I. INTRODUCTION

In 1993, WHO declared tuberculosis (TB) as global emergency and Revised the ongoing National Tuberculosis Programme. It adopted the technical and management package known by the strategy called DOTS - Directly Observed Treatment Short Course. This strategy has proven successful in countries like Peru, China, and Vietnam, etc. All countries in the South East region are implementing DOTS.

DOTS has:

- More than doubled the accuracy of diagnosis of TB from 27% in non-DOTS areas to 77% in DOTS areas.
- Tripled TB treatment success rates from 23% non-DOTS areas to 77% in DOTS area.
- Prolonged survival of HIV infected TB patients.
- Saved more than 50,000 lives, prevented more than 2 million TB infections.
- Averted more than 2,00,000 TB cases and saved more than US $ 1,00 million.

DOTS is the internationally recommended strategy to ensure cure of TB(1). It is based on five key principles that are common to disease control strategies, relying on early diagnosis and cure of infectious cases to stop spread of TB. These components are:

a. Political Commitment: Government commitment to ensuring sustained, comprehensive tuberculosis control activities.

b. Good Quality Diagnosis: Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services.

c. Effective Drugs: A regular uninterrupted supply of all essential anti-tuberculosis drugs.

d. Effective Management (DOT): Standardized short course treatment using regimen of six - eight months under direct observation.

e. Evaluation and Monitoring: A standardized recording and reporting system that allows assessment of case-detection and treatment results for each patient and of the tuberculosis programme’s overall performance.

This package of interventions was first formulated by Karel Styblo - based on management unit of the district. The district has the staff and resources to organise diagnostic and treatment services, maintain supplies and monitor programme performance. He showed that short course treatment was essential to reach adequate cure rates on programme basis, verified the necessity of directly observed treatment and development principles of recording, reporting and drug management that are integral to DOTS.

The global targets for TB control are to achieve a cure of 85% in new sputum positive tuberculosis cases detected and to detect 70% of the estimated new-smeared positive TB cases. Adoption of the targets is based on the principles of impact and feasibility. First epidemiological modeling has demonstrated that achieving the targets will result in significant decline in the tuberculosis epidemic, reducing incidence by about 50% in 8-12 years in the absence of human immuno-deficiency virus (HIV). A report prepared by Styblo in 1991 showed that cure rate in excess of 75% would lead to a substantial reduction in prevalence over time. Increasing case-detection without improving cure rate will actually worsen the epidemic(2).
These figures fit past and current experience. TB had declined rapidly in much of Europe over the last continuing fall of incidence of infection accelerated from 4-5% to 12-13% per year following the introduction of effective treatment(2). This has recently confirmed by data from Peru, which suggest that the decline in incidence has reached nearly 8% per year, double the rate before DOTS was introduced(3,4). Once the target of 85% cure of new sputum is achieved, programme can expand coverage to detect more cases and to detect them earlier. The first priority aims to directly cut the chain of transmission and to reduce mortality. This is done by accurate and prompt diagnosis, free provision of drugs, regular in-take of drugs and systematic monitoring of successive cohorts of pulmonary smear-positive patients.

II. ORGANIZING THE PROGRAMME DELIVERY

For this to occur, a programme must ensure :-

1. Organisation of out-patient treatment for TB patients (all forms, both new and re-treatment) including guidelines, training, supplies, registration, sputum smears, monitoring and supervision. These include directly observed treatment, decentralization to peripheral health workers and community volunteers who are available to the patients. (Chart I)

2. Organisation of diagnosis including the laboratory network, publication of guidelines, training, quality control, registration, monitoring and supervision.

3. Implementation of case detection in out-patient health facilities, including training and monitoring. This also includes information to the community regarding free availability of TB diagnosis and cure and the need of prompt evaluation for diagnosis of persons with prolonged cough.

Achievement of global targets depends on the ability of countries to accelerate population coverage with DOTS, sustaining high cure rates, effectiveness of strategies to address HIV-related tuberculosis, and the ability of tuberculosis programme to increase case detection through provision of effective series, social mobilization and involvement of other agencies like private practitioners and NGOs.

a) Patient flow and procedures

People with chest symptoms and other symptoms suggestive of TB consult medical staff at general health facility, which may be governmental, non-governmental or private. The physician should suspect TB in these individuals and request sputum smear examination. All persons having cough for three weeks duration or longer should have three sputum examinations. Government facilities provide free diagnostic and treatment facilities to all the TB patients.

The Medical Officer (MO) of health facility screens the patients with sputum examination (3 sputum collected in two days) - Spot- Early morning-Spot. Patients with two or more positive smear results are diagnosed by physician as having TB. They are further classified as new or old based on treatment history, patient with one positive smear result is referred to nearest X-ray facility. Patients with one sputum smear positive undergo an X-ray chest, if X-ray is suggestive, they are registered as smear positive cases. Patients in whom all 3 smears are negative are prescribed broad spectrum antibiotics for 1-2 weeks. If symptoms still persist then they are evaluated by X-ray and clinical examination. If X-ray findings are suggestive of tuberculosis, they will be classified as smear negative TB.

b) Treatment (Chart II)

Once patient has been diagnosed as having TB, the MO is responsible for indicating the treatment regimen according to following Categories.

All drugs are administered thrice weekly, the prefix indicates the duration of drug administration in months. The subscript indicates the number of doses per week.

c) Drug Administration

All these drugs are administered thrice a week under direct supervision of a health worker. This worker could be a peripheral health worker (PHW), Anganwadi worker or village health guide. In the initial intensive phase of treatment each and every dose of medicine is to be taken under direct observation of the DOT provider. The continuation phase is supervised weekly and the empty blister pack is returned back to the worker before a new pack is issued. By for India has achieved a cure rate of more than 80% in initial stage of implementation with some area consistently having cure rate more than 90%(6). For effective control of TB and to prevent emergence of multi drug resistance it is important to have uniform policy for all patients. Control measures applied by any agency (Government, Non-government, Private Practitioners) should therefore conform with
Chart I - Structure of the TB programme in India

National level (DDG [TB])
  ↓
State level (STO)
  ↓
District level (DTO)
  ↓
Sub-district level (MO-TC, STS, STLS)
  ↓
Tuberculosis Unit (5 lac)
  ↓
5 Microscopy / DOT centres (1 lac)
  ↓
CHC / BPHC
  ↓
DOT centres (PHI)
  ↓
DOT Providers
  ↓
(Anganwadi workers, Dai, VHG, Community volunteers)

Chart II - Treatment Schedule in RNTCP

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of Patients</th>
<th>Regimen</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>New pulmonary sputum +ve, seriously ill sputum -ve and seriously ill EP cases</td>
<td>$2(RHZE)_3$, $4(RH)_3$</td>
<td>6 months</td>
</tr>
<tr>
<td>II</td>
<td>Re-treatment cases, relapse, failure, treatment after default</td>
<td>$2(SHRZE)$, $1(RHZE)_5$, $5(RHE)$</td>
<td>8 months</td>
</tr>
<tr>
<td>III</td>
<td>New non-seriously ill sputum negative and extra-pulmonary cases</td>
<td>$2(RHZ)_3$, $4(RH)_3$</td>
<td>6 months</td>
</tr>
</tbody>
</table>
the programme guidelines. Participation of Village Panchayat, Community Health Workers, non-governmental organisations, religious groups, other community representatives and voluntary agencies is essential to achieve success in TB control. Keeping this in mind the Government has issued guidelines for involvement of all such agencies.

III. INVOLVEMENT OF NGOS

Involvement of Non Governmental Organisations (NGOs) in RNTCP is of vital importance. They play an active role in health promotion in community and many patients seek treatment through them. Depending on the capacity of the NGOs, their possible areas of involvement can be health education, service delivery, planning, programming implementation, training and evaluation. There are various schemes for collaboration with NGOs.

a. Scheme-1: Health education and community outreach.

Under this scheme, NGO will sensitize and train volunteers, disseminate information, provide counselling, orient and advocate the key groups. They can formulate, develop and revise information, education and communication (IEC) material which are appropriate in local context.


NGO is required to ensure that treatment is observed strictly as per policy, “every dose in intensive phase and at least the first of three doses in continuous phase”. Records to be maintained as per policy and no charges are levied on patients for any service rendered.

c. Scheme-3: In hospital care for tuberculosis disease.

NGO must adhere to diagnostic and treatment guidelines. DTC would provide training, medication, quality assurance of lab, supervisory and monitoring activity. Hospital must have infrastructure, staff, volunteers etc.

d. Scheme-4: Microscopy and treatment centre

NGO will provide microscope and treatment services strictly as per guidelines, free of charge. Registered NGO with 3 Years experience having a trained microscopist with lab facilities and regular services of Medical officer.

e. Scheme-5: Tuberculosis Unit Module

NGO must ensure full services for microscopy, treatment, direct observation, default retrieval, recording and registration, supervision etc.

Approximately 500 NGOs all over India are participating under different schemes. The collaborations by far have been successful and many patients have benefited from this.

IV. INVOLVEMENT OF PPs

There has been a 25 fold expansion in RNTCP coverage since 1998. By end of 2001, a population of 450 million in 221 districts in 21 States / Union Territories have been covered under RNTCP. RNTCP’s success has increased the credibility of the public health sector, with the community. Private practitioners (PPs)(7) are generally the first point of contact for significant proportion of patients with tuberculosis. Studies in the past has shown general lack of knowledge and attitude regarding tuberculosis(S) in the PPs, but with a good programme implementation and with governments initiative in involving them the PPs can support and encourage effective tuberculosis control by

* Ensuring prompt referral of patients with cough for 3 weeks or more for sputum smear examinations.
* Providing reassurance that TB can be cured.
* Giving only RNTCP recommended drug regimen, starting treatment with rifampicin containing regimen only if it can be ensured that treatment can be completed under observation.

In addition to the above, PPs may opt to

* Serve as treatment provider for patients who prefer to receive treatment from them.
* Get their laboratories included in the quality control network of the RNTCP.
* Serve as a microscopy centre for the RNTCP. Either providing services which are free to the patients and reimbursed by the DTCs or which are paid for by the patient but whose quality and reporting is ensured DTCs.

The following schemes are as per guidelines for collaborating between private practitioners and the Government for the TB control activities.

Scheme 1: Referral of patients suspected of having TB under this scheme the PP refers patients or the sputum samples to designated microscopy centre. The physician can charge the consultation but not for sputum examination.

Scheme 2: Provision of treatment observation : - PP or their staff provides directly observed treatment to patients as per RNTCP guidelines. Patients may either have been referred by PPs or may have been
diagnosed elsewhere and referred to PP for DOT. Practitioners could be individual physicians or from other private sector like industrial house, public sector undertaking etc.

Scheme 3a: Designated paid microscopy centre (Microscopy only): A private health facility having its own laboratory serves as an approved microscopy centre under RNTCP. Microscopy policy is as per RNTCP, including record-keeping and supervision by the DTO / MO-TC / STLS of the DTCs.

Scheme 3b: Designated paid microscopy centre with treatment centre: A private health facility having its own lab, serves as an approval microscopy centre in addition also serves as treatments centre, providing categorization and treatment of the patient.

Scheme 4a: Designated microscopy centre (Microscopy only): A private health facility having its own laboratory serves as an approved microscopy centre and is designated as such by RNTCP. Patients are not charged for microscopy and the material for microscopy is provided to the microscopy centre.

Scheme 4b: Designated microscopy centre with treatment centre: A private health facility having its own laboratory serves as an approved microscopy and treatment centre. Patients are not charged for microscopy and the material for microscopy and treatment are provided by the programme.

V. INVOLVEMENT OF COMMUNITY DOT PROVIDERS

With more and more PPs enrolling for DOTS, it may not be feasible to distribute drugs only through DOT centres hence, its programme’s endeavour to involve community for the purpose of provision of DOTS. These providers can be anybody, an anganwadi worker, teacher, postman, a shopkeeper, etc. They can be given a short training to observe medication and record keeping.

The programme had given options of involving the government mechanism, the NGOs, the private practitioners, the community. More and more innovative methods are encouraged.

REFERENCES


6. Khatri GR. The Revised National Tuberculosis Control Programme: A status report on first 1,00,000 patients. *Ind J Tub 1999;157-166*.
