



# PERFORMANCE OF DIRECTLY OBSERVED TREATMENT PROVIDER AFFECTING THE TREATMENT OUTCOME OF TUBERCULOSIS CASES IN AMRITSAR CITY

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## ABSTRACT

**Introduction:** DOT providers are the key persons in the implementation of the RNTCP at ground level.

**Objective:** To assess the working of DOT providers and DOT centre affecting the treatment outcome in sputum positive TB patients under RNTCP.

**Materials and Methods:** With the help of self designed questionnaire, patients were asked about the working, availability and behaviour of the DOT provider, the distance, timing of DOT, facilities for taking drugs and privacy at the DOT centre. Data management and analysis was done by using Microsoft excel and SPSS version 17.00.

**Results:** Of 250 patients, 149 (59.6%) were men and 101 (40.4%) women. It was found that the initial verification of the address by the DOT provider, availability of the DOT provider and the availability of clean water, disposable cups and privacy for the patient were significantly associated with the treatment outcome ( $p = 0.021$ ,  $p = 0.006$  and  $p = 0.04$  respectively). Behaviour of the DOT provider and the distance of the DOT centre were not significantly associated with the outcome.

**Conclusion:** Direct observation alone is not sufficient for treating TB, quality of working of the DOT provider and facilities at the DOT centre are significantly associated with treatment success.

**Key Words:** Tuberculosis, DOTS, DOT provider, DOT centre.

## INTRODUCTION

Tuberculosis, the word, evokes feelings of fear, anxiety, stigma and despair, known for centuries, to afflict, debilitate, impoverish large section of the population and even kill, continues to ravage the world.<sup>1</sup> In India today, two deaths occur every three minutes from tuberculosis (TB), but these deaths can be prevented. With proper care and treatment, TB patients can be cured and the battle against TB can be won. The concept of Di-

rectly Observed Treatment Short course (DOTS) as a part of the Revised National Tuberculosis Control Programme (RNTCP) has come to the rescue of programme managers in different countries. It is a strategy that not only cures TB, but also stops the deadly cycle of infection.<sup>2</sup>

DOTS providers are the key persons in the implementation of the program at ground level. A DOTS observer watches and helps the patient to swallow the drug and ensures the treatment for

the entire course. It is accepted that the most effective DOT provider will be the one who is accessible, acceptable to the patient and accountable to the health system.<sup>3</sup>

In recent year quality assurance not only in the form of material but also of behavior of health care provider has emerged as an international important aspect in the provision of health care services. Health care system depends upon availability affordability, efficiency, feasibility & other factors. Patient's satisfaction is recognized as an important parameter for assessing the quality of patient care services and satisfaction regarding behavior of health care provider towards these services is expected to affect outcome & prognosis.<sup>4</sup> DOTS centre is specific centre for TB patient. It is an alternative and practical method of delivering effective treatment to patient. It involves community participation in tuberculosis treatment delivery in which community volunteers, local leader; colleagues in the work place, shopkeeper, teachers and many others can be actively and usefully involved in offering ambulatory treatment at home.<sup>5</sup> There is a need to analyze the DOT providers and DOT centre as often as possible.<sup>4</sup>

Therefore, just providing anti-TB medication is not sufficient to ensure that patients are cured. To prevent defaults, the programme guideline recommends prompt and repeated retrieval actions through home visits for patients missing a dose. Consequently, address verification before treatment initiation becomes mandatory for successful patient retrieval.<sup>6</sup> The present study is an attempt to evaluate the performance of DOT providers and DOT centres both qualitatively and quantitatively.

## MATERIAL AND METHODS

This prospective observational study was conducted on new smear positive patients registered under DOTS in two Treatment Units (TUs) present in Amritsar city. One TU is located in the Chest and TB Hospital, Amritsar and the other is located in the Civil Hospital, Amritsar. A pre designed and pretested proforma was administered to the subject after taking his or her consent. Approval of college ethical committee was granted at the time of submission of the plan of the study.

**Sampling Technique:** Based on the quarterly reports of both the TUs and by the expected incidence of new smear positive (NSP) cases in the

northern zone of India which is 95/lac population/ yr, a quota of 250 cases was affixed (As population covered under two TUs is approximately 11 lac, the expected NSP cases in a year comes around 1045 and expected cases in a quarterly cohort is around 250).

**Study Sample:** The study sample consisted of 250 new smear positive (NSP) cases that were enrolled from December 1, 2009 to February 28, 2010. The study period was extended till the projected number achieved.

**Inclusion & exclusion Criteria:** New smear positive patients of >15 years of age were included in the study. Patients with extra pulmonary tuberculosis and smear negative tuberculosis patients were excluded.

The **possible outcomes** of the new smear positive patients under DOTS can be: **Cured, Treatment completed Died, Failure, Defaulted or Transferred out.**

For statistical analysis, outcomes were divided in two categories:

**Favourable Outcome (F.O.)** - include cured and treatment completed

**Unfavourable Outcome (U.O.)** - include failure, defaulted, transferred out and died.

House to house visits were done and socio-epidemiological parameters were studied and with the help of self designed questionnaire, patients were asked about the working, availability and behaviour of the DOT provider. They were enquired about the distance, timing of DOT and facilities for taking drugs and privacy at the DOT centre.

**Statistical Analysis:** Data management and analysis was done by using Microsoft excel and SPSS version 17.00. Mantel Hanzel Odds Ratio (OR) and 95% CI were calculated for dichotomous variables.

## RESULTS

The present study to assess the efficacy of DOTS was carried out on 250 newly diagnosed smear positive pulmonary tuberculosis cases registered under two Treatment Units present in Amritsar city. The total sample consisted of 149 (59.6%) males and 101(40.4%) females. Out of these 113(75.8%) males and 98(87.2%) females were in the age group of 15-44 years.

**Table - 1 Distribution of cases according to the socio-demographic profile**

Parameter	Cases (n=250)	(%)
<b>Place of Residence</b>		
Native	212	84.8
Migrant	38	15.2
<b>Marital Status</b>		
Married	133	53.2
Single	114	45.6
Widow/Widower	3	1.2
<b>Religion</b>		
Hindu	148	59.2
Sikh	97	38.8
Others	5	2.0
<b>Caste</b>		
Upper caste	43	17.2
Artisan caste	23	9.2
Lower caste	184	73.6
<b>Family type</b>		
Nuclear	95	38
Joint	155	62
<b>Family size*</b>		
Large	34	13.6
Medium	136	54.4
Small	80	32.0
<b>Education</b>		
Above Matric/Matric	66	26.4
Below Matric	104	41.6
No Schooling	80	32.0
<b>Occupation</b>		
IGA*		
Cultivator/Businessman	13	5.2
Service	33	13.2
Labourer	90	36.0
Working female	15	6.0
Non IGA		
Housewife	63	25.2
Student	32	12.8
No work	4	1.6

\*According to the number of persons in the household: >8: large, 5-8: medium and 1-4: small \*\* IGA- Income generating activity

Table-1 illustrates distribution of cases according to their socio-demographic profile. Out of the total 250 cases, 212 (84.8%) were native and 38 (15.2%) were migrant. More than half i.e. 133 (53.2%) were married, 114 (45.6%) were unmarried and 3 (1.2%) were bereaved (widow/widower). Hindus were 148 (59.2%) and 97 (38.8%) were Sikhs. Almost three fourth of the cases i.e. 184 (73.6%) belonged to lower caste. It was observed that 155 (62%) cases belonged to joint families and more than half i.e. 136 (54.4%) had medium sized families having 5-8 members in the household. There were only 66 (26.4%) cases who were matric or above matric. Income Generating Activity (IGA) group comprised of labourers 90 (36%), service men 33 (13.2%), working females 15 (6%) and cultivators/businessmen 13 (5.2%) in number. Non IGA group comprised of housewives 63 (25.2%), students 32 (12.8%) and those doing no work were 4 (1.6%).

**Table- 2 Distribution showing the treatment outcome of NSP cases under study**

Outcome	Cases (n= 250) (%)
Cured	210 (84.0)
Treatment completed	1 (0.4)
Failure	13 (5.2)
Defaulted	12 (4.8)
Transferred out	4 (1.6)
Died	10 (4.0)

Table 2 illustrates that among the total 250 cases under study, 210 (84%) were cured and 1 (0.4%) was completed treatment. Sputum positive cases even 5 months after treatment were 13 i.e. failure rate was 5.2%, 12 (4.8%) cases defaulted, 4(1.6%) transferred out and 10 (4%) cases died during the treatment.

**Table - 3 Distribution of cases showing the relation of working of the DOT provider and DOT centre with the outcome**

Variables	No. (%) (n=250)	Favourable Outcome (n=211) (%)	Unfavourable Outcome (n=39) (%)	OR	95% CI	P value
Address verified by the DOT provider	201(80.4)	175 (82.9)	26 (66.7)	2.431	1.141-5.178	0.021
DOT provider available	219(87.6)	190 (90.0)	29 (74.4)	3.120	1.34-7.29	0.006
Satisfied with the behavior of the DOT provider	239(95.6)	201 (95.3)	38 (97.4)	0.529	0.065-4.25	0.549
Availability of clean water , disposable cups and privacy at the DOT centre	15 (63.2)	139 (65.9)	19 (48.7)	2.03	1.02-4.05	0.041
Distance of the DOT centre from residence is ≤1km	111(44.4)	94 (44.5)	17 (43.6)	1.039	0.49-2.19	0.911
Waiting time at the DOT centre is ≤10min	231(92.4)	198 (93.8)	33 (84.6)	2.769	0.87-8.56	0.053

\*According to F.O. and U.O.

Above table reveals that the initial verification of the address by the DOT provider was done in 201 (80.4%) cases and availability of the DOT provider was present in 219 (87.6%) cases. Both these factors were significantly associated with the treatment outcome ( $p = 0.021$  and  $p = 0.006$  respectively). Satisfaction with the behaviour of the DOT provider was observed in 239 (95.6%) cases. Regarding the working of the DOT centre, the availability of clean water, disposable cups and privacy for the patient was significantly associated with the outcome ( $p = 0.04$ ). Favourable outcome was seen in 198 (85.7%) cases with waiting time of  $\leq 10$  min at the DOT centre while there were 13 (68.4%) cases that had to wait for more than 10 min. Distance of the DOT centre was not significantly associated with the outcome.

## DISCUSSION

The age wise distribution showed that 94.8% cases are from 15-59 years age group and only 5.2% are 60 years or above. According to RNTCP status report 2011, TB primarily affects people in their most productive years of life. Almost 70% of TB patients are aged between the ages of 15-54 years of age and more than 50% of the female cases occur before 34 years of age.<sup>7</sup> In our study also 63.4% of the females are in the 15-29 years age group. In the present study it was observed that out of the total 250 cases, 59.6% were males and 40.4% were females i.e. male to female ratio of 1.5:1 approximately. Male preponderance was also supported by the studies conducted by Chadha and Bhagi (2000) and Acharya and Majra (2007) showing male to female ratio of 2:1 and 3:1 respectively.<sup>8,9</sup>

Treatment outcomes of the NSP cases observed in the present study were: cured (84%), treatment completed (0.4%), failure (5.2%), defaulted (4.8%), transferred out (1.6%) and died (4%). The outcome was categorized as favourable and unfavourable. Similar categorization (favourable, death and other unfavourable outcome) was done by Vasankari et al (2007) in their study on risk factors for poor treatment outcome in Finland<sup>10</sup> and another study by Mukherjee et al (2009) on comparing outcomes in new pulmonary sputum positive and sputum negative cases under RNTCP in West Bengal, India.<sup>11</sup>

The findings are in accordance with the study conducted by Chennaveerappa et al (2011) at Hassan, Karnataka showing that among 58 NSP

patients treatment 49 patients (84%) got cured, 4 (6%) patients died, 3 (5%) patients were defaulters and 2 patients were treatment failures.<sup>12</sup>

According to RNTCP status report, treatment outcome of new smear positive cases for the year 2009 in Punjab was observed as: cure 85.7%, treatment completed 1.9%, died 4.5%, failure 2.2%, defaulted 4.0% and transfer out 1.7%.<sup>7</sup>

The findings in the present study are supported by the district-wise performance report of RNTCP which shows that treatment success rate (cure rate and treatment completion rate) of new smear positive patients in the year 2010 in district Amritsar is 84%.<sup>7</sup>

Table-1 reveals distribution of cases according to their socio-demographic profile. Out of the total 250 cases, 212 (84.8%) were native and 38 (15.2%) were migrant. More than half i.e. 133 (53.2%) were married, 114 (45.6%) were unmarried and 3 (1.2%) were bereaved (widow/widower). A study at Chennai by Mohanarani et al (2005) reported that 39 (63%) of the total 62 patients under study were married.<sup>13</sup> 148 (59.2%) were Hindus and 97 (38.8%) were Sikhs. Almost three fourth of the cases i.e. 184 (73.6%) belonged to lower caste. Although Punjab is a Sikh dominated state but proportion of Hindus is more as the present study is conducted in the city. This is supported by the report of DLHS-3 that in Punjab the percent distribution of household characteristics showed that 75.5% belonged to Sikh religion in rural areas and 40.6% in urban areas.<sup>14</sup>

It was observed that 155 (62%) of cases belonged to joint families and more than half i.e. 136 (54.4%) had medium sized families having 5-8 members in the household. Similar findings were reported by Muniyandi et al (2005) in their study at Tamil Nadu that out of 467 TB cases registered, 65% had family size 4+.<sup>15</sup>

The present study shows that 80 (32%) of the cases were illiterate. Among others, 104 (41.6%) were below matric and 26.4% were matriculate or above. The similar literacy rates were reported by Muniyandi et al (2006) in their study showing that out of the total TB patients registered under government health facility, 37% were illiterate.<sup>16</sup>

A perusal of **table 3** shows that the address verification by the DOT provider was 80.4% and the availability of the DOT provider was 87.6% in the present study and both of these factors were significantly associated with the treatment outcome ( $p = 0.02$  and  $p = 0.006$  respectively). Also facilities available at the DOT centre like clean

water, disposable cups and confidentiality which was just 63.2%, significantly affected the treatment outcome ( $p = 0.04$ ). Other factors like distance and waiting time were mostly within the RNTCP norms and did not affect the outcome.

A study by Vijay et al (2010) reported that factors associated with default were poor patient provider interaction, lack of support from the health staff and dissatisfaction with the services provided.<sup>17</sup>

Another study carried out by Raman et al (1997) in Madurai reported that the health care providers were partially responsible for the ignorance of the patients. Regarding the defaulters, 36% of them had resumed treatment from other sources for reasons ascribable to more faith in the quality of diagnosis and treatment, accessibility and convenient timings.<sup>18</sup>

Formative research, conducted by PATH as part of a USAID-funded TB control project in the Ukraine, suggested that the quality of interaction between TB patients and medical personnel might hinder timely diagnosis and continuation of treatment.<sup>19</sup>

## CONCLUSION AND RECOMMENDATIONS

This work shows that emphasizing direct observation alone is not sufficient for treating TB, quality of working of the DOT provider and facilities at the DOT centre are significantly associated with treatment success. Although the overall treatment success obtained in this study is in line with the RNTCP target, a more comprehensive approach, incorporating easier access to drugs, good capacity building of health care providers, effective solutions addressing travel-related concerns, modification of lifestyle behaviors, and emphasizing on motivating and counseling patients are essential for treatment completion among patients. The findings of our review could help inform the development of patient-centred interventions and of interventions to address structural barriers to treatment adherence.

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