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CHAPTER 3

Directly Observed Treatment Short Course (DOTS) Strategy

INTRODUCTION

The World Health Organization has recommended the employment of Directly Observed Treatment Short course (DOTS) strategy to combat tuberculosis [1]. In addition, the WHO has provided technical support to the India's – Revised National TB Control Program (RNTCP) in the areas of planning, monitoring, surveillance, training, evaluation, drug related parameters, public private partnership and operational research [1]. Since the introduction of the DOTS strategy in the Revised National TB Control Program (RNTCP), a remarkable progress has been observed in many of the indicators – improvement in case detection rate, sustained treatment success rate, reduction in relapse rate / treatment after default rate / initial defaulter rate [2]. This is the result of direct support from WHO and its contracted local consultants who have provided adequate technical support and guidance at the district / state / national level [2,3].

SCIENTIFIC BASIS FOR DOTS

Directly Observed Treatment Short course (DOTS) strategy is a systematic initiative to control TB disease and a scientific rationale has been proposed to justify the same.

Sputum Microscopy

Sputum microscopy is the adopted diagnostic tool under the DOTS strategy as it is

- Simple to perform – does not involve a highly scientific and exhaustive procedure;
- High specificity – possesses high predictability to correctly identify those who do not have the disease and hence prevents unnecessary prescription of anti-TB drugs (which was very much common with chest X-rays);
- Less expensive – no expensive equipment required and is being offered free of cost to the patients;
- More reliable;
- Can be repeated (viz. as the process of smear preparation & staining involves air dried / heat fixation – whatever might be the grading of the slide will remain the same even after months / years);

- Negates the intra-observer and inter-observer bias phenomenon widely prevalent in chest X-ray;
- Indicates infectiousness of the patient (viz. as slides are graded from negative – scanty – 1 plus - 2 plus - 3plus, respectively in the order of higher infectiousness);
- Can be used for diagnosis, monitoring progress and defining cure (as discussed in chapter 2, under RNTCP each patient put either on category-I or Category-II ATT will be subjected to sputum microscopy during the course of treatment on a periodic basis to assess improvement or deterioration {may be treatment failure or drug resistant TB}); and
- Feasibility at peripheral health centre (does not require different machines / equipments to perform; is not dependent upon electricity; minimal occupational health hazard) [4-7].

Domiciliary Treatment

Findings of a study done by the Tuberculosis Research Centre, Chennai (now known as National Institute of Research in Tuberculosis) revealed that TB can be managed at home-level (viz. almost equal treatment success rate for patients treated in home and hospital settings) and that hospitalization is not necessary [8]. In-fact, research findings of a study done in the western world also supported the home-based management of TB cases [9]. Domiciliary therapy not only prevents acquisition of nosocomial infections, but even prevents the transmission of infection to other susceptible contacts and improves the quality of life of patients (as they continue to live in their familiar surroundings along with their loved ones) [10,11].

Intermittent Chemotherapy

Although, the newly proposed Indian standards for TB care recommend that daily therapy is the ideal line of management for TB patients, the national TB program still recommends intermittent therapy as the preferred one [12,13]. This is because of

- ***The long life cycle of the Mycobacterium tuberculosis bacilli –*** often termed as "Lazy bacilli". As three of the first line drugs are bactericidal, most of the bacilli get killed on the day which the dose of anti-TB drugs is consumed. Thus at least, one day should be given to allow multiplication of bacilli to adequate number [13].
- ***Hepato-toxic nature of the drugs and regenerative capacity of the liver –*** As Isoniazid, Rifampicin and Pyrazinamide are strongly hepato-toxic, administration of these drugs on alternate day allows liver to recover [14-16].
- ***Social reasons –*** As it has been observed that a major proportion of TB patients are addicted to alcohol, and in absence of psychological support, most of them revert back to consuming alcohol, once their symptoms subsides (due to administration of four-

drugs during the intensive phase. Thus again, simultaneous consumption of alcohol and anti-TB drugs on a daily basis will lead to a definite increase in hepatic enzymes [13].

Directly Observed Treatment (DOT)

Considering the long duration of anti-TB treatment, ensuring compliance to the treatment regimen for the entire duration is of immense significance. The DOT component of the DOTS strategy takes care of this important aspect of the management of TB [17]. It also plays a crucial role in reducing the default rate and the emergence of drug-resistant forms of TB [18].

COMPONENTS OF DOTS

The DOTS strategy is developed on five major pillars / components, namely - Political and administrative commitment; Good quality diagnosis, primarily by sputum smear microscopy; Uninterrupted supply of quality drugs; Directly observed treatment (DOT); and Systematic monitoring and accountability [13].

Political and Administrative Commitment

This component is the most important element in the DOTS strategy as the success of other four components is directly or indirectly dependent on the political support [13,19]. In-fact, it will not be wrong to say that the absence of the political commitment was one of the key reasons for the failure of National TB Program launched in 1962 [13].

The political and administrative commitment does not mean only initiating a program to look after the TB prevention and control related activity [19]. However, the government's commitment is actually measured in terms of continued financial assistance in response to the needs and rationale demands of the program managers, capacity building, strengthening the existing infrastructure, expansion of the program on both diagnostic / therapeutic front, human resources development (viz. recruitment for filling up of sanctioned posts, training & re-training of the program managers / private practitioners / health workers / laboratory technicians), fostering international collaboration, supporting the program managers to build linkages with the private sector and ensure adequate administrative support [19-21].

Quality Assured Diagnosis through Sputum Microscopy

As opposed to the recommendations of the National TB program in which chest X-ray was the main investigation to establish the diagnosis, RNTCP has advocated for sputum microscopy as the primary tool for detection of infectious TB cases [13]. This component has two parts – Quality assurance and Sputum microscopy.

a) Quality assurance

In order to enhance the credibility of sputum microscopy results, under the diagnostic arm of RNTCP a system of quality assurance (QA) has been established to ensuring the reliability of

data obtained from the National reference laboratory (NRLs), Intermediate reference laboratory (IRLs), and designated microscopy centers (DMCs) [2,13,19]. QA system in RNTCP comprises of three essential elements namely internal quality control (IQC), external quality assessment (EQA), and continuous efforts for quality improvement (QI) of laboratory services [13,22].

- **Internal quality control:** It is the streamlined process of internally monitoring the working practices (viz. technical procedures, instrument maintenance, preparation of reagents, the quality of reagents, smear preparation, smear gradation, equipment related infection control measures, biomedical waste management, etc) [13].
- **External quality assessment:** It itself includes three types of check - On-site evaluation (OSE), Panel testing (PT), and Random blinded re-checking (RBRC).

✓ ***On-site evaluation:*** It offers an opportunity to the concerned supervisor (viz. Senior TB laboratory supervisor (STLS) in the DMC once a month; IRL laboratory supervisors in District TB Centers (DTCs) / TB units once a year; and laboratory supervisors of NRLs in STDCs / IRLs once a year) for immediate problem-solving, taking corrective action and giving on-site retraining, at the time of their visits [22].

✓ ***Panel testing:*** It is done to assess the efficiency of laboratory technicians (LTs) in performing smear microscopy, with no emphasis on other routine activities. Annually five unstained smears per technician are given to the supervisory laboratory staff of IRLs and DTCs [22,23].

✓ ***Random blinded re-checking (RBRC):*** It is done to assess the performance of a laboratory by re-reading a sample of slides collected from a laboratory on a monthly basis for every DMC. The District TB Officer plays a key role in ensuring blinding [22,23].

- **Quality improvement (QI):** It is an ongoing process in which all integral components of sputum microscopy are analyzed. It mainly deals with the recognition of mistakes followed by implementing corrective measures to avoid the recurrence of similar problems [22,24].

b) Sputum microscopy

Sputum microscopy is the gold standard diagnostic tool as it not only provides a confirmatory diagnosis but also enables monitoring the response to the treatment [6,7]. Ziehl-Neelsen staining technique is used in RNTCP and needs to be performed by a trained laboratory technician [19]. The program recommends a collection of two sputum samples (viz. Spot - under supervision and Early morning - by the patient at home) in the sputum containers within a day or two consecutive days [13]. For collection of sputum patients should be appropriately instructed so that at least 2 ml of preferably muco-purulent sputum can be obtained [13]. Also, the laboratory technicians are instructed to report the results within a day so that unnecessary delay can be avoided as the

smear positive patients are the potential source of infection to their susceptible contacts [13,19].

1. **Uninterrupted supply of quality drugs:** In order to ensure continuous supply of the drugs at all levels, a special mechanism has been designed that necessitates maintenance of buffer stocks of both first-line and other anti-TB drugs [13,25]. At the Central TB Division level, depending upon the prevalent trends regarding number of cases of TB diagnosed in the entire country in a pre-defined interval, officials plan for procurement and distribution of drugs [25]. From the program manager aspects, it is of crucial significance that all the respective District TB Officers ensure that adequate buffer stock is available at TU and DTC level [25]. The issue of supply of quality-assured drugs drives more attention for the second-line drugs – as these drugs are expensive and also have a very short expiry date – the Central TB Division cannot procure any drugs in excess [13,25].

Furthermore, to ensure compliance the RNTCP has developed "patient-wise boxes" (PWB) for both adult and pediatric TB cases based on their weight-band [19]. As soon as the patient is initiated on anti-TB treatment, their name is written on the respective PWB, and they are counseled that

- The concerned PWB belongs to them; and
- They have to consume all the blisters present in the PWB even if the symptoms subside to warrant complete cure.

Finally, patient wise boxes have not only assisted the program officials in improving patient care and treatment adherence but also in streamlining the mechanism of drug supply and drug stock management [19].

2. **Directly Observed Treatment (DOT):** DOT is the most important pillar of DOTS strategy, in which a DOT provider (a trained health worker / volunteer except patient's family member) ensures the consumption of anti-TB drugs during the complete duration of therapy [13,25]. Administration of DOT is not restricted with consumption of drugs in front of DOT provider by the patient. It is definitely more than that – Ideally when a patient comes to the DOT center, the DOT provider

1. Should ask the patient first to sit down and relax;
2. Inquire about any complaints / issue
3. Offer a glass of drinking water;
4. Trace the patient wise box of the patient as per his TB identification number;
5. Take out one blister from the concerned box (intensive phase / continuous phase);
6. Remove the drugs from the blister and give in the hands of the patient;

7. Ask the patient to consume the drugs;
8. Ensure that patient has swollen the drugs by using a tongue depressor (if possible); and
9. Motivate the patient to continue their treatment for the complete duration

DOT is justified as most of the patients who are not provided with DOT, avoid consuming drugs once their symptoms subside, which directly amplifies the problem of emergence of drug resistance [2,13]. Research work has shown that on adoption of DOT strategy a significant reduction in failure / relapse / drug resistance / death rates and early detection of adverse effects, drug intolerance [26,27]. In addition, settings where DOT was not implemented, poor treatment outcome have been observed [13,28].

The RNTCP has started a "treatment adherence scheme" in which every DOT provider will be given an honorarium for every patient who has completed treatment [20]. In-fact, RNTCP annual report 2011 showed that close to 2000 NGOs and in excess of 10,000 private doctors have enrolled them in the public-private mix projects [29]. In addition, initiatives like development of a comprehensive streetwise DOT directory by health workers; motivating private medical practitioners / volunteers to become DOT provider; and extending periodic counseling of the patients / family members regarding the need of adherence to treatment; can be tried upon to further enhance the practice of DOT [30,31].

3. Systematic monitoring and accountability: As other components of DOTS strategy, this element also deserves a special place [13]. The RNTCP has developed a standardized format to enable rigorous monitoring and evaluation of indicators (viz. case detection rate, sputum conversion rate, cure rates, default rate, etc.) pertaining to every patient put under treatment [2,19]. Multiple meetings like district review meeting by District TB Officer, quarterly review meetings by State TB Officer, etc. are organized on a periodic basis to assess the quality of work, identify the gaps and plan appropriate measures to counter the identified barriers [13]. In-fact, even for assisting the program officers, a special supervisor check-list has been developed to allow them to comprehensively assess the different aspects of program implementation in a particular center / district at the time of their visit [20]. This monitoring and accountability even extend to logistics like drugs / stains / microscope, etc. and eventually allows the comprehensive assessment of the entire program [2]. The key characteristic of the program is that it shifts the responsibility of cure from the patient to the health system [13].

CONCLUSION

In conclusion, Directly Observed Treatment and Short Course Chemotherapy (DOTS) is the most vital constituent of RNTCP. In-fact, the success of DOTS and the program on the national level in itself is dependent upon its five integral components of the DOTS strategy.

SUMMARY

The World Health Organization has recommended the employment of Directly Observed Treatment Short course (DOTS) strategy to combat tuberculosis. DOTS strategy is a systematic initiative to control TB disease and a scientific rationale has been proposed to justify the same - Sputum microscopy; domiciliary treatment; intermittent chemotherapy; and directly observed treatment. The DOTS strategy is developed on five major pillars / components, namely - political and administrative commitment; good quality diagnosis, primarily by sputum smear microscopy; uninterrupted supply of quality drugs; directly observed treatment; and systematic monitoring and accountability. In conclusion, Directly Observed Treatment and Short Course Chemotherapy (DOTS) is the most vital constituent of RNTCP. In-fact, the success of DOTS and the program on the national level in itself is dependent upon its five integral components of the DOTS strategy.

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