Assessing the Change of Community Pharmacist’s Knowledge on Tuberculosis and Attitude to practice as a Tuberculosis DOTS provider after an Educational Intervention

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ABSTRACT

Government of India officially launched Directly Observed Treatment-Short course (DOTS) strategy in 1997. Under this strategy, DOTS providers need to observe and assist the tuberculosis patient to take their DOTS medicine and document the same after each dosing. As part of Public-Private Mix (PPM) partnership under RNTCP, Community Pharmacists (CPs) needs be trained to observe DOTS. This study was aimed to assess the change of CPs basic knowledge on tuberculosis; and attitude to practice as TB-DOTS provider after an educational intervention. Pretest and post test were carried out for 149 participants, to measure the changes in their TB Knowledge and attitude. The changes in the proportions of choices the subjects were analyzed using inferential statistical tests. It was evident from our study that CPs were found largely unaware of the Government DOTS-TB treatment national policy and the role they can play in their private practice setups.

INTRODUCTION

World Health Organization (WHO) declared Tuberculosis (TB) as a global emergency in 1993; and devised Directly Observed Treatment-Short course (DOTS) strategy, to implement in all countries (TB Control in India, 2016; Jaggarajamma et al., 2007). Government of India officially launched DOTS in 1997 under the Revised National Tuberculosis Control Program (RNTCP) strategy (Konduri et al., 2017). Three recently renamed as National Tuberculosis Elimination Program (NTEP) in January 2020 (Singhania, 2020). Under this strategy, DOTS
providers need to observe and assist the tuberculosis patient in taking their TB medicine and document the same after each dosing (Choi et al., 2016).

In India, the outpatient care for any ailments is provided majorly by private healthcare sectors; it is approximately about 80%. It necessitates leveraging their capacity to involve them in TB care roles for better health coverage (Ruru et al., 2018). Public-Private Mix (PPM) partnership approaches being tried to engage private healthcare providers and community pharmacists to report individual TB cases and; also to extend TB care services to them in Partnership with the public health sector (Ruru et al., 2018). Retail pharmacy or community pharmacy outlets are generally the first points of contact for any common illness including any respiratory ailments (Padmanabhan, 2016). Hence, Central TB division of India developed a module in 2003, to train the community pharmacists to become DOTS provider and TB suspect referral services (RNTCP, 2013). The expected TB care services from private medical sectors are notifying individual patients to District TB Office, referring TB suspects to RNTCP designated laboratory for early screening and for providing DOTS medicines to TB patients as per the advised treatment schedule of RNTCP medical officers after necessary evaluations (Cohen, 1960).

This training module was prepared in association with Indian Pharmaceutical Association (IPA)'s Community Pharmacy division. TB-DOTS pharmacist lead from IPA has taken the initiative in India, to bring the community pharmacists in TB care role in Mumbai between 2010-2012, with few pilot studies. It continues even now in some pockets, with an excellent tie-up between RNTCP and Chemist association (Krampe and Kuhnt, 2016). Later the pilot study was tried in Gujarat in 2013, and few other cities (Krampe and Kuhnt, 2016). However, the awareness and training of community pharmacists were not attempted at Karnataka region by IPA-CPD. The potential role of retail, medical stores in providing DOTS treatment for Tuberculosis under RNTCP program is still untapped. Basic Knowledge of Tuberculosis is essential for any DOTS providers, which contributes to the success of the RNTCP programme. Hence, to support the delivery of DOTS through community pharmacies and to meet the public health needs of the community, authors devised a liaison model (Ramasamy et al., 2020) and arranged an educational intervention programme as a pilot study for community pharmacists in Bangalore City.

**Objectives**

To assess the change of community pharmacist’s basic knowledge on tuberculosis; and attitude to practice as tuberculosis DOTS provider after an educational intervention in Bangalore City, India.

**MATERIALS AND METHODS**

The study was conducted after getting requisite approvals from the Institutional Ethical Committee from a tertiary care teaching hospital. An educational intervention method was followed to assess the change in knowledge and attitude.

The plan for enrolling the trained pharmacist was discussed with to District Tuberculosis Office (DTO) and Drugs Control Board Drug Inspectors of the selected Jurisdiction for the proper coordination to create liaison (Ramasamy et al., 2020) between multiple stakeholders. An appeal from the Drug Control Department was circulated and was detailed to the community pharmacists by the investigator with the active support of the Drugs Control Department personnel.

A pre-test was administered to participants using a validated questionnaire to assess the baseline Knowledge on TB, and TB suspects referral programme, their attitude towards practising as DOTS provider for their neighbouring community. The training was given as per the RNTCP training module for Community Pharmacist, developed jointly by Indian Pharmaceutical Association (IPA) Community Pharmacy Division and Government of India, central TB division and in 2013 (RNTCP, 2013).

The Schematic flow Diagram for the training program (model 1) is given in Figure 1. After the training programme, post-test was taken to analyze the change in Knowledge and Attitude of participants. The interested community pharmacy representatives were enrolled as a DOTS provider under public-private Partnership RNTCP programme. The difference in the knowledge on the basics of tuberculosis and their attitude to practice were analyzed using inferential statistical tests. These tests were done using JMP Pro (SAS Inc., USA) Version 13.2.

Researchers, who are interested in replicating the study in their Jurisdiction, must consider the participant’s time concern and type of resource members. Hence authors have shared the model training plan in Table 1, which may give an idea on time considerations and preferred resource members.

**Statistical Analysis**

The data collected from the pre-test and post-test were posted as contingency tables, and the chi-squares were computed to understand the changes in the proportions of choices the subjects made.
Table 1: Training Agenda Model for replication

| Duration      | Session/Topic                                                                                     | Preferred Resource Member                                                  |
|---------------|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| 20 Minutes    | Welcome and Introduction with special focus on Purpose of meeting/workshop                       | Researcher/Member from Drugs Control Department/ Chemist Association member /member from FDA (If available) |
| 10 minutes    | Pre-test                                                                                        | RNTCP representative/researcher(s)                                         |
| 20 minutes    | Session 1: Tuberculosis- Overview on Disease, Burden in Society, RNTCP-DOTS Treatment strategy details- in a simple way | DTO/STDC representative/researcher(s)                                      |
| 30 minutes    | Session 2: Role of Pharmacist - What all expected to do under Private-Public Mix partnership, Honorary benefits and distribution of Leaflets & Posters from RNTCP centre of the respective state/district. | Researcher(s) or IPA-CPP representatives or RNTCP -MO/CTO/DTO             |
| 30 minutes    | Session 3: Activities – Distribution of Documentation material including TB suspect referral form, a practice session for documentary works, Observation and Handling of DOTS treatment kit | RNCTP Personnel preferably STLS for TB suspect referral and STS for Treatment referral from the Private sector. |
| 20 minutes    | Session 4: Interaction and Linking of Pharmacist with RNTCP field staff (STS and STLS) – area wise | Researchers                                                                |
| 10 minutes    | Session 5: Post Test (Optional)                                                                  | Researchers                                                                |
| 10 minutes    | Session 6: Undertaking form – Signing by Pharmacists to become DOTS provider                      | Researchers                                                                |
| 20 minutes    | Feedback/Concerns/Certificate Distribution                                                       | Pharmacist Association representative and Researchers                      |

Legends: FDA-Food and Drug Administration, RNTCP-Revised National Tuberculosis Control Program, DOTS-Directly Observed Treatment Short-course, DTO-District Tuberculosis Office, STDC-State Tuberculosis Training and Demonstration Center; MO-Medical Officer, CTO-City Tuberculosis Office, STS-Senior Treatment Supervisor; STLS-Senior Tuberculosis Laboratory Supervisor.

during the educational intervention. This was followed by computation of agreement statistics measures namely, Fisher’s Exact test, Cohen’s Kappa Coefficient and Bowker’s Symmetry of disagreement (Cohen, 1960; Krampe and Kuhnt, 2016).

Cohen’s kappa coefficient measures the inter-rater agreement for qualitative (categorical) items. It takes into account the possibility of the agreement occurring by chance, is a measure of interrater agreement. When the observed agreement exceeds chance agreement, kappa is positive, with its magnitude reflecting the strength of agreement. Bowker’s test (symmetry of disagreement) computes the disagreement levels among the inter-rater agreement occurring in between the subjects by measuring the frequency of dissenting answers. The observed disagreement is inversely related to the lower values of the observed result.

RESULTS AND DISCUSSION

One forty-nine members from 125 community pharmacies participated in the TB-DOTS training programme. From the computed agreement statistic measures and in the light of education intervention given during the study, the significant changes in the Knowledge and Attitude for practising as DOTS pharmacist occurred for each question is mentioned in Table 2.

The change in the Level of basic TB knowledge for retail pharmacists after the educational intervention programme was highly significant. Still, the difference in the attitude towards the practice was not much significant.

Question 1: Knowledge | Causative Paradigm (n=125)
This question was directed to the CPs to assess their basic knowledge of the type of pathogen causing TB disease. The subjects were able to distinguish the different causative paradigms of infectious diseases, and they were able to consolidate their knowledge on the causation of TB.

**Question 2: Knowledge | Presenting symptoms of TB (n=125)**

The prominent presenting symptoms of TB are varied, and the CPs in the role of a counsellor for TB suspect referral for an early diagnostic procedure, needs to know about it. Hence this question with distracting choices was put forth to make sure the CPs are capable of this role. A significant difference was observed in the subjects between the pre and post-test conditions on the symptoms of TB.

**Question 3: Knowledge | TB Transmission (n=125)**

The transmission of TB from one person to other poses by air poses challenges for the family members who are in direct contact. Subjects demonstrated a significant difference in different forms of TB and their routes of transmission.

**Question 4: Knowledge | The most infectious form of TB (n=125)**
Table 2: Changes in the Knowledge and Attitude for practising as DOTS pharmacist

| Sl | Domain                        | N  | Likelihood Ratio (Prob>Chi$^2$) | Pearson (Prob>Chi$^2$) | Fisher’s Exact Test (Two-Sided Prob ≤ P) | McNemar - Bowker’s Test symmetry of disagreement (Prob>Chi$^2$) | Cochran Armitage Trend Test (Prob>|Z|) |
|----|-------------------------------|----|---------------------------------|------------------------|------------------------------------------|-----------------------------------------------------------------|---------------------------------------|
| 1  | Knowledge                     | 125| 0.0016*                        | 0.0011*                | 0.0021*                                  | 0.001*                                                          | 0.0011*                               |
| 2  | Knowledge                     | 125| 0.0001*                        | 0.0002*                | 0.0003*                                  | 0.0001*                                                         | 0.0002*                               |
| 3  | Knowledge                     | 125| 0.0378*                        | 0.0442*                | 0.0704                                   | 0.0001*                                                         | 0.0442*                               |
| 4  | Knowledge                     | 125| 0.7207                         | 0.7208                 | 0.8381                                   | 0.0001*                                                         | 0.72058                               |
| 5  | Knowledge                     | 125| 0.8643                         | 0.8626                 | 0.8328                                   | 0.0001*                                                         | 0.73243                               |
| 6  | Knowledge                     | 125| 0.6647                         | 0.6652                 | 0.7909                                   | 0.0001*                                                         | 0.7208                                |
| 7  | Knowledge                     | 125| 0.2589                         | 0.2845                 | 0.3496                                   | 0.0001*                                                         | 0.3850                                |
| 8  | Knowledge                     | 125| 0.3646                         | 0.3850                 | 0.50460                                  | 0.0001*                                                         | 0.3850                                |
| 9  | General Attitude              | 125| 0.0562                         | 0.0470*                | 0.4539                                   | 0.0001*                                                         | 0.4056                                |
| 10 | Practising Attitude           | 125| 0.2185                         | 0.0638                 | 0.0082*                                  | 0.0001*                                                         | 0.7208                                |

One of the significant challenges of combating TB is the type of TB. The clinical presentations of TB vary with its type of TB. Hence this question was put forth. The most infectious form of TB, in terms of fast transmission, was correctly discerned by the subjects, and there was a significant difference between the pre and post-test knowledge as exhibited by the subjects.

**Question 5: Knowledge | Counseling aspects (n=125)**

This question tested how the TB cases are presented, and the subjects were able to correctly learn and counsel the needs to the patients cared for by the CPs.

**Question 6: Knowledge | DOTS (n=125)**

The abbreviations for the DOTS were presented to the subject with distracting choices, and they were not able to make a significant difference in the learning pre and post-test. Given this sample size and sample homogeneity, it is of concern because the CPs were not able to demonstrate a considerable difference in their learning.

**Question 7: Knowledge | DOTS Providers as per RNTCP (n=125)**

This question constituted the crux of the study objective. The subjects were not able to make a statistically tenable difference pre and post-test. This is of concern since this question was aimed to test the DOTS provision choices. The outcome points to the evidence that CPs needs to be sensitized about their roles in DOTS provision.

**Question 8: Knowledge | Responsibilities of CPs in DOTS provision (n=125)**

This question, too, was aimed to test the roles of CPs in the current paradigm of TB prevention. The subjects were not able to make a difference pre and
post-test and the multiple roles they can play in the TB prevention and mitigation, which needs to be communicated to them.

**Question 9: General Attitude | Pharmacists as DOTS providers (n=125)**

The CPs were divided on their opinion on what their roles as a DOTS provider would be. This evidence points to the fact that CPs needs to be sensitized. Given the dissenting options given by the subjects – points to the fact that the policy level changes in the ease of enrolling them to be DOTS providers and counsellors need to be revisited and rethought in its strategy.

**Question 10: Practicing Attitude | willingness to be DOTS providers (n=125)**

On asked on their willingness to be DOTS providers, the CPs gave an emphatic choice on their desire; however, the proportion of their change in the willingness was not statistically significant. This might be due to the sequence of questions, and to the inherent fact due to the conviction of CPs to becoming DOTS, providers have not changed to a negative attribute post-test. Many pharmacists raised the question on the benefit for the pharmacist to do this service for the neighbouring community.

The 'DOT' centre is a place where DOT is given, convenient to both patient and DOT provider. Retail pharmacists are the most accessible primary health-care provider. Despite the inclusion of chemists in Public-Private Partnership programme under RNTCP in India, for being DOT provider, case finder, and counsellor in the training manual designed by central TB division, the awareness and training the pharmacist by primary TB centre is found inadequate in Karnataka due to lack of support from chemist association (Ramasamy et al., 2020).

Chemists were unaware of the government policy on TB-DOTS pharmacist in the study area. When investigator approached for the TB DOTS training awareness and enrollment, most of the pharmacists were not ready to join for the training programme as they had a concern about their losing the business hours. Most of the chemists were enquiring, what will be their benefit if they attend the training programme.

This is the first scientific study conducted in India, to understand the change in awareness level, Knowledge Attitude and practising interest of chemist in Bangalore as DOTS provider for TB patients in their neighbouring community. This study used dynamic method (Ramasamy et al., 2020) discussed in the research article from the same authors, to bring the chemists in a single platform. This has been the main challenge for TB centre, to enrol the pharmacist under RNTCP programme.

Strategies for the prospective remuneration for community pharmacist must be assured and publicized by the concerned department controlling PPM partnership. Many community pharmacist attended the programme were enquiring about their benefits in taking up this tedious documentary works and attending any regulatory concerns about storing Government supply medicines in their commercial premises. Assuring honorarium payment for the services, and making policy-level changes for getting NOC from the drugs control department for PPM TB care role may encourage the community pharmacists to take part in DOTS provider and TB suspect referral role. Future research should be focusing on creating awareness in all the states and districts in India, to tap the potential of the community pharmacist in TB eradication should be taken up.

Participation of community pharmacist in TB suspects' referral role and DOTS provision will give special recognition for the pharmacist in society. Flexibility in regulations for making the DOTS medicines available in retail, medical stores, will improve the accessibility to the needy population. In turn, it may contribute to the reduction of non-adherence to TB medicines, and possibly may contribute to the decrease of TB burden in the society.

**CONCLUSIONS**

State Pharmacy Council and drugs control department in all states in India can come forward to create awareness amongst CPs on their DOTS provision role. This initiative will encourage the community pharmacists to take part in the DOTS treatment provision and TB suspect referral role, which can contribute to early diagnosis of TB and better treatment outcomes.

Future research should be focusing on creating awareness, finding the impact of pharmacist role in TB elimination should be taken up. The common factors affecting/inhibiting the community pharmacist for enrolling as TB-DOTS pharmacist has to be studied in detail for the better understanding of the practical difficulties of chemists to deliver their role.

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in DOTS provision and TB suspect referral programme.

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Conflict of Interest
The authors declare no conflict of interest for this study.

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