

**ASSESSMENT OF THE FUNCTIONING OF THE DOTS CENTERS IN DISTRICT
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ABSTRACT

Background: DOTS forms the core of the Revised National Tuberculosis Control Programme (RNTCP)-Stop TB Strategy and is implemented through DOTS Centers and Treatment Supporters that act as focal point of delivery of preventive, promotive and curative services under the programme. Despite this efficacy of DOTS implementation is not well evidenced in literature. **Objectives:** To assess the functioning of DOTS Centers and knowledge of Treatment Supporters in District Kangra of Himachal Pradesh. **Methods:** Assessment of organization and working conditions, TB Register, Treatment records and drug storage area of 4 randomly selected DOTS Centers was done using structured performa over a period of 2 months. Questionnaire based interview of Treatment Supporters to assess their knowledge was done. Patient interviews were carried out to corroborate and refine the findings of the study. **Results and Discussion:** Although the overall implementation of RNTCP-DOTS is reasonably acceptable but there still are gaps in the theoretical structure of Tuberculosis diagnosis and treatment and its ground level execution which must be addressed effectively to achieve the goal of 'TB Free India'. Follow-up sputum microscopy was delayed by 3-4 weeks in many cases while the patient had been started on Continuation Phase of treatment which may lead to delay in identifying and probable subsequent increase in (Multidrug Resistant) MDR-TB cases. Patients are inconvenienced in terms of time and distance of the facility, which may result in eventual loss to follow-up (LFU). There are no Community/TB Support groups for the patients pointing towards a lack of social support system which otherwise helps in reducing LFU rates. Treatment records are written illegibly and poorly maintained. The drug storage facility is in gross neglect in all centers with insufficient stock of drugs in some centers.

KEYWORDS: Tuberculosis, DOTS, Multidrug Resistance, Program Evaluation, Health services, Organization and Administration, Program Activities, Delivery of Healthcare.

INTRODUCTION

Directly observed treatment-short course (DOTS) is an internationally recognized strategy for delivering the basics of TB case finding and cure. It is not simply a clinical approach to patients, but rather a management strategy for public health systems. DOTS is the heart of the Stop TB Strategy. As per WHO, DOTS include five elements, which are a) political commitment b) case-detection through quality-assured bacteriology c) short-course chemotherapy, ensuring patient adherence to treatment. d) effective drug supply and management system. e) monitoring and evaluation system, and impact measurement. Worldwide, between 1995 and 2008, a cumulative total of 36 million TB patients were successfully treated in DOTS programs, and up to 6 million deaths were averted. The treatment success rate (~86%) achieved in DOTS cohorts worldwide exceeded the global target of 85% for the first time in 2007.^[1,2,3]

Treatment Supporters play pivotal role in the implementation of RNTCP by acting as a bridge between TB Health Worker and patients. They carry out IEC (Information, education and communication) activity in the community. They are responsible for verification of the address of the tuberculosis patients, motivation of the patient with respect to treatment requirements and expected duration of treatment, examination of contacts of sputum positive patients, recording of the results in the treatment card, ensuring that all doses in the intensive phase and the first dose of each weekly blister during the continuation phase is taken under direct observation, ensuring collection of empty blister packs which should be preserved till the end of treatment, ensuring timely examination of sputum at specific defined intervals until the patient completes the course of treatment, immediate retrieval of patients who are late for their treatment, referring all TB suspects for sputum examination to the

nearest microscopy centre and to provide health education to patients and their families. Their performance determines the outcome of the TB cases and their role is quintessential in ensuring the success of the RNTCP. Thus operational studies like ours are indispensable to monitor and assess the ground level working of the DOTS through DOTS Centers and Treatment Supporters and hence the eventual success of the programme.^[4,5,6]

METHODOLOGY

After due permission granted by Institute Ethics Committee (IEC) of Dr. Rajendra Prasad Government Medical College, Kangra cross sectional observational study was carried out in 4 randomly selected DOTS centers in District Kangra over a period of 2 months. List of all DOTS Centers was made and 4 were chosen for evaluation on the basis of lottery using folded slips. The 4 centers selected were based in PHC (Primary Health Center), CHC (Community Health Center), Civil Hospital and a private clinic. Kangra has been chosen as the region for research due to convenience and lack of data available in this regard for the region. The investigators visited the DOTS Centers wherein assessment of the working conditions of the centre, review of the treatment records, inspection of the drug storage area, review of the TB register and review of the organization of directly observed treatment was carried out. Evaluation of the knowledge and working of the Treatment Supporters was done by interviewing and observing respective Treatment Supporters. Patient interview of a random patient who had come for his/her DOTS medication was also carried out.

Treatment Supporters were initially explained in detail the objective and methodology of the study being

conducted and any queries pertaining to this were resolved. The Treatment Supporters were interviewed and observed based on the ensuing questionnaire in their respective rooms. The questions were asked in English/vernacular language and any clarification regarding the questions sought, were provided by the investigator. Subsequently review of the organization of the direct observation treatment, the drug storage area and treatment cards at the centre was done bearing the enquiries of the questionnaire in mind. Treatment supporters were interviewed about the administration of DOTS, retrieval action taken, maintenance of drugs and completion of treatment cards. The performa used to evaluate the DOTS Centers included questions pertaining to use of alternative community resources, proper drug storage and correct filling up of the treatment cards.

Patient interview was carried out on 1 random patient who had come to the facility for the administration of DOTS. The patient was informed about the goals and procedure of the study being conducted and assured of their privacy and the confidentiality of their responses. The investigator obtained written and informed consent before conducting the interview in privacy of a room at the DOTS Centre, ensuring that none of the staff was present at the time of the interview. The questions were asked in English/local vernacular language and any queries raised or any clarification sought was resolved and cleared by the investigator. Patient interview questionnaire included questions about the disease awareness, diagnosis and treatment process and convenience in accessing the facility.

The data from the study was then compiled and analyzed using Microsoft Office 2016 to obtain the outcome of the evaluation.

RESULTS

Table 1: Results of Patient Interview.

Questions	Response – Yes(Y)	Response – No(N)
Patient was aware that he/she is under treatment for TB	4 Y	-
Patients knew the correct duration of treatment	4Y	-
Treatment was started within 7 days of sputum microscopy	3Y	1N
Patient had taken Anti-TB Treatment for more than 1 month in past	-	4N
Patient had taken at least 20 of 24 doses under direct observation in the Intensive Phase?	4Y	-
Was DOTS Centre convenient in terms of location	-	4N
Was coming to DOTS Centre convenient in terms of timing	1Y	3N
Was referred to ICTC for HIV Testing was done	3Y	1N
HIV Positive- patient got CPT	N/A	N/A
HIV Positive- Referred to ART Centre	N/A	N/A
Attended any Patient Provider/ Community Meeting		4N
Paid for sputum/culture DST/ pre-treatment examination in MDR-TB or TB Drugs under RNTCP	1Y	3N
Patient had paid for travel/consultation to get injection	1Y	3N
Provided sputum sample before start of treatment	3Y	1N
Provided sputum sample at the end of 2 months of treatment	3Y	1N

Provided sputum sample at the end of treatment	N/A (Still on Treatment)	N/A (Still on Treatment)
Patient was satisfied with the interaction and support provided by the program staff	3Y	1N
Findings of the patient interview consistent with TB Register	4Y	

Table 1: A Patients interviewed at all the centers were aware that they were on treatment for TB and knew the correct duration of the treatment. All patients interviewed at least 20 out of 24 doses in IP. The findings of the patient interview were consistent with the TB Register. In one of the centers patient had been initiated on DOTS without sputum examination and only upon clinical suspicion. HIV testing had not been carried out and also had to pay out of their own pocket for the pre-

treatment examination, otherwise free under RNTCP. It was observed at one of the centers that the patient was not asked to provide sputum sample at the end of 2 months of treatment. In all of the centers it was observed that participating in DOTS was not convenient to the patient in terms of location and timing. In none of the centers patients attend any patient provider/community meeting.

Table 2: Results of review Patient Treatment Cards at the DOTS Centers.

Questions	Response – YES(Y)	Response – NO(N)	Response – NOT APPLICABLE
The entries were correct and legible.	1 Y	3N(Illegible, Incomplete)	-
The correct regimen was prescribed.	4 Y	-	-
The intensive phase of treatment was prolonged for one month for all patients who remained sputum smears positive at the end of intensive phase.	1 Y	2 N	1 N/A
Treatment cards were maintained correctly and upto date.	4 Y	-	-
DOT administration was done correctly.	3 Y	1 N	-
Details on past history of TB treatment were mentioned on the card.	3 Y	-	1 N/A
Follow up sputum examination were done at the correct time.	1 Y	3 N	-
Reviewed the treatment of 5 smear positive patients found to be AFB smear-positive during follow up examination.	3 Y	-	1 N/A
The HIV-TB block on the treatment card was filled for all patients.	2 Y	2 N	-
All under 6 years contacts of sputum positive patients got chemoprophylaxis.	2 Y	-	2 N/A

Table 2: Correct regimen was prescribed and treatment cards were complete and upto date in all the centers. At 3 out of 4 centers evaluation of the Treatment Cards the entries on the Treatment cards were found to be illegible and were even incomplete in some cases. Follow-up

sputum examination had not been carried out at the correct time and was mostly delayed by upto 3-4 weeks in most cases. At 2 centers TB-HIV Block on the treatment card was left unfilled in most treatment cards.

Table 3: Results of DOTS-Provider Interview and Observation.

Questions	Response – YES(Y)	Response – NO(N)
DOT was administered correctly.	3 Y	1 N
The retrieval action was done within one day during intensive phase and within one week during continuation phase.	3 Y	1 N
The Tuberculosis Treatment Cards were completed at the same time when treatment was given.	3 Y	1 N
Patient wise boxes were marked for each patient.	4 Y	-
Empty blisters were preserved in PWB (Patient Wise Boxes).	4 Y	-
The amount of drugs in the boxes tallied with those mentioned in the Treatment card.	3 Y	1 N
Community volunteer received honorarium for all patients treated successfully till that date.	-	2 N 2 N/A

Table 3: In all the centers PWB were marked for each patient and empty blisters were preserved in PWB. Administration of DOTS was mostly correct. The empty blister packs from the IP and CP kept in PWB were mixed and not segregated. In 2 centers it was noted that either no or inadequate retrieval action was done when a patient did not report for medication.

Table 4: Results of review of the organization of DOTS.

Questions	Response – YES(Y)	Response – NO(N)
The alternative resources for observation (community volunteers, hospital staff) were used as necessary.	1 Y	3 N
The sufficient stocks of drugs and other consumables were available at Peripheral Health Institution (PHI) level.	2 Y	2 N

Table 5: Results from inspection of Drug Storage Area.

Questions	Response – YES(Y)	Response – NO(N)
It was locked.	2 Y	2 N
The shelves were in place.	3 Y	1 N
The inventory system was in place.	4 Y	-
Drugs with an early date of expiry placed in front.	1 Y	3 N
All drugs were kept off the floor and away from the wall.	-	4 N
There were enough drugs and other consumables.	2 Y	2 N

Table 4,5: In all the centers inspected an inventory system was in place and drugs were mostly well shelved. In 2 centers there were inadequate drugs and other consumables and the drug storage area was unlocked. Drugs were either kept on the floor or adjacent to damp walls in all the facilities. Mostly centers did not place drugs with imminent expiry in front.

DISCUSSION AND CONCLUSION

The study helped obtain a comprehensive understanding of the ground level functioning of the DOTS Centre and the Treatment Supporters and helped link it to the overall progress of the RNTCP. In 3 out of 4 centers it was noticed upon patient interview and upon the evaluation of the treatment cards that the follow-up sputum microscopy was not done at correct time and was delayed by 3-4 weeks in many cases while the treatment for CP was started. This may be associated with a subsequent increase in the number of Multidrug-Resistant TB (MDR-TB) cases in future as the patients would not be shifted from one Category of DOTS to the

other within appropriate time. This would result in overall devaluation of the efficacy of the DOTS Regimen.

Patients interviewed at the DOTS Centers admitted to being inconvenienced in terms of time and the distance of the facility, as they would have to spend a lot of time to come and take their medication especially during the IP. There was also no Community meeting or TB Support Group for the patients availing DOTS at the centers. Such strong social support structure is shown to have decreased the number of loss to follow-up cases of DOTS. In one center it was revealed adequate measures were not taken to track the patient if he/she did not report for medication. Inconvenience due to distance and time consumption along with lack of a social support structure for patients and lack of immediate effective retrieval action following patient non-reporting could be responsible for the number of cases who default on treatment or are lost to follow-up, which can in turn be linked to development of multidrug resistance.

More deficiencies were found in the DOTS Center which is attached to a private practitioner's clinic such as starting of the patient on DOTS without sputum exam and only upon clinical suspicion, out-of-pocket expenditure for pre-treatment investigation otherwise free under RNTCP, lack of HIV testing and most treatment cards with vacant TB-HIV block. All the labor and accomplishment of RNTCP can be possibly undone by the persistent mismanagement of TB by private practitioners. For effective TB Control in India it would be a grave mistake to continue ignoring the burgeoning private sector or to deal with it superficially given the enormosity of TB/ MDR-TB. A number of successful small projects have shown that local public-private practice are not very effective^[7] and hence RNTCP must take measures to ensure initiation and fostering of greater collaboration between the RNTCP Staff and private medical sector.^[8] RNTCP has done a commendable job in the inclusion of the private medical sector in TB Control and this can be made more efficient by stricter monitoring and surveillance.

Scrutiny of the treatment cards at the centers revealed that the entries in the cards were not easily readable. Such illegible entries on the treatment card can lead to misreading of vital information of the patient such as patient details, treatment category, contact information, date of administration of the last dose, date of sputum microscopy, HIV Status. If the patient details and contact information are not mentioned clearly then it will result in difficulty in retrieval of the patient. HIV status of the patient is very important for us, as the patient with AIDS need to be put on ART as soon as possible otherwise it will result in wastage of time and effort as AIDS will ultimately cause mortality if not TB. Among people living with HIV, TB is a leading cause of morbidity and mortality, and HIV is driving the TB epidemic in many regions.^[9] Illegible entries may sometime result in

misreading of category for which patient is taking drugs. This will ultimately result in failure of DOTS, as category II patient may get the treatment of category I. Date of administration of last dose is important as it annotates whether patient will be regarded as a new case or loss to follow up. If the results of sputum microscopy are not mentioned clearly then it will be difficult for us to label the patient as cured, treatment completed, treatment success or failure.

In most of the centers evaluated it was observed that the drug storage facility was in gross neglect. Drug boxes were kept in direct contact with damp walls and were even kept on the floor. In two centers the boxes were not kept locked but were rather kept open. This makes the drugs more likely to get damaged and even turn harmful due to environmental exposure and degradation. Drugs with an imminent expiry date were also not placed in front for first use. This would lead to large number of drugs being wasted due to neglect on part of the Treatment Supporters and result in an overall increase in the costs of the programme since these drugs would need to be replaced. This was evident as there was inadequate medication of the CP in two evaluated centers.

There are no community volunteers in the population who haven't proven to be of great aid in refining the knowledge and attitude among general public about TB and its treatment.^[10] They can be of help in more efficacious administration and implementation of the DOTS programme and can be of benefit to the entire RNTCP Programme in general.

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CONFLICT OF INTEREST

Authors declare no conflict of interest.

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