

Assessment of Directly Observed Treatment in Revised National Tuberculosis Control Programme: A Study from North India

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Abstract

Introduction: Directly observed treatment short-course (DOTS) strategy is one of the vital components of Revised National Tuberculosis Control Programme (RNTCP) came into existence in 1997. Directly observed treatment providers (DOT providers) are the grass root level link between program and clients. **Aims:** This study was undertaken to assess the quality of DOTS and facilities available at DOT centers and association between program input and outcome. **Materials and Methods:** This prospective study was carried out to evaluate RNTCP in a North Indian District. Totally, 42 DOT providers providing treatment to registered RNTCP patients in four designated microscopy centers were included in this study. Program input was assessed based on a ten-point questionnaire regarding processes and facilities followed DOT center. Treatment outcome of 302 patients receiving DOTS under these providers was also assessed. **Statistical Analysis:** Data were analyzed using SPSS version 20. Categorical variables such as age group, sex, religion, location, work experience of DOT providers are measured in frequency and percentage. Chi-square was used to find association between quality of DOTS and outcome of treatment. $P < 0.05$ was considered statistically significant. **Results:** The basic principle of DOTS was followed only in half (47.6%) of the DOT centers, counseling was not being done by 40.5% of the providers. Formal training of DOTS was given to two-thirds of the providers. The treatment outcome of patients was significantly associated with program input at DOT center level (Chi-square = 4.02, $P < 0.05$). **Conclusions:** There are few gaps in DOT practices such as administration of DOTS, patient counseling, and tracing of follow-up. This study also concluded that improved program input can enable to get a better outcome.

Keywords: Directly observed treatment provider, directly observed treatment short-course, input, quality

INTRODUCTION

Directly observed treatment short-course (DOTS) strategy is one of the components of Revised National Tuberculosis Control Programme (RNTCP) which came into existence in the year 1997. The goal was to achieve and maintain a cure rate of at least 85% among newly detected infectious (new sputum smear positive) cases and to achieve and maintain detection rate of at least 70% of estimated new sputum positive cases in the population.^[1] The treatment success rate has increased from 25% in 1998 to 86% in 2009, and the death rate has come down 7-fold, from 29% to 4%.^[2] India has already achieved tuberculosis (TB)-related millennium development goal by 2015 and is committed to reduce mortality and incidence to 10% and 20%, respectively by 2030 as per sustainable development goal.^[3,4]

Despite high cure rates, queries and doubts have been raised about the effectiveness of RNTCP regimens, inadequate

diagnosis, method of administration, wrong categorization, and increased rate of multi-drug resistant TB.^[5] It was observed that among all patients recorded to have received directly observed treatment (DOT); more than a quarter did not actually receive it in the district of Kerala, India. This accounts for 86% of total treatment failure and relapse.^[6] DOT being the most important component of the treatment strategy needs to be followed meticulously. Besides, directly observation documentation, follow-up, and counseling of patients make this strategy more patient-friendly. To maintain the quality of DOTS, DOT provider should be properly trained and equipped with essential consumables and facilities. That includes optimum numbers of

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drugs, syringes, patient cards, and drinking water facilities. As DOTS is meant for better adherence and favorable result, its efficacy can be assessed by monitoring treatment outcome.^[7]

DOT centers are the grass root level link between program and beneficiaries in RNTCP. Varied groups of people from the health or community can be DOT providers, who supervise TB treatment. Hence, a well-trained and adequately equipped DOT provider can ensure a good program. In RNTCP onus of cure is on program rather than the patient. Even though direct observation of therapy activities are difficult to verify and monitor, they are absolutely critical to curing the patient, preventing further transmission of TB, and preventing the emergence of drug-resistant bacteria.

Human resources, physical facilities, equipment, clinical guidelines, and operational policies are the core ingredients of any program which enable the delivery of health services. The input of a program is consisted of all these components. Outcomes are changes measured at the population level, some or all of which may be the result of a given program or intervention. Outcomes may refer to specific results such as treatment success rates.

There are limited numbers of studies in India regarding the role of DOT providers and program input at DOT center level on the outcome.^[8,9] Therefore, the present study was undertaken to assess the quality of DOTS, facilities available at DOT centers and also to find out the association between program input and treatment outcome.^[10]

MATERIALS AND METHODS

The present study was a part of a prospective study which was conducted in four designated microscopy centers (DMCs) of a North Indian district from April 2012 to June 2013. In this study, total 302 patients registered in the second quarter (April–June 2012) in these DMCs were followed up till June 2013. This period allowed the patients placed in any category of treatment, including those whose intensive phase was extended for 1 month, to complete the entire period of treatment, thus providing the researchers with sufficient time for the collection and collation of information. The detailed methodology for this study has been published by the same authors.^[11]

The present work is concerned with 42 DOT centers where all 302 patients were under DOT. A pretested semi-structured questionnaire was developed to interview the DOT providers after discussion with experts from Government, RNTCP, and Medical College related to program monitoring/functioning and restraints/challenges. The questionnaire was developed keeping basic the norms of RNTCP in focus to assess the quality of DOT provision. The questionnaire also could capture information regarding sociodemography and training status of DOT providers, availability of facilities, and processes followed at DOT center.

The quality of DOTS including directly observation of swallowing of drugs, documentation of DOTS doses, retrieval

of patients with missing doses, and counseling of patients were assessed by asking close-ended questions (yes/no) and observing the procedures at DOT centers. In case of discrepancies in their responses and our observations, the later one was considered as final. Facilities such as drinking water and drug storage were assessed by direct observation of DOT center.

Program input at the DOT center was assessed by a composite scoring consisted of ten questions regarding quality of DOTS (6), facilities and logistics (3), and training of DOT provider (1). This is accordance with the study done in Kangra, Himachal Pradesh, to evaluate RNTCP, in which input indicators were comprised of quality, logistics, and training of workforce.^[9] In the present study, each question was given a score “1” for positive or good practice or presence of facility while “0” for negative or bad practice or lack of facility. The maximum score was 10 and a cutoff score of 5 was considered for the differentiation of poor or good scoring. DOT centers having score 5 or less considered as poor performing in program input.

The outcome of treatment was categorized as good (cured and treatment completed) and poor (default, death, and failure) as used in some other studies conducted in Brazil and England.^[12,13] This study was approved by the Institute Ethical Committee of JN Medical College, Aligarh Muslim University (AMU), Aligarh. Permission from the college and written consent from the district program authority were taken. Written consent was taken from all participants of the study. DOT providers were informed before the interview and interviewed in their center. Statistical Product and Service Solutions [IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.] was used to enter and analyze data. IBM SPSS statistics was used for analysis through the academic research facilities provided by the AMU. Data were analyzed in terms of proportions for variables such as age group, sex, designation, experience of DOT provider, and outcome of treatment (good/poor). Responses of DOT provider against above mentioned 10 questions regarding the quality of DOTS and availability of facilities were expressed in frequency and percentage. The association between DOT center category in term of input (≥ 5 vs. < 5 score) and treatment outcome of patient was tested using Chi-square considering $P < 0.05$ as statistically significant.

RESULTS

The majority (85.7%) of these DOT providers were in the age group of 30–60 years. Male DOT providers comprised around 61.9%. Almost two-third (59.5%) of DOT providers were from rural area. The majority (73.8%) were Hindu. Regarding their experience in supervision of treatment, the majority (85.7%) of them were providing DOTS for at least 3 years with an average of 4.7 year. Less than half of the (45.2%) DOT providers were traditional practitioners or quacks without any professional degree while one-third

of them was Accredited Social Health Activist. 9.5% were AYUSH practitioners, providing DOT service to our study population and of them, 2 were TB health visitors. Regarding training status, it was observed that two-third of them (28/42) were trained in RNTCP [Table 1].

It was found in this study that direct observation of treatment, the basic principle of DOTS was followed at less than half (20/42) of the centers. Marking patients' treatment card and duplicate card were followed in most of the DOT centers in the present study. Again 60% of DOT providers responded that they were counseling all patients about the disease, treatment, and adverse effect. In most of the

centers (95.2%), patient-wise boxes were properly marked with patient's name, category, and treatment initiation date. The number of empty blisters did not tally with the treatment card entries (for the treatment taken) in 38% DOT centers. Around one-third of DOT providers were not following Retrieval action or tracing of patient who missed dose [Table 2].

In the present study, 64.3% DOT centers did not have any storage facility like almirah or shelf. Drinking water facility was available only at 33.3% centers. However, sufficient stock of syringes and drugs was found in the majority (83.3%) of DOT centers [Table 3].

Table 1: Sociodemographic profile of directly observed treatment providers (n=42)

Variables	Characteristic	Frequency	Percentage
Age group (year)	<30	05	11.9
	30–60	36	85.7
	>60	01	2.4
Sex	Male	26	61.9
	Female	16	38.1
Location	Rural	25	59.5
	Urban	17	40.5
Religion	Hindu	31	73.8
	Muslim	10	23.8
	Others	01	2.4
Experience as DOT provider (years)	<3	06	14.3
	3–6	24	57.1
	>6	12	28.6
Designation	Health worker male	03	7.1
	ASHA	14	33.3
	Traditional practitioner	19	45.2
	TB health visitor	02	4.8
	AYUSH	04	9.5
Training status	Trained	28	66.7
	Untrained	14	33.3

ASHA: Accredited Social Health Activist, DOT: Directly observed treatment, TB: Tuberculosis, AYUSH: Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy

Table 2: Assessment of directly observed treatment (n=42)

Activities under DOTS	Positive response, n (%)
Supervision of drug administration in IP	20 (47.6)
Documentation of card and ID card simultaneously	39 (92.9)
Patient counseling	25 (59.5)
Retrieval or tracing of patients when missing doses	27 (64.3)
Marking of patient-wise boxes	40 (95.2)
Matching of empty blisters and treatment cards	26 (61.9)

DOTS: Directly observed treatment short, IP: Intensive phase

Table 3: Assessment of directly observed treatment center (n=42)

Facility	Available at center, n (%)
Drug storage facility	15 (35.7)
Adequate amount of drugs and syringes	35 (83.3)
Drinking water facility	14 (33.3)

The cohort of TB patients ($n = 302$) who were under the treatment of these 42 DOT providers, was followed until the end of the treatment in 15 months of the study period. Good and poor outcome was found in 86.8% and 13.2% among our study population [Table 4].

Based on the input scoring system as mentioned in the methodology, 31 (73.8%) DOT centers were found to have scored more than 5 while rest 11 (26.2%) had a score of 5 or less. Then, the treatment outcome of the patients treated under these two groups of DOT providers was analyzed to assess the efficacy of DOTs. Out of 56 patients who were being treated under DOT center with score ≤ 5 , 21.4% ended with poor outcome while only 11.3% of the patients under good scored DOT center had poor outcome. This association was found to be statistically significant [Chi-square = 4.02, $P < 0.05$, Table 5].

DISCUSSION

This study is one among the first to investigate the input and outcome of RNTCP. The first time a composite scoring system was used to measure program input at the level of DOT center. Although the majority of DOT providers had at least 3 years of experience, it was observed that two-third of them were trained in RNTCP. In our study, those who had got RNTCP formal training, 70% of them were following DOTs. Untrained workers will ultimately undermine the objectives and performance of program. Bhagat and Gattani observed only 16.7% trained DOT provider in their study in Jamnagar.^[8]

Quality of directly observed treatment-short course

Various studies in India reflect directly observation practice rates in the range of 26.4–82.4%.^[6,8,14] While this study shows DOT prevalence in less than half of the DOT providers. According to program guideline, it is mandatory that patients should swallow drugs under the supervision of DOT provider in the initial intensive phase.^[15] A direct supervision not only ensures treatment compliance but also creates a bonding between patient and health provider.^[16] Prapanwonge *et al.*

found DOT providers who practiced rigorous DOT produced better outcome than the others.^[17] Marking patients' treatment card and duplicate card should be followed simultaneously according to program so that dose status utilized from the patient-wise box and compliance can be easily assessed. This practice was followed in most of the centers. In a study by Lee *et al.*, it was found that patient education by health workers regarding TB disease and treatment showed an increased adherence to treatment in Bangladesh.^[18] TB being a chronic disease needs the long duration of treatment with multiple numbers of drugs. Therefore, adherence would be less without constant motivation and counseling. This strategy brings treatment more close to patients and helps to complete in time. Hence, compliance of treatment may be undermined by patients due to the early relief of symptoms or adverse effect of treatment. Therefore, counseling is an essential and easy tool to maintain the adherence. More than one-third of DOT providers had admitted of not counseling patients regarding disease, complications, and adverse effects of drugs. That might be the reason of high default rate (6%) in our study cohort.^[11] Finlay *et al.* observed that conveying enough education about TB at the beginning of the treatment and counseling decreased the default rate.^[19] The lack of correlation between empty blisters in patient-wise boxes and entries in treatment cards indicates the absence of DOT. In the present study, we observed a correlation of empty blisters in boxes and entries in cards were in about 62% centers. Our finding is in consonance with finding of Bhagat and Gattani which showed agreement in 66% DOT centers.^[8] Retrieval action or tracing of patient who misses dose is an essential and basic tool recommended by RNTCP to decrease the default. It is recommended to trace the patients within 1 day in intensive phase and 7 days in continuation phase. In the present study, this practice was seen in 60% of the centers. Bhagat and Gattani found this practice in almost half of the center.^[8] Bronner *et al.* found community mobilization of teams to trace TB patients that missed a clinic appointment or treatment dose might be an effective strategy to mitigate default rates and improve treatment outcomes in South Africa.^[20]

Facility and logistics at directly observed treatment center

As per program recommendation directly observation of swallowing of drugs ensures adequate intensive phase. Therefore, it is necessary that each center should have drinking water facility for swallowing of tablets by patients. However, this facility was available only at one-third centers in our study. The majority of the centers did not have disposable

Table 4: Distribution of cases according to outcome of treatment ($n = 302$)

Outcome	Frequency	Percentage
Good	262	86.8
Poor	40	13.2
Total	302	100.0

Table 5: Association of directly observed treatment provider score and treatment outcome[#]

DOT provider score	Outcome		Total, n (%)
	Good, n (%)	Poor, n (%)	
≤ 5 (poor)	44 (16.8)	12 (30.0)	56 (18.5)
> 5 (good)	218 (83.2)	28 (70.0)	246 (81.5)
Total	262 (100.0)	40 (100.0)	302 (100.0)

[#] $\chi^2 = 4.02$, $df = 1$, $P = 0.04$. DOT: Directly observed treatment

glasses for drinking water. Program may take necessary steps to ensure this facility at the centers. Although the majority of centers had adequate amount of drugs, syringes, and logistics as per findings from this study, storage facility like almirah or shelf was not available in two-third of centers. In a study from another North Indian district, it was found that most of the centers had adequate amount of drugs.^[21]

Input and outcome

This study is first of its kind in this setting to highlight outcomes depend on inputs at the DOT center level. This brings out an implication that improved inputs in term of quality of DOTS and adequate logistics and facilities will enable to get better outcomes. A study from Kangra, Himachal Pradesh, also found few shortcomings in inputs at DOT centers. Despite of the gaps, outcome indicators in their study was quite satisfactory.^[9]

Limitation

The scoring for program input, used in the study was not standardized. However, being a first of its kind, this was prepared after consultation with experts from medical college and RNTCP.

CONCLUSIONS

DOTS was not followed meticulously in some DOTS center. This study finds some gap in DOT, tracing or retrieval of loss to follow-up, patient counseling. Basic facilities such as drinking water, drug storage, and disposable glasses were not available at many DOT centers. This study also concludes that treatment outcome in the program associated with program input in term of quality of DOTS provision and maintenance of basic facilities. In addition, there is a need of timely training and retraining the DOT providers and supportive supervision to achieve and sustain program goals.

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Conflicts of interest

There are no conflicts of interest.

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