



## DOTS STRATEGY IN INDIA

### - THE CHALLENGES

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### INTRODUCTION

*The DOTS strategy has emerged as a possible solution to the rising number of TB cases in different parts of the world and has been incorporated in India's Revised National Tuberculosis Control Programme as well.*

*The strategy assures a compulsory and free availability of good quality drugs to all TB cases and necessitates drug administration under direct supervision, thereby ensuring the requisite regimen-compliance.*

*RNTCP has already covered 450 million population of the country and has succeeded in achieving an overall cure rate of 80% for new smear-positive TB cases. Yet, there is an urgent need*

*implementation but also to achieve RNTCP objectives at the national level.*

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**M***ycobacterium tuberculosis* (TB) has played havoc with the mankind for ages. It has destroyed the families and adversely affected the societies. It has been reported to infect one-third of the world's population. The number of globally prevalent TB cases "is 16-20 million of which, one-third is contributed by the Indian sub-continent (with the figures ever increasing). Financial burden of treating TB costs the country about Rs. 1300 crore per year. Lately, the multi-drug resistant tuberculosis (MDR-TB) and the human immunodeficiency virus (HIV) infection have threatened to worsen the existent global TB scenario.

### CHANGING TREATMENT TRENDS

Later half of the last century has witnessed significant changes in the management of this killer disease. The unscientific beliefs of cure such as touching the king's feet, drinking goat's milk etc. and the traditional open air sanatorium treatment have gradually given way to a more rational method of management, which has consisted of the chemotherapy constituted by **the anti-TB drugs such as Streptomycin (S), Para-amino salicylic acid (P), Isoniazid (H), Thiacetazone (T), Ethambutol (E), Rifampicin (R) and Pyrazinamide (Z).** Last two drugs have brought down



the treatment duration from 1-2 years to 6-9 months and made a **Short Course Chemotherapy (SCC)** really possible.

Subsequent to these drug-discoveries, **National Tuberculosis Programmes (NTPs)** all over the world began to employ the daily regimens of anti-TB drugs. The programme largely remained a failure in the developing countries like India, which has had the scarcity of finances and resources. Other developing countries of world also witnessed quite the similar scenario. When multi-drug resistance and HIV infection resulted in a rise of TB cases in the developed countries as well, a need was globally felt for the review of existent TB control policies.

**REVELATION OF DOTS**

Soon a revised strategy for TB control came into existence. This was based upon the research conducted in India in the early 1960s, which showed that intermittent regimens were highly effective as compared to the daily regimens. The revised strategy was also made possible with realisation of the need for a **Directly Observed Treatment (DOT)**, following the observations of Fox, Moodie and many other workers over a period of time. Results were highly encouraging, when trials with **Directly Observed Treatment - Short Course<sup>1</sup> or DOTS** were carried out in Tanzania, China, USA and other countries of the world, which showed a decline in the TB cases alongwith an increase in the cure rates. There-after in 1993, **the WHO laid down broad guidelines for National TB Control Programmes, classifying the TB cases into various categories and recommending a use of either the daily or the intermittent regimens.** Most countries gradually began to incorporate DOTS in their **NTPs.**

NOTE : SCC : Short Course Chemotherapy  
 DOTS : Directly Observed Treatment-Short Course  
 NTPs : National Tuberculosis Programmes  
 DTCs : District TB Centres  
 STDC : State TB Training and Demonstration Centres

**EVOLUTION OF RNTCF IN INDIA**

In India, the NTP had already been in place for 3 decades, and though created an infrastructure for TB control (comprising of 446 District TB Centres [DTCs], 330 TB Clinics, 16 State TB Training and Demonstration Centres [STDCs] and 47,000 TB beds), but remained a failure in terms of the case finding (around 30% only) and the treatment completion rates (between 35 and 40%). An Expert Committee, set up in 1992 by the Government of India to review the NTP, highlighted programme-deficiencies and recommended the corrective measures, based upon which, **the Revised National Tuberculosis Control Programme (RNTCP)** was framed for the entire country.

**Essentials of the RNTCP are as follows:**

1. Cases should be detected by sputum microscopy than radiologically and atleast 3 sputum smears should be examined for diagnosis. Sputum microscopy facilities should be strengthened by ensuring the availability of good quality equipments, training of the laboratory technicians, establishing sputum microscopy centres per one lakh population and creating appropriate cross-checking mechanisms for quality control assurance.
2. Highest priority should be accorded for treating smear positive patients with Short Course Chemotherapy (SCC) under the direct supervision in intensive phase and the appropriate supervision in continuation phase through the involvement of most peripheral health functionaries (such as multi-purpose workers, anganwadi workers, trained dais, village health guides, community volunteers etc.) closest to the patient's residence.
3. A regular and an uninterrupted supply of drugs should be assured right upto the periphery.



4. Training capabilities of all the health personnel should be improved.
5. Capabilities of the DTCs and the STDCs should be enhanced for an effective implementation, monitoring and evaluation of the programme.
6. Non-Governmental Organisations (NGOs) and private practitioners should be involved in RNTCP, in view of the fact that a large number of patients visit them.
7. A sub-district supervisory level (termed as the **Tuberculosis Unit<sup>f</sup> or TU**) should be created for every 0.5 million population for registration of cases at the unit instead of a district. The team should consist of one **Senior Tuberculosis Supervisor (STS)** and one **Senior Tuberculosis Laboratory Technician (STLT)**, under the supervision of a medical officer designated as Medical Officer - TB Control (**MO-TC**).
8. Recording and reporting system should be strengthened for ensuring the accountability and emphasis be laid on the monitoring of treatment outcomes.
9. Operational research should be encouraged for improvement of the programme efficiency.
10. Professionally designed Information, Education and Communication (IEC) activities should be established for supporting the programme.

### **RNTCP OBJECTIVES**

**Whereas, overall objectives of the revised TB programme are to reduce the morbidity and mortality from the disease and interrupt the chain of transmission of infection, the operational objectives are :**

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NOTE : STS : Senior Tuberculosis Supervisor  
 STLT : Senior Tuberculosis Laboratory Technician MO-TC : Medical Officer - TB Control

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- (i) To provide SCC to all detected TB patients for the recommended duration of treatment till they are cured.
- (ii) To treat annually on an average about 750 sputum positive cases per million population as against the existing rate of 375 per million population.
- (iii) To cure, atleast 85% of all newly detected cases of pulmonary tuberculosis.
- (iv) To detect atleast 70% of the estimated incidence of smear-positive pulmonary cases. Efforts targeted at the case-detection should be made only after achieving 85% cure rates in the already detected cases, which is the prime target of RNTCP.

### **PROGRAMME COVERAGE**

The country saw an implementation of RNTCP in 1993 as a **pilot-phase (Phase I) in 5** project areas (Delhi, Bombay, Calcutta, Bangalore and Mehsana district of Gujarat) covering a population of 2.35 million. Following its success, it was extended in 1995 (**Phase II**) to cover a 14 million population in 13 States. Again, the results were highly encouraging and led to the formal launching of RNTCP in the country (**Phase III**) in 1997. The programme has achieved atleast 80% of the cure rates, whereas certain areas have consistently achieved even higher cure rates. Following a rapid programme expansion in the late 1998 and early 1999, a population of 450 million was covered by the end of 2001. The Government plans to cover half of the country by 2002, 80% by 2004 and the entire country as soon as feasible.

### **STRUCTURAL ORGANISATION OF RNTCP**

**The structural organisation of RNTCP consists of :**



- i) **Central TB Division** (headed by the Deputy Director General of TB) at the Central level;
- ii) **STDC**, under the charge of a **State TB Officer (STO)** at the State level;
- iii) **DTC**, led by a **District TB Officer (DTO)** and comprising of a Medical Officer (MO), Statistical Assistant and other paramedical staff at the District level;
- iv) **TU**, headed by an **MO-TC** and the team consisting of an **STLT** and **STS** at the Sub-district level;
- v) The rural hospital, a dispensary or a peripheral health facility at the Health Unit level, that comprises of peripheral health functionaries under the charge of an **MO**.

All the centres, as stated above, are involved in supervision, monitoring and evaluation of the TB control activities within their areas of operation and also co-ordinate with the centres in their jurisdiction.

**The TB control activities may include the supply of anti-TB drugs, laboratory equipments and study material related to disease and the training of nodal personnel.**

### COMPONENTS OF DOTS

**The DOTS comprises of five essential components :**

1. **Political and administrative commitment:**  
This component makes available the financial resources which are necessary for success of the programme.
2. **Good quality diagnosis:** A good quality microscopy is essential for an accurate diagnosis of patients.

**NOTE :** **STO** : State TB officer **TU** :  
Tuberculosis Unit **DTO** : District  
Tuberculosis Officer

3. **Good quality drugs:** The component ensures a compulsory and free availability of medicines to the patients.

**Directly observed treatment:** This component is the core of the DOTS programme and basically means that a patient takes SCC drugs directly in the presence of health workers or other trained persons.

5. **Systematic monitoring and accountability:**  
The component ensures the shifting of responsibility for cure from a patient to the health system.

### WHEN TO SUSPECT TB IN A PATIENT

Pulmonary TB may be suspected in a person, who has persistent cough for 3 weeks or more with or without associated respiratory or constitutional symptoms. Such a person should have his sputum examined for acid-fast bacilli (AFB) on 3 consecutive days. Similarly, a person with extra-pulmonary TB may have organ-specific disease along with constitutional symptoms. Contacts of a smear-positive patient must also be examined for the presence of disease, if symptoms are suspected.

### SPUTUM MICROSCOPY

Sputum examination for AFB, the easiest and the most accurate method for diagnosis of pulmonary TB, but its collection should be done very meticulously in a labeled container after explaining the correct method of bringing out the sputum. The method consists of 2-3 deep inhalations with an open mouth followed by a deep coughing from the chest. At least 3 sputum specimens should be collected for microscopic examination in a suspected case of pulmonary TB. These include a **SPOT** specimen on the first day, followed by the **EARLY MORNING and SPOT** specimens on the second day.

If a centre is not equipped with microscopy,  
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there is a need for the container to be transported to another centre with such laboratory facilities. In the case of a delay, it should be stored in a refrigerator and sent to the laboratory as soon as feasible, but definitely within a week.

### **CLASSIFICATION AND CATEGORISATION OF TB CASES**

If at least 2 out of 3 sputum specimens are positive for AFB, the patient is classified as **smear-positive** and put on appropriate treatment. If one specimen is smear-positive for AFB and the radiographic abnormalities determined by an MO are consistent with the active pulmonary TB, the patient is still diagnosed as having smear-positive TB and put on appropriate treatment.

If all 3 sputum specimens are negative and the symptoms persist despite giving antibiotics for 1-2 weeks, an X-ray examination is carried out. If radiographic abnormalities are consistent with active pulmonary TB and the MO decides to

treat the patient with ATT, a diagnosis of **smear-negative** TB is made and an appropriate treatment started.

In either case, the patient's **TB Treatment and Identification Cards** are prepared. He is given a thorough information about the various aspects of disease, the instituted treatment, the possible unpleasant effects and the need for a regular follow-up.

**Various categories of TB cases and their treatment regimens under the RNTCP are specified in Table 1.**

### **TREATMENT**

The treatment in **Category I** consists of an intensive phase of H, R, Z and E administered under a direct supervision thrice weekly on alternate days for 2 months (24 dosages), followed by a continuation phase of H and R thrice weekly on alternate days for 4 months (18 weeks, 54

**TABLE NO.1  
CATEGORIES OF TB CASES\* AND TREATMENT REGIMENS UNDER RNTCP**

Category	Characteristic of a TB case	Treatment regimen	
		Intensive phase	Continuation phase
Category I	New sputum smear-positive Seriously ill, sputum smear-negative • Seriously ill, extra-pulmonary	2 ( HRZE ) <sub>3</sub> **	4 ( HR ) <sub>3</sub>
Category II	Relapse Failure Treatment after default Others	2 ( SHRZE ) <sub>3</sub> *** followed by 1 ( HRZE ) <sub>3</sub>	5 ( HRE ) <sub>3</sub>
Category III	Sputum smear-negative Not seriously ill, extra-pulmonary	2 ( HRZ ) <sub>3</sub>	4 ( HR ) <sub>3</sub>
NOTE: * Various definitions under the RNTCP may be referred in annexure I. ** A prefix denotes the number of months and the subscript 3 indicates thrice in a week. *** Abbreviations have been mentioned in the text.			



dosages) ‘appropriately supervised’, with the first dose of each week given directly supervised and the patient self-administering next two doses of the week, at home.

The intensive phase of **Category II**, consisting of S, H, R, Z and E for 2 months followed by 1 month of H, R, Z and E (total 36 dosages), is administered in the same supervised manner as Category I and is followed by an appropriately supervised continuation phase consisting of 5 months (22 weeks, 66 dosages) of H, R and E.

**Category III** treatment is similar to that of Category I, but is executed without an inclusion of ethambutol.

**Drug dosages as recommended under the RNTCP are mentioned in Table 2.**

For the sake of convenience, the drugs are dispensed in **category-wise boxes** that are prepared at the start of therapy itself. Each box contains drugs in different blister packs. The pack for **an intensive phase** consists of one day’s medications, while that for **the continuation phase** contains one week’s supply. The drug administration days are fixed for a particular patient

and either a Monday-Wednesday-Friday or a Tuesday-Thursday-Saturday schedule is followed. If the patient ‘misses’ a dose, he must be contacted within a day of the missed dose during an intensive phase and within a week of the missed dose during the continuation phase. In case of drug non-collection due to whatever reasons, the patient and the peripheral health functionary may agree on a mutually convenient location for the drug collection/administration. A **‘Specialised’ model** exists in certain metropolitan cities, where diagnosis is done in the Chest Clinics and patient is referred to the ‘area’ treatment centre for DOTS (that is nearest to the residence of a patient).

Both the ‘General’ and the ‘Special’ (Metropolitan) models follow similar patterns in the continuation phases of treatment, with the first dose of each week being administered under direct supervision, and the next 2 doses of week supplied to the patient (following his presentation of the empty blister pack of consumed drugs of the previous week).

**FOLLOW-UP**

As in the diagnosis of pulmonary TB, sputum examination remains the method of choice in the

**TABLE NO.2  
RECOMMENDED DRUG DOSAGES UNDER THE RNTCP**

Drug	Dose in mg (thrice a week) in adults	Dose in mg per kg body weight (thrice a week) in children
• Isoniazid	600	10 - 15
• Rifampicin	450*	10
• Pyrazinamide	1500	35
• Ethambutol **	1200	30
• Streptomycin	750***	15

NOTE : \* Patients weighing > 60 kg are given an additional 150 mg of Rifampicin.  
 \*\* Ethambutol is not given to children < 6 years of age.  
 \*\*\* Patients > 50 years of age or weighing < 30 kg are given 500 mg of Streptomycin.



follow-up during treatment as well. Two specimens are examined at specified treatment intervals.

In the **Category 1** follow-up, sputum examination is done at 2, 4 and 6 months of treatment. If smear is positive after 2 months, the intensive phase is extended for one more month and sputum examinations done at 3, 5 and 7 months. In the follow-up of **Category II**, sputum smear examination is performed at 3, 5 and 8 months of treatment. If smear is positive after 3 months, the intensive phase is extended for 1 more month and the sputum examinations there-after, carried out at 4, 6 and 9 months.

In the case of **Category III** follow-up, sputum is examined at 2 and 6 months of treatment. If the result is positive at 2 months, patient is re-registered and put on Category II treatment. Any patient treated with Category I or III, who has a positive smear at 5, 6 or 7 months of treatment, should be considered a failure and started on Category II treatment afresh. Follow-up is not required for the patient who has completed treatment and has been declared cured.

**At all times in the subsequent visits, communication is done with patients to ensure a regular and correct drug-intake, provide remedial measures in case of minor unpleasant drug-effects, motivate them for treatment-adherence and provide them health education.**

### SPECIAL SITUATIONS

Extremely ill patients with significant haemoptysis, pneumothorax, large pleural effusions (leading to breathlessness) and tubercular meningitis should be referred to a chest specialist in a hospital. Streptomycin should be avoided, while other drugs can be used safely **during pregnancy. Breast-feeding** should continue regardless of the mother's TB status.

In the presence of **renal disease, H, R and**

Z are relatively safe for administration, while S and E are avoided. **In liver disease**, the reverse procedure is followed i.e. S and E are considered to be safe, whereas H, R and Z should be stopped. Children under 6 years of age, having a family member with smear-positive TB, should be screened for symptoms.

### CHALLENGES IN IMPLEMENTATION

**Major challenges** that stand in the implementation of RNTCP are as follows :

1. **Expansion:** Achievement of National Targets is a great challenge in the programme-implementation, since the current overall cure rate of 80% for new smear-positive patients is still below the targeted cure rate of 85%. Further, the default rate at many centres continues to be high.
2. **Private sector involvement:** Involvement of the private practitioners, from whom 80% of the patients seek medical attention, constitutes a big challenge, as it would require them to cooperate with the programme guidelines and even possibly incur initial losses in the earnings.
3. **IEC and health education:** Religious practices of people, such as the Muslims keeping fasts during Roza days and the Hindus during festivals or on particular days of a week, largely hinder the drug administration to them. Active IEC campaigns and health education are necessary to remove superstitions prevalent in the society.
4. **Multiplicity of control programmes:** It leads to a prevalence of confusion in the minds of treatment providers. Therefore, a uniform practice needs to be evolved with respect to the control programmes all over the country.
5. **MDR-TB** : Efforts are on to gradually



introduce the 'DOTS plus', a complementary DOTS based therapy, comprising of the second line drugs, to tackle the MDR-TB problem.

6. **Migratory population:** Difficulties may be experienced in getting migratory population registered under the RNTCP.
7. **Social stigma:** Notions restricting the acceptance of TB patients, are still prevalent in the minds of people and require a propagation of frequent IEC campaigns to remove the superstitions amongst the people.
8. **Integration:** Priorities need to be instituted in respect of the TB control programme in minds of the health staff and doctors, so that RNTCP takes a higher status of execution from the present level, in comparison to the other diseases of national interest.
9. **Involvement of medical colleges:** The medical college fraternity needs to be integrally involved in the implementation of DOTS at the national level.

### **CLINICAL FOCUS**

- \* **Treating physicians should strictly follow the guidelines recommended by WHO in respect of the categorisation of TB cases, the institution of appropriate drug-regimens in correct dosages and the required protocol of sputum examination before treatment and during follow-up of patients.**
- \* **The patient should be adequately educated and motivated about the treatment, so as to ensure the requisite regimen-compliance.**
- \* **A clear message should be perceived by the patient that a non-compliance of therapy would be detrimental to his**

health and may result *in* making him a case of MDR-TB, which is much difficult to treat and requires a prolonged treatment with the costlier second-line drugs.

- \* **Special situations, like diabetes, HIV-infection, pregnancy, renal and liver disease, demand modifications in the drug-regimens.**

### **CONCLUSION**

Acceptance of DOTS strategy in the Indian RNTCP has certainly brought encouraging success in the management of TB cases within the country.

However, there are challenges to be met in the programme-implementation, before the RNTCP objectives are finally realized.



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