

A STUDY ON EXCLUSION GROUP FROM THE INITIATION OF DOTS UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME IN WEST BENGAL, INDIA

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### ABSTRACT

**Background:** Revised National Tuberculosis Control Program (RNTCP) in on from 1990s. But outcome is not satisfactory in many states including West Bengal. Our objective is to profile people coming at microscopy centre for sputum examination early and late. It tries to identify factors adversely influencing early sputum examination and causes of exclusion from initiation of Directly Observed Treatment Short Course (DOTS) therapy.

**Methods:** Survey was conducted on 577 persons with cough for minimum two weeks from 36 microscopy centres. Important variables explored were sputum positivity level, a proxy indicator of delay in seeking services and initiation of DOTS. Apart that, information on poverty level, religion, caste, mode of journey to facility was also captured.

**Results:** Patients coming late in the microscopy centre were expected to be high positive and those came earlier to be low positive. For both sex, late diagnosis (88.24% and 81.58%) was much more than early diagnosis (11.76% and 18.42%). Across all religions, late diagnosis was much higher than early diagnosis (Hindu 83.05%, Muslim 88.89% and others 100.0% for late diagnosis). Variables significantly influencing initial default of DOTS are age, sex, caste, religion, education, employment status, access to facility and service providers. Upper caste and above poverty line people are more complaint to DOTS.

**Conclusion:** Present study recommends developing an overall community mobilization strategy so that TB suspects reach facilities for early diagnosis and start DOTS. Stigma reduction strategy may be developed so that community does not hesitate to access the existing microscopy health care services.

Key Words: DOTS, Initial defaulter, Treatment Compliance, Exclusion group

### **INTRODUCTION**

Tuberculosis (TB) continues to be the leading communicable disease and second most reason of death after AIDS (1). It accounts for more deaths among women than all other causes of maternal mortality combined (2). Tuberculosis disproportionately affects poorer and marginalized sections of the society (3, 4).

India introduced the Revised National Tuberculosis Control Program (RNTCP) in mid-1990s for the prevention, containment, and cure of TB infections in the country through World Health Organization (WHO) endorsed Directly Observed Treatment Short Course (DOTS) strategy. The RNTCP currently works in conjunction with 'Stop TB Partnership' with a goal of world wide reduction of TB prevalence by 50% within 2015 and less than 1 TB case per million population within 2050 (5). At the country level and as well as in the state of West Bengal; progress is much behind the target of 'Stop TB Partnership' (5, 6).

RNTCP's overarching objective is to "achieve and maintain a cure rate of at least 85 percent in new cases, and to achieve and maintain detection of at least 70 percent of sputum positive pulmonary TB patients" (6, 7). To comply fully the objective of RNTCP; the programme has to mobilize community to public facilities for sputum test as first and foremost strategy (5, 8).

Health care seeking is a dynamic process that is influenced by socio-demographic, cultural and other factors.

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Availability of a simple and rapid diagnostic TB test for use at the lowest level of health care and the involvement of all health providers in case finding activities are imperative for early TB case detection (9). In Taiwan, during the five-year study period, among the 78,118 new Pulmonary TB patients, the mean diagnosis and treatment times were 12 and 5 days and the median times 1 day and 0 days, respectively (10). Our previous study in this concern suggested that due to stigma and caste many people are delayed in accessing healthcare (11).

Compounded with the above problems that community is not coming to facilities for sputum examinations or coming very late leading to very late diagnosis; problems are again multi-folded. When there is delay in seeking care, the patient is suffering for long time but did not turn up for sputum test. It is expected that longer cough duration means more sputum positivity on examination. No initiation of DOTS therapy will cause spread of disease in the community. So more sputum positivity will indicate more delay in seeking care. In best of our knowledge, there is no information available that reflects difference in socioeconomic profile between the two groups; who are coming to microscopy centre early and who are coming late.

Hence, the objective of this study is to look at the people, detected sputum positive and two groups; one who are coming early for diagnosis and the other who are coming late through sputum examination at the microscopy centre. Also efforts are made to identify factors adversely affecting early seeking of sputum examination services under RNTCP and initiation of DOTS.

### **METHODOLOGY ADOPTED**

### **Study setting**

**Selection of district:** In West Bengal there are 20 districts and out of which three districts - Birbhum, Jalpaiguri and North 24 Parganas have been selected those geo-ethnographically represent the state. There are three sub-divisions – Jalpaiguri, Presidency and Bardhaman. From each sub-division one district has been selected to capture maximum variations - Birbhum for Scheduled Tribe (ST) population, Jalpaiguri for ST including North Bengal's variations and North 24 Pgs for Scheduled Caste (SC) and urban variations together with factors related to riverine variety.

**Selection of Tuberculosis Unit (TU):** Each TU covers around 0.5 million population. A total of 12 TUs have been selected – seven from North 24 Parganas, three from Jalpaiguri and two from Birbhum based on the population. TUs have been notified based on certain criteria like urban/rural, SC/ST, minority/majority and hard to reach/easy to reach areas. For North 24 Parganas, seven TUS have been selected, randomly one TU for each cri-

teria; for Jalpaiguri randomly three TUs have been selected for first three criteria and for Birbhum two TUs have been selected for first two criteria.

**Selection of Designated Microscopy Centre (DMC):** Each DMC covers 0.1 million population. Under the selected TUs again following above procedure; three DMCs have been selected from each TU. Therefore a total of 36 DMCs have been selected.

**Sampling:** When prevalence of suspected tuberculosis is 10% among persons attending in a medical OPD; we assume this as prevalence of tuberculosis among people with cough equal or more than two weeks. Considering 5% permissible error and design effect of 2, estimated sample size is 256. In the present study, 577 persons are included with cough equal or more than two weeks.

**Selection of respondents and data collection:** From the selected DMCs, on the day of data collection, we have collected available information of patients who have provided at least two cough samples in last three years. Some information as desired in the survey tool are collected by the laboratory technicians, but not mentioned in the laboratory register, through telephone or home visits. Most of the time, patients found sputum positive, have started DOTS or completed DOTS. Therefore, they are known to laboratory technicians. Personal contact and home visit have been used to collect data. 2506 people are identified by laboratory technicians as eligible respondents, but out of them, only 577 respondents have been reached and their information also has been collected.

Variables measured and its analysis plan: Important variables those have been captured from the laboratory registers are age, sex, sputum positivity level, started DOTS or not. In addition, information on Above Poverty Line (APL)/Below Poverty Line (BPL) status, religion, caste, mode of journey to DMC and others have also been captured. The most important dependent variables used under the study are sputum positivity level i.e. proxy indicator of delay in cares seeking and started DOTS or not i.e. treatment compliance. Apart from frequency, percentages, bivariate analysis is done through chi-square method and multinomial logistic regression was done to reflect on strength of association. Sputum test is done in microscopy and its positivity has been defined as low positive (scanty to 1+) as early diagnosis and high positive (> 1+) as late diagnosis. Patients coming late in the microscopy centre are expected to be high positive and those coming earlier are expected to be low positive.

### **Informed Consent**

Informed consent was part of all interviews conducted. The proforma for consent was approved by the Ph.D. Committee, Dept. of Bio-Medical Laboratory Science and Management, Vidyasagar University.

### **Ethical Clearance**

Data collection was done on human on issues of tuberculosis. The study protocol was reviewed by the State TB Cell, Health & Family Welfare Department, Government of West Bengal. Administrative approval in respect of ethical consideration was taken from that end (Memo No./ HTB/31-2008/1054 Dt. 25<sup>th</sup> August 2012).

### RESULTS

#### **Profile of the participants**

There are 425 males (73.7%) and 152 females (26.3%) out of 557 respondents who have completed sputum tests twice. There are 413 Hindus (71.6%), 72 Muslims (12.5%) and 92 others (15.9%) like Christian, Jainism, Sikh etc. Majority of the participants falls within the age group of 21-40 years, 270 (32.6%) and 41-60 years, 188 (32.6%). Scheduled tribe (ST) constitutes 230 (39.9%), Scheduled Caste (SC) 208 (36.0%). General caste and Other Backward Caste (OBC) constitute together 139 (24.1%). Daily wage labours count maximum proportion 236 (40.9%) compared to government employee 43 (7.5%) and 157 (27.2%) are self employees. People who have tested sputum, among them 436 (75.6%) belong to Below Poverty Line (BPL). Results are summarized in table 1a and table 1b.

# Delay in seeking sputum examination services and its covariates

Sputum test is done in DMC. Its positivity is here defined as low positive (scanty to 1+) as early diagnosis and high positive (> 1+) as late diagnosis. Patients coming late in the microscopy centre are expected to be high positive and those coming earlier are expected to be low positive. For both male and female, late diagnosis (88.24% and 81.58%) is much higher in proportion compared to early diagnosis (11.76% and 18.42%). Across all religions, late diagnosis is much higher than early diagnosis. For Hindu, Muslim and others; late diagnosis is 83.05%, 88.89% and 100.0% respectively. Similarly for other factors like caste, employment, literacy, type of service providers and mode of journey; participants have a tendency to opt for late diagnosis and their associations are statistically significant at 95% confidence interval except for mode of journey. The results are depicted in table 2. Covariates of late diagnosis of sputum positive cases are provided in figure 1.

#### **Compliance of DOTS and its covariates**

If sputum test is positive for one sample out of two tests done at DMC, DOTS must be started. Majority of the patients who are tested positive, have been put on DOTS. Among those who are positive in sputum test, around 10.84% of them have come back to the community without DOTS and have started spreading TB infection among household and other contacts. Covariates related to compliance with DOTS are provided in table 3 and covariates of non compliance in figure 2.

Compared with SC, OBC and general people, STs are found to remain 9.2, 4.3 and 2.8 times more complied to initiate DOTS. Similarly people with higher age group (> 60 years) are less interested to initiate DOTS. Respectively people of age groups 41-60 years, 21-40 years and up to 20 years are 1.5, 1.6 and 1.2 times more complied to initiate DOTS that people of age more than 60 years (table 4).

### DISCUSSION

## Delay in sputum examination from microscopy centre

Important factors associated with diagnosis delay include age, reporting year, living with family and a positive sputum culture (p < 0.0001) (10). The results indicated that 78 i.e. 13.52% accessed sputum service examination early and 499 i.e. 86.48% accessed sputum examination services late. Our study has identified similar factors to have statistical significant relationship with either access to sputum examination services or initiation of DOTS.

Current global TB control policy emphasizes case finding through sputum smear microscopy for patients who self report to primary health centres. Low case detection rates remain an obstacle to the long-term success of TB control programs. Current World Health Organization policy emphasizes passive case finding in contrast with the identification of cases through screening. This strategy has been based on the expectation that (i) passive detection of individuals will ensure to seek medical care is far more cost-effective than population-based screening. The failure of national TB programs to detect the vast majority of new infectious cases suggests that active screening strategies should be re evaluated in an attempt to improve case detection and thereby, increase access to TB treatment (12).

The institutional and community norms leading to stigmatization on tuberculosis may hinder TB control. Stigma out of TB has adverse socioeconomic consequences, especially on women. Stigma is believed to delay access to TB diagnostic services and treatment compliance. There are some interventions that may reduce TB stigma

(14). TB suspect referral of tuberculosis in West Bengal is around 157 per 0.1 million population, when the expected rate is 203 per 0.1 million (15). A study in Jalpaiguri, Birbhum and North 24 Parganas, 26.7% showed that people with cough equal or more than two weeks are susceptible to have tuberculosis (11). If people do not know that cough equal or more than two weeks may be symptom of tuberculosis, naturally they will not approach the facility for sputum test. This describes why suspect referral of tuberculosis in West Bengal is poor (15). It is found that stigma is significantly associated with duration of cough (<0.010) and caste (p < 0.014). While analyzing the covariates of delay in seeking sputum examination, it is found that delay is significantly associated with stigma (p < 0.010) and number of family members (p< 0.018). The later may be due to fact that due more family members, each member is getting less priority in getting healthcare attention (11). Consequences of stigma on TB patient are under researched (16). To achieve objectives of RNTCP; the health system has to mobilize community to RNTCP designated public facilities for sputum test as first and fore most strategy (5). Stigma, lower caste and poor knowledge enhance delay in healthcare seeking. There is a need of a comprehensive communication strategy for the RNTCP that covers people from all strata justification of which is strengthened through another study report (11). Annual Action Plans of the state of West Bengal denotes that there is no comprehensive communication strategy that exists for the programme except some IEC materials. There is a scope to develop a communication strategy aiming towards certain health goals. On the other hand, because the caste and stigma have influence on seeking care; stigma reduction strategies are also required. This can gear up community mobilization towards government facilities for early sputum examination services.

### **Compliance with DOTS**

In our study, upper caste and above poverty line people have very high odds ratio of DOTS compliance compared to the lower caste and people of below poverty line. Regarding initiation of DOTS; general, OBC and scheduled tribe people are 2.85, 4.35 and 9.20 times more likely to initiate DOTS that the scheduled tribe people. APL people are 2.44 times more like to initiate DOTS than the BPL people.

The World Health Organization policy identifies that DOTS compliance will be higher in those who have identified themselves as symptomatic. Nonetheless, the failure of national TB programs to detect the vast majority of new infectious cases suggests that active screening strategies should be re evaluated in an attempt to improve case detection and thereby, increase access to TB treatment (12). A recent analysis of global tuberculosis case notification estimated that only 27% of new smear positive cases that arose in 2000 were detected by the DOTS strategy and only 19% were successfully treated (13). The risk factors significantly associated with treatment delay were increased age, an aboriginal ethnic background, a positive sputum culture and diagnosis at a non-medical centre (p < 0.0001) (10). Our study could identify that 520 i.e. 90.12% persons started DOTS and 57 i.e. 10.84% persons did not start DOTS therapy. Similarly with the above mentioned studies and findings from there, our study could raise similar question about efficacy of DOTS strategy, when 10.84% positive persons are not initiating DOTS and going back to the community to spread infections further in the environment.

### CONCLUSION

Finally the present study recommends developing overall community mobilization strategy so that TB suspects reach facilities for early diagnosis and start DOTS. Also it has been recommended to develop stigma reduction strategy so that community does not hesitate to access the existing microscopy health care services. Caste specific community strategy may be developed to ensure that people from lower caste group feel confident to access services.

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Table 1a: Profile of the participants in respect of age, sex and religion (n=number of participants).

Category	Ν	%
Age group		
up to 20 years	78	13.5
21-40 years	270	46.8
41-60 years	188	32.6
above 60 years	41	7.1
Sex		
Male	425	73.7
Female	152	26.3
Religion		
Hindu	413	71.6
Muslim	72	12.5
Others	92	15.9
Total	577	100.0

Table	1b: Profile of the participants in respect of
caste,	employment status, education level and eco-
nomic	condition (n = number of participants)

Category	n	%
Caste		
General	73	12.7
OBC	66	11.4
SC	208	36.0
ST	230	39.9

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Category	n	%
Literacy		
Illiterate	217	37.6
Primary	284	49.2
Upper Primary	42	7.3
Secondary	34	5.9
Employment		
Unemployed	141	24.4
Self employed	157	27.2
Govt. employee	43	7.5
Daily wage labour	236	40.9
Economic status		
APL	141	24.4
BPL	436	75.6
Total	577	100.0

## Table 2: Covariates of delay in seeking sputum examination

	n Early Diagnosis	%	n Late diagnosis	%	Ν	р
Sex	-					
Male	50	11.76	375	88.24	425	0.052
Female	28	18.42	124	81.58	152	
Religion						
Hindu	70	16.95	343	83.05	413	0.000
Muslim	8	11.11	64	88.89	72	
Others	0	0.00	92	100.00	92	
Caste						
General	14	19.18	59	80.82	73	0.002
OBC	25	12.02	183	87.98	208	
Scheduled Caste	39	16.96	191	83.04	230	
Scheduled Tribe	0	0.00	66	100.00	66	
Employment						
Unemployed	13	9.22	128	90.78	141	0.002
Self employed	16	10.19	141	89.81	157	
Govt. employee	2	4.65	41	95.35	43	
Daily wage labour	47	19.92	189	80.08	236	
Education						
Illiterate	18	8.29	199	91.71	217	0.021
Primary	44	15.49	240	84.51	284	
Upper Primary	9	21.43	33	78.57	42	
Secondary	7	20.59	27	79.41	34	
Referral services						
Private Physician	1	3.85	25	96.15	26	
Government Providers	77	15.28	427	84.72	504	0.005
Self	0	0.00	47	100.00	47	
Travel for access						
River	5	9.80	46	90.20	51	0.532
Road	73	13.88	453	86.12	526	
Total	78	13.52	499	86.48	577	

### Table 3: Covariates of DOTS compliance

	n	%	n	%	Ν	р
	Started		Did not start			
Sev	0015		0015			
Male	375	88 24	50	11 76	425	0.011
Female	145	05.24	7	4.61	150	0.011
Religion	145	90.09	1	4.01	152	
Hindu	363	87 80	50	10 11	/13	0.005
Muslim	66	01.09	50 6	8 33	70	0.005
Christian	00	91.07	1	1.00	02	
Casto	91	90.91	I	1.09	92	
Gonoral	63	86.20	10	12 70	72	0.001
	192	87.50	10	12.50	208	0.001
OBC SC	102	07.50	20	12.50	200	
SC ST	221	96.09	9	3.91	230	
SI	54	01.02	12	10.10	00	
Employment	104	05.04	7	4.06	4 4 4	0.000
Onempioyed	134	95.04	7	4.90	141	0.002
Self employed	127	80.89	30	19.11	157	
Govt. employee	33	76.74	10	23.26	43	
Dally wage labour	226	95.76	10	4.24	236	
Literacy	100				a	
Illiterate	183	84.33	34	15.67	217	0.001
Primary	266	93.66	18	6.34	284	
Upper Primary	37	88.10	5	11.90	42	
Secondary	34	100.00	0	0.00	34	
Providers						
Private Physician	520	66.09	57	33.91	577	
Government Healthcare Providers	26	100.00	0	0.00	26	0.032
Self	448	88.89	56	11.11	504	
Access	520	86.76	57	13.24	577	
By river	51	100.00	0	0.00	51	0.006
By road	469	89.16	57	10.84	526	
Total	520	90.12	57	9.87	577	

### Table 4: Strength of covariates on compliance of DOTS

	Significance	Odds Ratio (OR)	Lower Bound OR	Upper Bound OR
Age				
Up to 20 years	.722	1.279	.329	4.967
21-40 years	.373	1.624	.559	4.719
41-60 years	.468	1.502	.500	4.512
Above 60 years				
Sex				
Male	.028	0.352	.139	.892
Female				
Religion				
Hindu	.136	0.195	.023	1.677
Muslim	.844	1.288	.104	16.013
Others				
Caste				

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### Table 4: (Continued)

	Significance	Odds Ratio (OR)	Lower Bound OR	Upper Bound OR
General	.113	2.850	.779	10.426
OBC	.012	4.352	1.377	13.760
Scheduled Caste	.001	9.202	2.555	33.136
Scheduled Tribe				
Employment				
Unemployed	.219	.483	.152	1.541
Self employed	.001	.214	.088	.518
Govt. employed	.005	.218	.076	.628
Daily wage labour				
Poverty				
APL	.022	2.447	1.141	5.250
BPL				



Figure 1: Covariates of delay in sputum examination (% out of 577)

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Figure 2: Covariates of DOTS non compliance (% out of 577)