A Cross Sectional Study on the Effectiveness of RNTCP - DOT Providers in Thiruvananthapuram, Kerala

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ABSTRACT

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Background: The purpose of this study was to determine the factors influencing the effectiveness of RNTCP – DOT providers in Thiruvananthapuram district of Kerala, India.

Method: During July 1st 2006 to March 31st 2007, 93 DOT providers and their 93 patients from 4 Tuberculosis Units (TU) in Thiruvananthapuram were interviewed separately to determine their general characteristics and whether the DOT providers effectively discharged the responsibilities laid down under RNTCP.

Results: Significant associations were found between Effectiveness of DOT Provider with DOT provider category, training in RNTCP, experience more than 2 years, experience in terms of higher number of patients and the knowledge regarding DOTS and RNTCP.

Conclusion: There is a need for a comprehensive training strategy for each and every DOT provider so as to improve their effectiveness which will ensure better treatment compliance under RNTCP. Also, the mechanism of supervision of DOT Providers must be restructured.

Keywords: RNTCP, DOTS, treatment compliance

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BACKGROUND

Tuberculosis (TB) has been a major killer disease for thousands of years. It is one of the leading causes of morbidity and mortality globally; especially so in the developing world. In 2005, there were globally an estimated 8.8 million new cases of TB of which 3.9 million were sputum smear positive for Mycobacterium tuberculosis and an estimated 1.6 million TB deaths. 80% of the TB cases were in 22 high burden countries of which India tops the list.

India has the highest number of active TB cases among the countries of the world. Every year 1.8 million new cases occur in the country of which 0.8 million are infectious. Every day, about 5000 people develop the disease while over 1000 die of it.

In the early 1990s, the global public-health community woke up to the reality that despite the availability of effective diagnostic and therapeutic tools, tuberculosis was one of the world's leading killers. In 1991 the World Health Assembly recognized TB as a major neglected public health problem. The strategy that was subsequently devised, DOTS, was based on decades-old principles and technologies and set a target to achieve 70% case detection and 85% cure rate by 2005.

India launched RNTCP in 1993 and large scale expansion of the programme was commenced in 1997. The rapid expansion of Revised National Tuberculosis Control Programme (RNTCP) contributed much of the global expansion of DOTS. The coverage increased to 30% of the population by 2000, 50% by 2002 and 87% by end of 2004. Kerala achieved 100% RNTCP implementation by March 2002. Revised National Tuberculosis Control Programme has covered the entire population of the country on the eve of 24th March 2006 – World TB Day.

Systematic monitoring and accountability is one of the five principles of DOTS strategy. RNTCP shifts the responsibility of cure from the patient to the health system. A standardized set of performance indicators have been identified to monitor RNTCP. These indicators help the programme managers at various

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levels in assessing the performance of the programme for corrective action.

Kerala has always been in the forefront in implementing and promoting public health activities and National health programmes.Kerala was the first state to achieve 100% coverage under RNTCP_DOTS. But, in terms of case detection rates and cure rates, Kerala has been lagging behind many other states. The case detection rate in 2006 was only 43% and the cure rate of NSP cases was 81.8% (2005). The low detection rate may be attributed to the lower ARI compared to other states, but we need to look for the reasons of <85% cure rate.

Anyone who is acceptable and accessible to the patient, and accountable to the health system, except a family member, could be the DOT Provider. Since the patient is given the choice of selecting the DP, the problem of stigma can be overcome to a great extent.

The success of RNTCP at the field level depends on the interaction between the DOT Provider and patient. Only a few studies have been done in India to evaluate this, most of them comparing the cure rate achieved and the DOT Provider characteristics.

The RNTCP has laid down a list of responsibilities for the DOT provider. The treatment outcome depends considerably on how well they perform in terms of these parameters. Hence, the objective of the study was to assess the effectiveness of DOT Providers and the factors influencing it based on their performance, among the DOT Providers of Thiruvananthapuram District.

METHODS

All the 93 DOT providers and 93 patients involved in the study provided their written informed consent before participating in the survey. The study protocol was reviewed and approved by the Ethics Committee of the Government Medical College, Thiruvananthapuram.

This cross sectional study was conducted among the DOT providers and TB patients of Thiruvananthapuram district from July 1st 2006 to March 31st 2007. 6 Tuberculosis units (TU) are present in Thiruvananthapuram district. Out of these, 4 TU's Thiruvananthapuram, Neyyattinkara, Peroorkada and Chirayinkeezhu were randomly selected to obtain the DOT providers.

3 Focus Group discussions were conducted separately with patients, DOT providers and Senior Treatment Supervisors before the development of the proforma and the semi-structured questionnaire. DOT providers with at least one adult (>18 years) patient, who is into the 5th month or more of DOTS currently, were included in the study.

For each TU selected, the list of patients who are into the 5th month of treatment or more were collected from the TB register. The investigators visited all the Peripheral Health Institutions where the patient's original treatment cards were kept, to prepare the list of DOT providers giving DOTS to the selected patients. Each provider and his/her patient (in case of more than one patient, one was randomly selected) were personally interviewed by the investigators.

STUDY VARIABLES

Most of the details regarding the performance of the provider were obtained by interviewing the patient. The patient were asked whether their DOT providers ensured DOT during intensive phase and continuation phase, motivated them regarding duration of treatment, sent them for timely sputum follow up, contacted them within the stipulated time whenever they were late for their treatment, ensured the examination of their contacts (>6 years), gave them health education and fixed the time and place of DOT after consulting with them (applicable only for JPHN & JHI). Details regarding maintenance of the treatment card and empty blister packs were checked by the investigator personally.

The effectiveness was assessed by looking into how the DOT providers discharged the above stated responsibilities which were laid down under RNTCP.

An effective DOT provider is the one who ensures that at least 80% of doses are taken under direct observation during Intensive Phase and scores at least 50% with respect to the rest of the queries (each item, if done properly was given a score of one).

Sample Size

Sample size was fixed based on the pilot study which found 55% of the DOT providers fulfilling the criteria for effectiveness. By applying $4PQ/d^2$ the required sample size was found to be 82.

Data Statistics and Analysis

The data was collected regarding General characteristics of DOT providers and patients, Knowledge of DOT providers regarding tuberculosis and RNTCP, Effectiveness of DOT providers and the Factors which

are influencing this effectiveness.

Data were entered into excel sheets and analysis was done using SPSS 11 software.

Independent Sample t-test and Chi-square tests were done to ascertain statistical significance.

RESULTS

Most (73.2%) of the DOT Providers were between 30 and 49 years of age and 80(86%) were females. This reflects the significant participation of Anganwadi workers in the programme. Also most of the health services staff (JPHNs, staff nurses and pharmacists) providing DOTS were also females.

Majority of DOT Providers included in the study (97.8%) had studied up to or beyond SSLC. 36(38.7%) were degree holders or had professional education in allied medical fields, like, D Pharm, nursing etc. Of the 93 DOT Providers studied 52(55.9%) were effective in discharging their duties laid down under RNTCP. 72(77.4%) of the DOT Providers ensured >80% direct observation during Intensive Phase while the direct observation (of the first dose of weekly blister) was done only in 36(38.7%) patients during the Continuation Phase. 51(54.8%) motivated their patients regarding timely sputum follow up and only 31 (33.3%) gave their patient, information regarding the correct duration of treatment.

Various details regarding the DOT Providers and their effectiveness is given in Table 1.

Of the 93 patients (all >18 years), 63 were above 40 years of age. 60 of them were male and 44(47.3%) of them had high school education and above while 11(11.8%) of them were illiterate. The number of patients taking Category 1, 2 and 3 treatment were 59, 15 and 19 respectively.

Statistical analysis revealed a significant association of Effectiveness of DOT Provider with DOT provider category, Training in RNTCP, Experience more than 2 years, Experience in terms of higher number of patients and their Knowledge regarding Dots and RNTCP. Age and sex of the DOT provider and the Supervisory visits were not found to be statistically significant. Refer Table 2.

Table 1. DOT Providers and Effectiveness

	Frequency	Percentage %
Sex		
Male	13	14
Female	80	86
Occupation		
JPHN / JHI	13	14
Pharmacist / Staff nurse	22	23.7
Anganwadi Worker	21	22.6
Private Hospital Staff	9	9.7
Others	28	30.1
Training in RNTCP		
Trained	32	34.4
Not trained	61	65.6
Years of experience		
2 Years or less	52	55.9
More than 2 years	41	44.1
Number of patients		
Less than 10	62	66.7
10 or more	31	33.3
Effectiveness of DOT Provider		
Effective	52	55.9
Not effective	41	44.1
Direct Observation in IP		
Yes	72	77.4
No	21	22.6
Direct Observation in CP		
Yes	36	38.7
No	57	61.3
Follow up Sputum Examination		
Proper	51	54.8
Not proper	42	45.2
Motivation: Treatment Duration		
Yes	31	33.3
No	62	66.7
Treatment card		
Proper	47	50.5
Not proper	46	49.5
Blister packs: Preservation		
Proper	71	76.3
Not proper	22	23.7

DISCUSSION

Tuberculosis is a major public health problem in India. To, combat this, the Government of India adopted the WHO-DOTS strategy and launched the Revised National Tuberculosis Control Programme; which now has nationwide coverage. Kerala has been lagging behind other states in achieving the targets of RNTCP. DOT providers play a vital role at the grass root level implementation of the programme. TR et al, in a study conducted in New York city found that DOT can decrease the caseload and interrupt the transmission because of high rate of treatment completion.

Table 2. Factors influencing Effectiveness	
Various factors & Effectiveness	p value
Age	.303
Sex	.445
Health sector related staff	.001
Educational Qualification	.084
Training in RNTP	.000
Experience more than 2 years	.001
Number of patients more than 10	.000
Higher Knowledge score	.000
Number of Supervisory visits	.576

The present study was conducted to determine the proportion of effective DOT providers according to a pre-fixed criteria. These were (1) at least 80% doses should be taken under direct observation during Intensive Phase and (2) at least 50% score with respect to other job responsibilities laid down under RNTCP. The determinants of effectiveness were also examined.

The study subjects were eligible DOT providers and their patients of 4 Tuberculosis Units in Thiruvananthapuram district. Through DOT providers, treatment is brought as close to the patient as possible. Since the patient is given the choice of selecting the provider, the problem of stigma can be overcome to a great extend. A total of 93 DOT providers and 93 patients were included in this cross-sectional study. 52 (55.9%) out of the 93 DOT providers were effective according to the criteria followed in this study.

91 of the DOT providers had studied up to or beyond SSLC. Among them 13 were JHI / JPHN, 22 were pharmacist / Staff Nurse, 9 were private hospital staff, 21 were Anganwadi workers and the remaining 28 were community volunteers. Only 32 (34.4%) had received training in RNTCP.

Interestingly, the proportion of patients receiving DOT decreased by about 50% during Continuation phase (38.7%) compared to Intensive phase (77.4%). Health education was another neglected area with 68 (73.1%) of the providers overlooking this aspect. Awareness should be created among the providers regarding the importance of giving health education to the patients. Treatment cards were properly maintained by 50.5% and timely sputum smear follow up was promoted by 54.8% of the providers. Blister packs were collected and preserved properly by 71 (76.3%).

Among the factors studied provider category, training in RNTCP, health sector related people as DOT provider and experience in terms of both number of years and patients were found to have significant association with effectiveness of DOT providers. There was a significant difference with regard to knowledge between two groups (p value .000) with the effective providers having a higher mean score. In a study conducted by C. Nirupama et al in Tamil Nadu, they concluded that community DOT providers were as effective as Government staff.[53] Another study in Gurgaon, Haryana had shown that Anganwadi workers who were given proper training can as effective DOT providers.

Other factors like gender, educational qualification, and supervisory visits were found to have no association with effectiveness. There is the need to restructure the mechanism of supervision of DOT Providers as ensuring the marking of treatment card and preservation of empty blister packs can play a major role in ensuring treatment compliance.

These findings support the need for a comprehensive training strategy for each and every DOT provider so as to sensitize him / her about the need to ensure DOT during the Continuation phase. This is because this is the time when the patient will be feeling better and more likely to show lower compliance and such a treatment discontinuation may cause the patient to develop drug resistant varieties of tuberculosis in future.

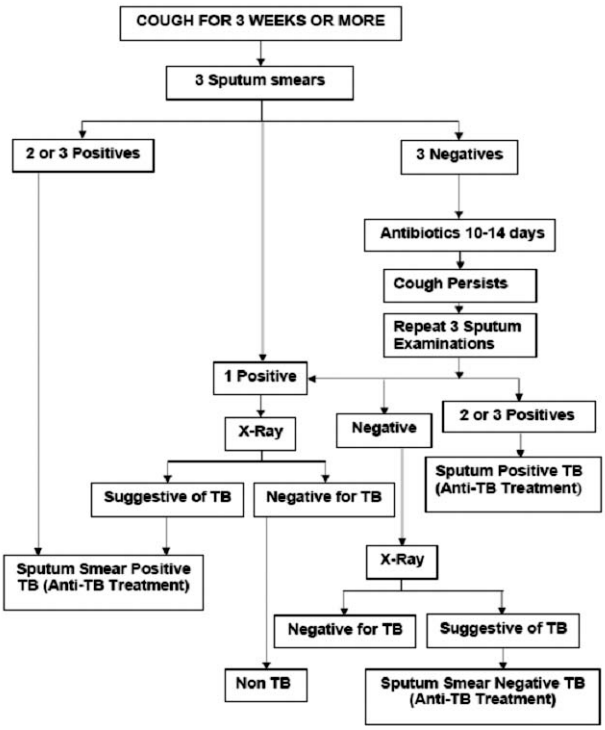

Figure 1. **Diagnositic Algorithm for Pulmonary TB**

Table 3. Categories of Treatments

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear-positive Seriously ill** new sputum smear-negative Seriously ill** new extra-pulmonary	$2H_3R_3Z_3E_3 + 4H_3R_3$
Category II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Treatment After Default Others***	$2H_3R_3Z_3E_3S_3 + 1H_3R_3Z_3E_3 + 5H_3R_3E_3$
Category III	New Sputum smear-negative, not seriously ill New Extra-pulmonary, not seriously ill	$2H_3R_3Z_3 + 4H_3R_3$

Job Responsibility of MPWS/DOTS Providers

Job Responsibilities of the Multi-purpose Worker/TB Health Visitor/DOT Providers in respect of RNTCP

1. Initial verification of address of the tuberculosis patients. During this period, the contact person whose name is also mentioned in the Treatment Card should also be contacted so as to ensure from him, his concern about the patient.
2. Motivation of the patient with respect to treatment requirements and expected duration of the treatment.
3. Ensure that every patient diagnosed as a case of tuberculosis is started on treatment within 7 days of diagnosis and treated for the full duration.
4. Examination of contacts of sputum-positive cases and recording of the result in the Treatment Card.
5. Fix the time and place for DOT, keeping in view the patient's convenience and operational feasibility, so that the DOT is ensured.
6. Ensure that all doses in the intensive phase and the first dose of each weekly blister during the continuation phase are taken under direct observation. Also ensure collection of empty blister packs which should be preserved till the end of treatment.
7. Ensure timely examination of sputum at defined intervals, until the patient completes the course of treatment.
8. Maintain the Treatment Card and update the original card at the PHI on a fortnightly basis.
9. Ensure that every Treatment Card you have received is given a TB Number. Put up this card to the Senior Treatment Supervisor (STS) during his visit for transfer of the required information to the TB Register.

Table 4. Schedule for follow-up sputum examinations during entire Course of treatment

Category	Pre- Treatment sputum	Test at month	If result is	Then...
Cat I	Positive	2	Neg	Start continuation phase, test sputum again at 4 and 6 months
			Pos	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months
	Negative	2	Neg	Start continuation phase, test sputum again at 6 months
			Pos	Continue intensive phase for one more month, test sputum again at 3,5 and 7 months
Cat II	Positive	3	Neg	Start continuation phase, test sputum again at 5 and 8 months
			Pos	Continue intensive phase for one more month, test sputum again at 4, 6 and 9 months
Cat III	Negative	2	Neg	Start continuation phase, test sputum again at 6 months
			Pos	Re-register the patient and begin Category II treatment

10. Immediate retrieval of patients who are late for their treatment. During the intensive phase it should be done with in 24 hrs and during the continuation phase within 7 days of the patient missing the dose. If the MPW is unable to retrieve the patient this should be intimated to the MO of the PHI and STS.
11. Refer all TB suspects for sputum examination to the nearest microscopy centre/sputum collection center.
12. To provide health education to the patient and their families.
13. If a community volunteer is a DOT Provider, the MPW needs to ensure that the community volunteer is trained on how to give DOT, how to mark the treatment card and ensure that the original treatment card at the PHI is updated at fortnightly basis. The MPW also needs to supervise the community DOT Provider to ensure that the patient gets DOT as per guidelines.
14. Ensure that partially used PWBs (of patients who have died/ defaulted / failed treatment/ transferred out) are returned to the PHI within a month of such event.
15. TBHVs working in the medical colleges should ensure coordination between various departments and RNTCP facilities for indoor DOTS.

END NOTE

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