugs under supervision by a designated provider under the RNTCP.

2.4. Statistical Analysis

The collected data were screened and entered into Microsoft Excel spreadsheet and then analyzed using Statistical Package for the Social Sciences (SPSS) for Windows Version 19.0 (SPSS Inc.; Chicago, IL, USA). Chi Square test was applied to find statistical difference between variables; $p < 0.05$ was considered as statistically significant.

3. Results

Majority of the participants of study (56.61%) belonged to 35-54 years age group followed by 15-34 years group (35.85%), male (75.47%), from rural areas (64.15%), literate up to primary (47.18%); 39.62 percent belonged to BPL category. Sputum was examined in 75.47 percent cases within 2-3 weeks after onset of cough and 89.62 percent were found sputum positive cases. DOTs providers completed initial home visit up to 70.75 percent cases; 71.70 percent initiated treatment within seven days after diagnosis [Table 1].

Table 1. Relation of Sputum Examination with Onset of Cough, Home Visit, Initiation of Treatment

Sputum examination time	Number	Percent
2-3 weeks after cough	80	75.47
> 3 weeks after cough	26	24.53
Sputum Smear Result		
Sputum positive	95	89.62
Sputum negative	11	10.38
Initial Home Visit By DOTS Providers		
Yes	75	70.75
No	31	24.25
Initiation Treatment After Diagnosis		
Within 7 days	76	71.70
> 7 days	30	28.30

Initial defaulter was in 28.30 percent of cases; Literacy status showed significant difference in timing of diagnosis

[χ2 value=27.53, and p value= 0.000], initiation of treatment. [χ2 value=9.89, and p value= 0.007]. Significance of difference with and without BPL Card was noted in delay of diagnosis between study population [χ2 value=8.184, and p value= 0.004] and initiation of treatment. [χ2 value=11.26, and p value= 0.000] Literacy status was significantly associated with both timing of diagnosis and initiation of treatment (p = 0.000 and 0.007 respectively). Socio economic status of study population was also found significantly associated with delay in diagnosis and initiation of treatment. p values were 0.004 and 0.000. According to opinion of study population (26), 30.77% of study population to whom diagnosis was delayed made first contact with unqualified local practitioner. Delay in advising sputum examination in Government health facility was present in 30.77% of cases, Delay in advising repeat sputum examination as per RNTCP was present in 23.07 percent of cases and Location of DOTs Microscopy Centre far from residence was present in 15.39 percent of cases. As per opinion of the study population (30), 33.33 percent opined that non availability of drugs on day of visit was the main cause of delay in initiation of treatment. DOTs time was inconvenient in 23.33 percent cases. Non availability of staffs or refusal to supply drug and fear from social stigma was observed in 13.34 percent cases and fear from side effects of drugs and long duration of treatment 16.67 percent [Table 2].

Table 2. Literacy and Socioeconomic Status of Study Participants (N=106)

Correlates	Diagnosed as per RNTCP		Total (n=106)	Statistical Analysis		
				χ2value	df	P value
Literacy status						
	Yes	**No**				
Illiterate	6(30.00)	14(70.00)	20	27.53	2	0.000
Primary	43(86.00)	7(14.00)	50			
Secondary and above	31(86.12)	5(13.88)	36			
Initial Defaulter						
	Yes	**No**				
Illiterate	12(60.00)	8(40.00)	20	9.89	2	0.007
Primary	15(30.00)	35(70.00)	50			
Secondary and above	7(19.44)	29(80.56)	36			
Socio Economic Status						
Socio economic status as per BPL Card	**Diagnosed as per RNTCP**					
	Yes	**No**				
Yes	17(40.48)	25(59.52)	42	8.184	1	0.004
No	9(14.06)	55(85.94)	64			
Initial Defaulter						
	Yes	**No**				
Yes	20(47.62)	22(52.38)	42	11.26	1	0.000
No	10(15.63)	54(84.37)	64			

(Figure in parenthesis indicates percentages).

4. Discussions

National Tuberculosis Control Program was launched in India since 1962. Initial default indicates low capacity of the program to find the patient and inform about diagnosis. Initial default of smear positive cases can be easily measured as the results and address or origins of the samples are recorded in the laboratory register. [8,9,10] RNTCP is based on the internationally recommended DOTs strategy, was launched in 1997 and expanded across the country in a phased manner. Full nationwide coverage was achieved in March 2006. The goal of TB control Programme is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem in India. The twin objectives of the Programme were to achieve and maintain a cure rate of at least 85 per cent among new sputum positive (NSP) patients, and to achieve and maintain case detection of at least 70 per cent of the estimated NSP cases in the community. [11,12] Medical Officers of health care facilities (governmental or non-governmental) need to identify all pulmonary TB suspects and refer them for sputum examination following which diagnosed cases are put on treatment within seven days. TB patients are classified into two groups before treatment. Group 1. New cases- all new pulmonary smear positive and negative cases, extra pulmonary and others TB patients are put on Category-I regimen consisting of two months of intensive and four months of continuation Phase. Group 2. Previously treated - includes sputum positive failure, relapse, treatment after default and others are put on Category-II regimen consisting of three months of intensive and five months of continuation Phase [13].

Age:

Among the participants, 56.61 percent belonged to 35-54 years and 35.85 percent in 15-34 years age group. Sen T K *et al* noted that 71 percent belonged to 15-44 years group. [3] In a study in the north-eastern India overall 90.76 percent of the participants were in the age group of 15 to 55 years. [4] Kesarwani P *et al* study revealed that half of the study participants were from 15-35 years age group followed by 42 percent from 36- 55 years age-group. [14].

Gender:

In our study 75.47 percent of TB cases were male. Sen T K *et al* observed 73 percent male [3] and Kesarwani. P *et al* 51 percent male in their studies. [14] In the study reported from Assam, there were more males (59.18%) than females (40.82%) who had reported to the health institution within first 6 weeks after the onset of symptom & among them altogether 91.84 percent were declared cured after completion of therapy [4].

Rural-Urban Divide:

In the present study indicated that 64.15 percent study population resided in rural areas were affected by TB. We are yet to find comparable reported literature from India.

Literacy:

Literacy status of study population was poor; 47.18 percent were literate up to Primary and 18.86 percent were illiterate. School dropout rate was quite high in the present study area. Sen T K *et al* showed that 67 percent of TB cases were either illiterate or did not cross primary level of education. [3] Similar proportion was found by others. [15]

Socio-Economic Conditions:

In the study population 39.62 percent of study population were belonged to BPL category. 73 percent had family income up to Rs.2000 and none above Rs.5000; 88 percent were either unemployed or casually employed Sen TK et al [3] In a study in Assam majority of them were unskilled workers and were the sole earning member of their family with more than half of new sputum positive TB cases were among the illiterate and underprivileged population who needs counselling for motivation for early intervention. [4] In another study, 65 percent of the study subjects belonged to middle class, while those belonging to upper-middle and lower middle were 20 percent and 15 percent respectively by Kesarwani P et al [14].

BPL Card Holder

Regarding socioeconomic status, 39.62 percent of study population possess BPL Card. This finding was supported by study conducted by Nirupa. C et al in [16].

Sputum Examination:

It was found that advice for sputum examination was not given as per RNTCP. Sputum was examined in 24.53 percent of study population after suffering from cough for more than 3 weeks duration. This finding was supported by study conducted by researchers in 2009 [17].

The present study showed that 89. 62 percent Tuberculosis cases were sputum positive and 10.38 percent of cases were sputum negative.

Role of DOTs Provider

We observed that 70.75 percent of cases had experienced visiting their home by DOTs provider before they initiated treatment that should be 100 percent as per RNTCP.

Timing of Diagnosis:

In the present study, Literacy status of study population was significantly associated with timing of diagnosis as per RNTCP. Literacy status of study population also showed significant difference in initiation of treatment. Higher the literacy status greater the proportion of initiation of treatment as per RNTCP compared to low literacy status.

In the present study, it was found that socio economic status of study population was significantly associated with delay in diagnosis. Significant difference was present between study population with BPL Card and without BPL Card. Significant impact of socio economic factors in timing of diagnosis was noted by previous studies [18].

Initiation of Treatment:

In the present study, 71.70 percent 0f study population were initiated treatment within 7 days after diagnosis and 28.90 percent initiated treatment after 7 days of treatment. As per RNTCP the norm, all patients must be put on treatment within 7 days after diagnosis. In Assam, only 40 percent of the patients initiating treatment after 6 weeks of the onset of symptoms were declared cured after completion of therapy. [4] Socio economic status was also found to be correlated significantly with initiation of treatment in the present study. Significant difference in initiation of treatment was present between study population with BPL Card and without BPL Card. Comparable observation had been reported in literature. [18].

Delay in Diagnosis:

It was evident that 30.77 percent of study population made first contact with unqualified local practitioner and delay in advising sputum examination in Government health facility was present in 30.77 percent of cases. Delay in advising repeat sputum examination as per RNTCP was present in 23.07 percent of cases and Location of DMC far from residence was present in 15.39 percent of cases. Nirupa C et al interviewed 1662 (92%) of 1815 patients registered for treatment from November 2000 to June 2002, for problems related to taking drugs. Among these, 982 (59%) patients reported having some problems due to drugs, 22 percent had personal problems, 15 percent reported disruption in the work routine, only 2 percent patients found the location of the DOT centre inconvenient. Giddiness was the main complaint of patients reporting drug related problems. Patients receiving DOTs from Anganwadi workers or community workers were more likely to report drug related problems than those receiving DOTs from government outreach workers [16].

Service Issues:

Regarding the issue of delay in initiation of treatment, non availability of drugs on day of visit was the commonest reason found in this study and the proportion is 33.33 percent. This is followed by inconvenient DOTs time in 23.33 percent cases. Among other causes of delay in initiation of treatment, non availability of staffs or refusal to supply drug and fear from social stigma were responsible in 13.34 percent cases each and fear from side effects of drugs and long duration of treatment 16.67 percent. Inconvenient DOT time in 20 percent cases and irregular drug supply in 26 percent cases was found by Sen et al in their study. [3] In the study reported from Assam, long distance to the treatment centre, unpleasant effect of the drug and personal inconvenience were cited as cause of irregular treatment and defaulting; all defaulters had more than one Km of distance of their house to the nearest DOTs centre. Therefore, it is clear that defaulters can be reduced if the service of treatment is provided nearer to the patient's house [4].

5. Conclusion

To sum up, initiation and continuation of treatment of TB is related with socio-demographic correlates that needs counselling & motivation for early intervention.

6. Strength of The Study

Initial default is a potentially serious problem, particularly in cases of smear positive patients because they continue transmitting the disease has been highlighted in our study.

7. Limitations of the Study

We had several limitations. First, we were unable to collect information from all the patients about the type of provider from whom they received DOT; patients who could not be interviewed and thus, from whom this information was not available, were more likely to have a poor outcome than those who were interviewed. Treatment success rates categorized by type of DOT provider could differ from those reported here, if information on the type of DOT provider was available for all patients. Second, it is possible that the patients who reported that they received treatment under direct observation may not have actually received DOT strictly as per the RNTCP guidelines. Finally, there may be confounding factors other than those studied here, which could affect treatment outcomes viz. 'Berksonian Bias', patients being treated at Orthopaedics and other departments in may not pass through DOTs clinic, a common practice in many hospitals in India.

8. Future Directions of the Study

In the next phase we have to work on inexpensive rapid point-of-care diagnostic methods that will have a far reaching impact on control of TB [19].

Abbreviations

RNTCP: Revised National Tuberculosis Control Program
DOT : Directly Observed Treatment
BPL : Below Poverty Line

Declaration of Conflicting Interests

The authors declare that there is no potential conflicts of interest with respect to the research, authorship and /or publication of this article.

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