

The principles of DOTS were first formulated in India. In the 1950s and 1960s, pioneering studies conducted at the Tuberculosis Research Centre (TRC), Chennai demonstrated the safety and efficacy of domiciliary treatment of TB, the efficacy of intermittent treatment with anti-TB drugs, and the necessity and feasibility of direct observation of treatment. In the 1960s, studies at the National Tuberculosis Institute, Bangalore documented the efficacy, feasibility and importance of case detection by sputum microscopy in primary health care institutions. These findings formed the foundation of the DOTS strategy, which has been adopted by 148 countries worldwide. In India, DOTS is implemented as the Revised National Tuberculosis Control Programme.

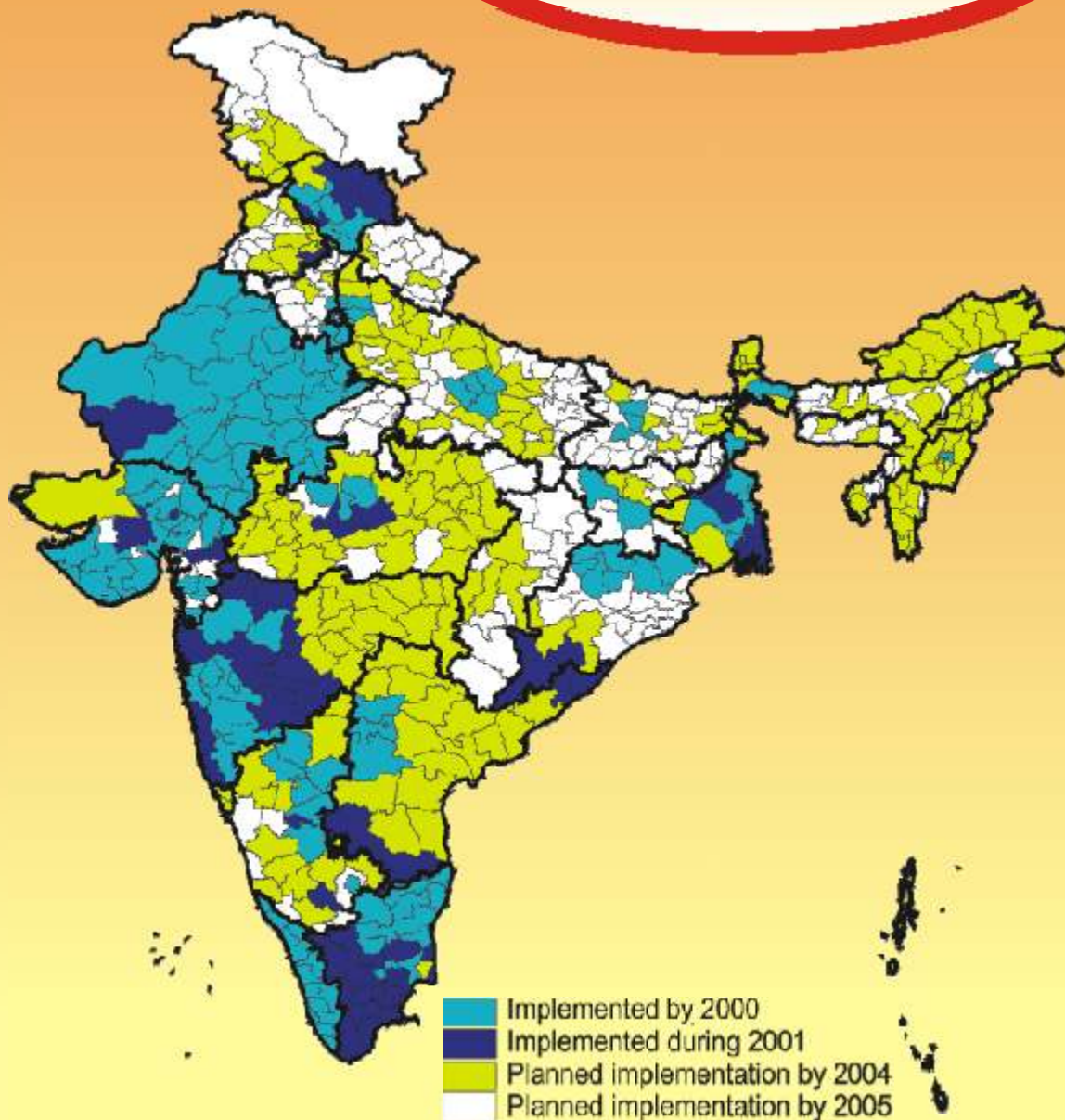


Honourable Health Minister, Padmashree Dr C.P. Thakur
at the treatment room in TRC, Chennai, where the first dose under
direct observation was given in 1962

RNTCP: Implementation Status

"The new strategy is achieving astounding success. Not since childhood immunization campaigns 20 years ago in India has a health project expanded so rapidly and maintained quality services."

—Dr Arata Kochi, Director
Global TB Programme, WHO
24 March 2000



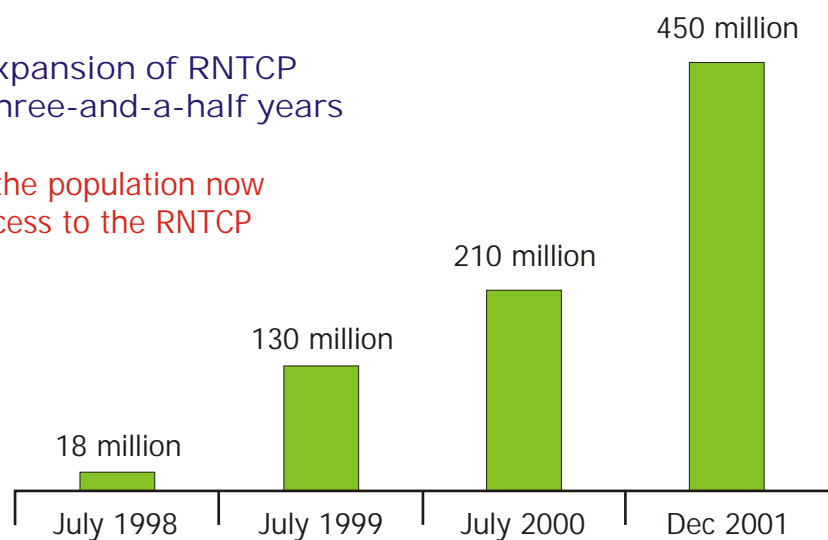


RNTCP Implementation

The Revised National Tuberculosis Control Programme (RNTCP) is an application of the principles of DOTS to the Indian context. Following a comprehensive review of national TB control activities in 1992, the Government of India adopted the RNTCP using the World Health Organization's (WHO) recommended strategy of directly observed treatment, short-course (DOTS). The programme was implemented in pilot areas beginning in 1993, and large-scale implementation began in late 1998. The RNTCP has now expanded to cover nearly half the country.

25-fold expansion of RNTCP
in the past three-and-a-half years

45% of the population now
has access to the RNTCP



RNTCP implementation time-line

1992: National programme review of tuberculosis concluded that efforts to control the disease had not made any significant impact.

1993: The RNTCP was pilot-tested applying the principles of DOTS.

1997: Government of India obtained a soft loan from the World Bank for US\$ 142 million to implement RNTCP in at least one-third of the country and to prepare the rest of the country for implementation of the RNTCP at a later date; the RNTCP in Orissa is supported by the Danish Government and the RNTCP in Andhra Pradesh is supported by the British Government.

1999: The RNTCP expanded 7-fold to become the second-largest such programme in the world.

2001: 450 million population covered under the RNTCP.

2002: One millionth patient started on treatment.

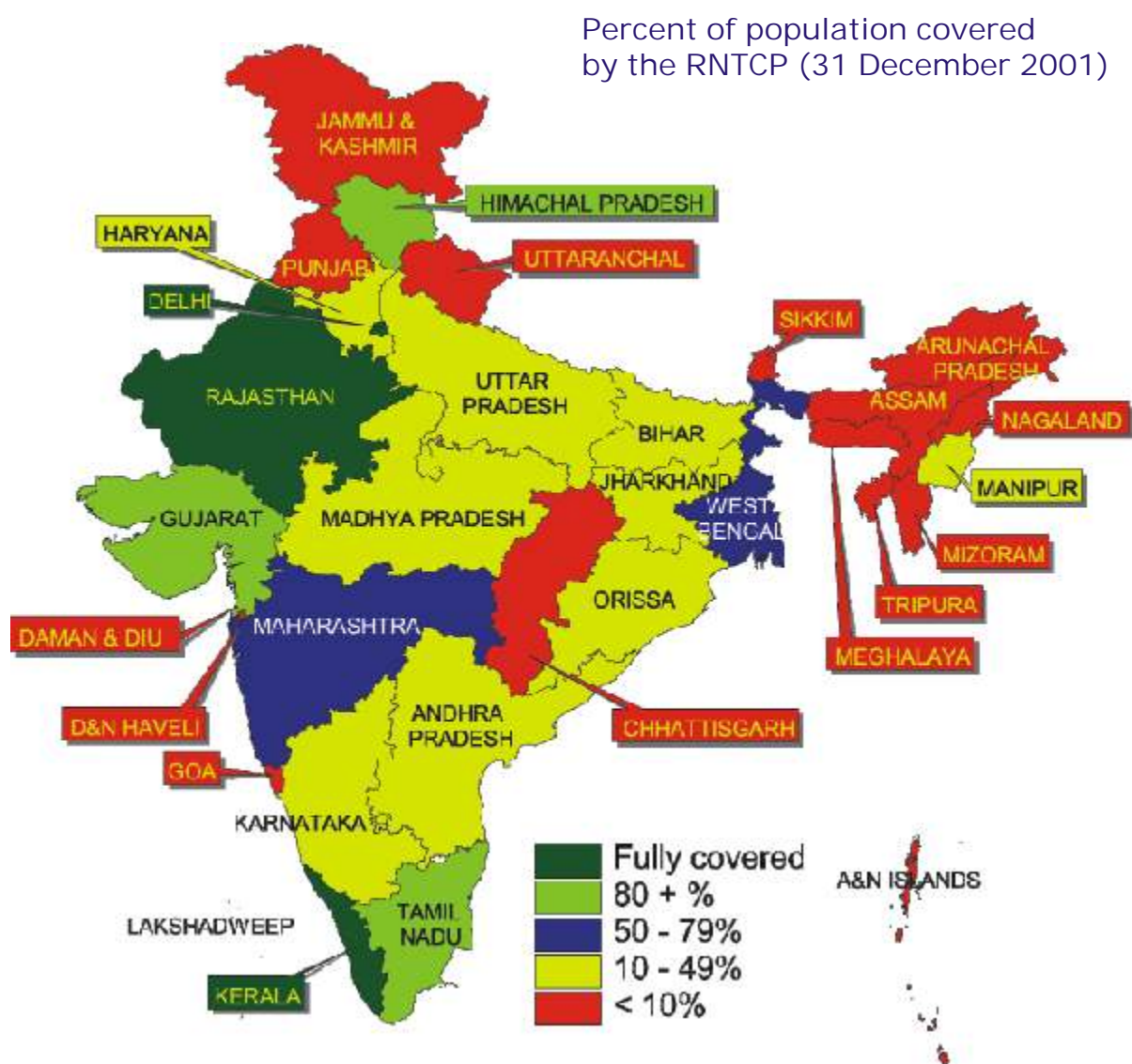
2004: 800 million population planned to be covered.

2005: Plan to cover the entire country.

Expansion Plan

Use
dots

Expansion of the RNTCP in India has in the past two years been one of the fastest accomplished by any country in the world. India now has the second largest DOTS programme in the world. As of December 2001, a population of more than 450 million in 221 districts in 21 states/Union territories had been covered under DOTS. It is planned to cover a population of 800 million (approximately 80% of the total population) by 2004, and the entire country by the year 2005. Sixteen states/Union territories have been approved for total coverage (Andhra Pradesh, Arunachal Pradesh, Chandigarh, Delhi, Goa, Gujarat, Himachal Pradesh, Kerala, Lakshadweep, Maharashtra, Manipur, Nagaland, Rajasthan, Sikkim, Tamil Nadu, West Bengal).





Elements for RNTCP success

- **Increased political commitment:** The TB Control Programme has received increased budgetary allocation from the Government of India: from Rs 52 crore in 1996–97 to Rs 136 crore in 2001–02.
- **Monitoring of districts preparing for RNTCP implementation:** Stringent appraisal criteria have been laid down to ensure quality of preparedness, which are verified by an external team. The district is not given permission for RNTCP implementation unless appropriate actions are taken to rectify the deficiencies identified by the appraisal team.
- **Good quality of diagnosis:** More than 7000 state-of-the-art binocular microscopes have been distributed to facilitate accurate diagnosis.
- **Uninterrupted supply and availability of drugs to all implementing districts:** All drugs are in patient-wise boxes to ensure standard treatment and to guarantee that no patient will ever stop treatment because of shortage of drugs.
- **Rigorous training of more than 200 000 health staff:** More than 25 000 Medical Officers and more than 5000 microscopists have been trained using the modular approach.
- **Reliable and accurate reporting and implementation of a new monitoring system** which accounts for each and every case diagnosed.



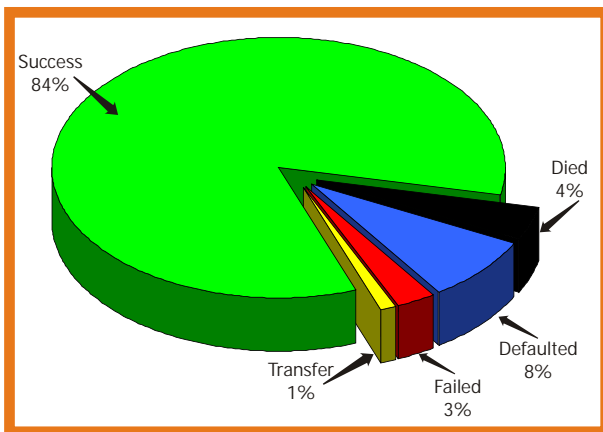
Inauguration of DTC, Wokha, Nagaland

Patient-provider interaction meeting, Orissa



Good quality of treatment

In the RNTCP, more than 8 out of 10 patients have been successfully treated.



“Results of treatment have been most encouraging.”

Sir John Crofton
Editorial: *Int J Tuberc Lung Dis*
4(3): 189–190, 2000

Economic benefits from national coverage with the RNTCP

By conservative estimates, countrywide effective DOTS implementation by 2005 would result in cumulative savings of more than US\$ 27 billion through the year 2020.

For an investment of US\$ 50 million per year, the yield would be more than US\$ 2.5 billion per year.

Full coverage would transfer US\$ 160 million every year to patients in medical expenses averted.



Chief Minister of Andhra Pradesh, Mr Chandrababu Naidu administering directly observed treatment to a patient on DOTS

Republic Day parade 2002, Chandigarh, Punjab

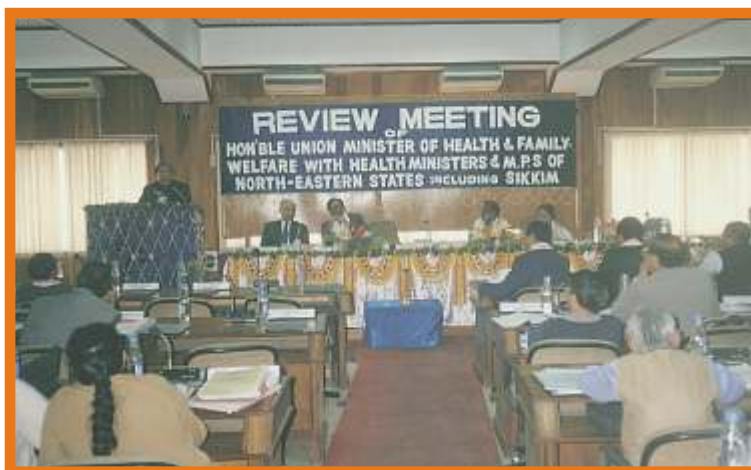




RNTCP Accomplishments

- More than 25-fold expansion in the past 3½ years.
- One of the fastest DOTS expansion in the world.
- In 2001, India treated more than 4.7 lakh cases. More patients were treated under DOTS than in any other country in the world.
- Till date, the RNTCP has placed more than 10 lakh patients on treatment, prevented more than 20 lakh people from being infected, and saved nearly 2 lakh lives.
- More than 200 000 health workers trained in DOTS.
- More than 7000 binocular microscopes distributed.
- Every month:
 - More than 160 000 patients examined
 - More than 4 lakh smears examined
 - More than 40 000 patients placed on treatment

"Remarkable progress has been made in DOTS expansion in India, which now has the largest DOTS programme in the world treating more people than any other country. The technical excellence that the programme has maintained from its inception has been a model for the world."
Dr J.W. Lee, Director Stop TB, World Health Organization
12 February 2002



"India has made considerable progress in expanding DOTS and in ensuring access to TB control services to all who need them. The technical performance has also been excellent. This is recognized worldwide."
Dr Uton Muchtar Rafei, Regional Director
Regional Office for South-East Asia, World Health Organization

Treatment and Treatment Observation

Treatment observation succeeds by building a human bond between the patient and the treatment observer



Anyone other than a family member, who is acceptable and accessible to the patient and accountable to the health system, can be a treatment observer.



Treatment and Treatment Observation

Standardized treatment regimens are recommended by WHO for each category of treatment. These recommended treatment regimens are proven to be effective. The treatment for TB under the DOTS strategy is divided into two phases: the intensive and continuation phases. Direct observation of treatment is recommended for all patients. During the intensive phase, each dose has to be directly observed. During the continuation phase, at least the first of the three weekly doses should be given under direct observation.

Treatment regimens under the RNTCP

Category of treatment	Type of patient	Regimen
Category I	New sputum smear-positive Seriously ill sputum smear-negative Seriously ill extrapulmonary	2(HRZE) ₄ / 4(HR) ₃
Category II	Previously treated Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Treatment After Default	2(HRZES) ₄ / 1(HRZE) ₄ / 5(HRE) ₃
Category III	New sputum smear-negative, not seriously ill Extrapulmonary, not seriously ill	2(HRZ) ₄ / 4(HR) ₃

Direct observation of treatment has emerged as the standard of care in developed as well as developing countries. Forty years ago, studies conducted at the Tuberculosis Research Centre, Chennai provided empirical evidence of the necessity and feasibility of directly observed treatment for achieving a high cure rate for TB. More recently, a study conducted in Pathanamthitta District, Kerala demonstrated that the probability of failure or relapse was 15 times higher among patients who did not receive directly observed treatment as against those who did. It is vitally important for the whole community that people with TB take all their medications on schedule. Interrupted treatment results in chronically infectious cases of TB, some of whom may develop multidrug-resistant TB.

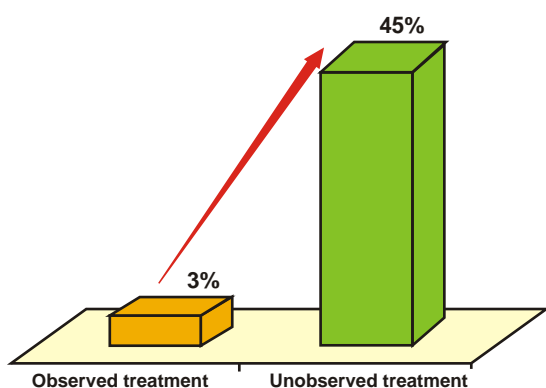
RNTCP treatment regimens are scientifically proven and highly effective.

Why do we need to observe treatment?

On their own, few people can be relied upon to take their medicines properly and for the correct period of time, particularly if the treatment is for a long period. Direct observation of treatment ensures that patients take treatment for the entire course with:

- the right drugs
- in the right doses, and
- at the right intervals.

Risk of failure or relapse was 15 times higher among patients treated without observation compared to patients receiving treatment under observation



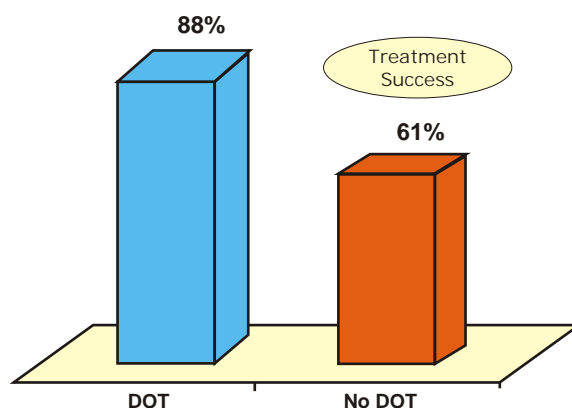
For effective treatment observation, the health staff should:

- Be respectful and considerate to the patient's needs.
- Ensure that the location and time of treatment observation is convenient to patients.
- Ensure that the patient does not lose wages.
- Ensure appropriate facilities such as drinking water, place to sit and cleanliness of the general surroundings.
- Make the patient feel that he/she is wanted.
- Retrieve the patient to return to treatment within one day of a missed dose.

Treatment observation is not "supervised swallowing". Treatment observation

- is a service to patients
- ensures cure
- protects the patient's family and community
- builds a bond between patients and health providers.

Direct observation of treatment is necessary even when drug supply is ensured



Even if drug supply is ensured, direct observation of treatment is necessary. Treatment without direct observation results in at best a 60% treatment success, compared with 85–95% with direct observation of treatment.



DIRECTLY OBSERVED TREATMENT SHOULD BE CONVENIENT TO THE PATIENT

"My name is Swaminathan. I am a watchman. In December 1998, I became sick with fever, cough and chest pain. After sputum tests, the doctor told me that I had TB. I was then asked to take 6 months of continuous treatment. The doctor arranged for my medicines for which I had to go to the clinic thrice a week. But when my shifts

at duty changed, I couldn't go to the clinic as before and so I started missing my medicines. I told the health worker about my problem. They asked if I had a friend who could observe my treatment. I asked my friend Johnson to be my DOT provider. He now gives me my medicine while we change shifts. I never have to miss my doses now. My sputum results have become negative and I feel much better. I am sure that I am on the way to cure. I am thankful to my doctor, my friend Johnson and the health worker who have taken a keen interest in my recovery." —Mr Swaminathan

TREATMENT OBSERVATION IS A SERVICE TO PATIENTS

Mrs CS Pankajam is a housewife who volunteered to treat 15 TB patients through direct observation of treatment. Her commitment and care towards the patients has enabled them to complete 6 months of treatment. She is a shining example of how a citizen can contribute towards TB control. Even today, she continues her work with the same spirit.



TREATMENT OBSERVATION IS A SERVICE TO THE PROVIDER

"I gave medicines to my friend. Sometimes I would wait till 10 o'clock to observe him swallowing the drugs. I felt as though I was the 'doctor' of the patient and he was getting cured because of my efforts. If given an opportunity I would like to help more patients."—Mr Pasupathy

TREATMENT OBSERVATION SUCCEEDS BY BUILDING A HUMAN BOND BETWEEN THE PATIENT AND THE TREATMENT OBSERVER

Asiti Devi is a community health volunteer working in a large slum community of Patna. She is a DOT provider for 6 patients in her community, all of whom are on their way to recovery. By building a bond with her patients, Asiti Devi has made a difference in their lives.



Anokhabai, a patient from Madhya Pradesh, before and after TB treatment



stop
TB



TREATMENT OBSERVATION IS
FEASIBLE IN EACH COMMUNITY BY
IDENTIFYING AND INVOLVING THE
STRENGTHS OF THE COMMUNITY

DOT provider Yashpal Pulani, a shoe shop owner in Gurgaon, Haryana is the son of a cured TB patient. With the help of his brother, he is a DOT provider for 24 patients in his community. The shop is centrally located and the timings are convenient to patients.

GRANDMOTHER'S STORY

"I was treated for TB a few years ago. At that time, I had to travel very far to collect my medicines for a period of two long years. The whole system has become so convenient for the patient, they now have to take medicines only for 6 months and the medicines are made available near their house itself!"

Comments of Mrs Senthamarai, a 60-year-old lady living in one of the slums of south Chennai and a DOT provider for two TB patients in her community

AN ACCEPTABLE, ACCESSIBLE AND ACCOUNTABLE TREATMENT OBSERVER IS THE KEY TO THE SUCCESS OF DOTS

"My neighbours thought I was going to die of TB. I was bedridden, very sick and unable to move. This was the opinion of my neighbours when the doctor diagnosed me with TB. The doctor asked me to identify a responsible person who would supervise my treatment. I introduced my Village Headman to the doctor and the ACT social worker who handed over the 6 months course of medication to him. After 6 months, I was declared 'cured' by the doctor. I am now able to continue my work as a fisherman again. My neighbours are amazed at my recovery."—Raja, a fisherman

RNTCP Activities during 2001

Success of the RNTCP depends on collaboration among the government, private practitioners, NGOs and medical colleges



Director of Health Services, Kerala inaugurating a private Microscopy Centre



Private Health Sector in the RNTCP

Involvement of health providers in the private sector is critical in increasing the coverage of RNTCP services. In recent years, many steps have been taken to involve private health care providers. Meetings have been arranged with private practitioners at the local and the national levels. Districts have been advised to make a directory listing private practitioners (PPs) and proactively identify prominent and willing PPs/institutions for their involvement in the programme. District societies are seeking representation from the private sector. Several private–public partnership models are in place, which include projects in Pune (Maharashtra), Sitapur (Uttar Pradesh), Patna (Bihar), Hyderabad (Andhra Pradesh), Chennai (Tamil Nadu) and Delhi. Draft guidelines for involvement of the private health sector in the RNTCP were developed. A national workshop, convened on 28 October 2001, Delhi to discuss draft guidelines, was attended by about 80 participants including PPs from all RNTCP implementing states, representatives of the Indian Medical Association, and some District TB Officers. Alternatives outlined in the guidelines for participation of PPs are: (1) PPs refer patients or send sputum samples of patients suspected of having TB to a designated microscopy centre; (2) PPs provide directly observed treatment (DOT) to patients on RNTCP; (3) A private health facility having its own laboratory, serves as a designated microscopy centre, or as a designated microscopy centre-cum-DOT centre if it has a full-fledged doctor attached to it.



Private practitioners participating in the National Workshop held in New Delhi on 28 October 2001

District Collector, Dr V. Venu
addressing private practitioners
at Payyannur, Kannur District, Kerala



Meeting with private practitioners in
Gujarat, 3 February 2002

Private microsocopy-cum-treatment
centre in Thane Municipal Corporation,
Maharashtra





Involvement of private practitioners in Kannur District, Kerala

Kannur District in Kerala has a large number of private hospitals, nursing homes and clinics. More than 60% of patients consult private health facilities. The district RNTCP staff has taken several steps to increase the involvement of PPs in the RNTCP. These steps include:

- (i) Identification of heavily utilized hospitals and nursing homes;
- (ii) Identification of independent laboratories where sputum microscopy for AFB was being done;
- (iii) Sensitization and training of leading PPs;
- (iv) Training of senior qualified laboratory technicians working in private laboratories; and
- (v) Training of DOT providers.

So far, 35 private health facilities (including 11 laboratories) have been involved in RNTCP implementation in Kannur. PPs screen and diagnose patients at their private clinics. Diagnosis is made by examination of 3 smears as per the RNTCP norms. When a patient is diagnosed to have TB, categorization is done by the private physicians, and a patient-wise box of drugs is procured from the District RNTCP staff. The private physician's clinic serves as the DOT centre and drugs are given free to the patient. The Senior Treatment Supervisor (STS), and the Medical Officer TB Control visit and supervise the DOT centres to provide the necessary support. The Senior TB Laboratory Supervisor visits laboratories and cross-checks slides as per RNTCP guidelines. While the staff of the PP administer treatment under direct observation, defaulter retrieval is assisted by the STS or other government health workers whenever required.

"This programme is really a blessing for the poor TB patients who find it difficult to buy their drugs. I can now help a number of poor TB patients. I should have been involved in the RNTCP much earlier so that a number of TB patients could have been saved."

Remark of a private practitioner, Kerala

Involvement of NGOs

NIDAN makes a difference in Patna, Bihar

NIDAN is an NGO supporting non-formal education and income-generation schemes for slum dwellers in 48 slum areas in Patna. In collaboration with the RNTCP, this NGO took up the provision of DOTS services to this population in a slum, Dusathi Pakadi with a population of 3.5 lakh. Within a short time, over 100 TB patients have been put on anti-TB treatment. Thirty-five DOTS centres are now in operation and provide services at convenient timings and locations. This has resulted in improved treatment outcomes among these TB patients.

Shri A. Raja, Honourable Minister of State for Health and Family Welfare delivering the inaugural address at the National workshop on RNTCP for involvement of medical colleges, 14 September 2001



"TB and its control are vitally important to the health of this country. Nearly four years back, we hosted a consensus conference which concluded that phased and effective implementation of the RNTCP is the best strategy and perhaps the only chance of controlling TB in India during this generation. In the past four years, the programme has succeeded beyond our highest expectations. The current conference is an important next step in making that chance a reality."

Dr S.P. Agarwal, Director General of Health Services, 14 September 2001



Dr S.P. Agarwal, Director General of Health Services, lighting the lamp during the medical college workshop, 14 September 2001

Medical colleges

Use dots

Under the RNTCP, the initiative to increase the involvement of medical colleges is gaining momentum. A 2-day workshop was inaugurated by the Honourable Minister of State for Health and Family Welfare, Government of India, Shri A. Raja, at the National Tuberculosis Institute, Bangalore in September 2001. Dr S.P. Agarwal, Director General of Health Services and other important policy-makers and 75 leading experts from 40 medical schools of the country participated in the workshop.

This workshop was built on an earlier consensus conference held in 1997. The earlier conference concluded that: "....phased and effective implementation of the RNTCP is the best strategy and perhaps the only chance of controlling TB in India during this generation."

The 2001 workshop was attended by leading medical professors throughout the country. This gathering of TB experts issued a consensus statement "....within its eight years of implementation and three years of large-scale service delivery, the RNTCP has proved its credibility as the most effective strategy to control TB in India".

Presently, two-thirds of the medical colleges in RNTCP implementing areas are participating in the programme. RNTCP nodal centres for medical colleges are proposed to be established in all zones of India to facilitate implementation of the recommendations.

Recommendations made by experts place emphasis on establishment of RNTCP centres in all medical colleges; prioritization and improvement of teaching on RNTCP; involvement in training, conducting operational research, monitoring and supervision; information, education and communication activities; private sector participation; quality assurance of drugs and sputum microscopy. Additionally, colleges should provide services for the management of complicated cases and develop model DOTS centres.