

## **TUBERCULOSIS CONTROL – INDIA**

In terms of population coverage, India now has the second largest DOTS (Directly Observed Treatment, Short course) programme in the world. However, India's DOTS programme is the fastest expanding programme, and the largest in the world in terms of patients initiated on treatment, placing more than 100,000 patients on treatment every month. This site provides information about tuberculosis and its control in India.

### **About RNTCP**

**In India today, two deaths occur every three minutes from tuberculosis (TB). But these deaths can be prevented. With proper care and treatment, TB patients can be cured and the battle against TB can be won**

**T**uberculosis (TB) is an infectious disease caused by a Bacterium, Mycobacterium tuberculosis. It is spread through the air by a person suffering from TB. A single patient can infect 10 or more people in a year.

India has a long and distinguished tradition of research in TB. Studies from the Tuberculosis Research Centre in Chennai and the National Tuberculosis Institute in Bangalore provided key knowledge to improve treatment of TB patients all around the world.

Modern anti-TB treatment can cure virtually all patients. It is, however, very important that treatment be taken for the prescribed duration, which in every case is a minimum of 6 months. Because treatment is of such a long duration and patients feel better after just 1-2 months, and because many TB patients face other problems such as poverty and unemployment, treatment is often interrupted.

Therefore, just providing anti-TB medication is not sufficient to ensure that patients are cured. The DOTS strategy ensures that infectious TB patients are diagnosed and treated effectively till cure, by ensuring availability of the full course of drugs and a system for monitoring patient compliance to the treatment.

### **Directly Observed Treatment, Short-course (DOTS)**

**T**he DOTS strategy along with the other components of the Stop TB strategy, implemented under the Revised National Tuberculosis Control Programme (RNTCP) in India, is a comprehensive package for TB control.

The DOTS strategy is cost-effective and is today the international standard for TB control programmes. To date, more than 180 countries are implementing the DOTS strategy. India has adapted and tested the DOTS strategy in various parts of the country since 1993, with excellent results, and by March 2006 nationwide DOTS coverage has been achieved.

## **DOTS is a systematic strategy which has five components**

- **Political and administrative commitment.** TB is the leading infectious cause of death among adults. TB kills more men than women, yet more women die of TB than all causes associated with childbirth combined. Since TB can be cured and the epidemic reversed, it warrants the topmost priority, which it has been accorded by the Government of India. This priority must be continued and expanded at the state, district and local levels.
- **Good quality diagnosis.** Good quality microscopy allows health workers to see the tubercle bacilli and is essential to identify the infectious patients who need treatment the most.
- **Good quality drugs. An uninterrupted supply of good quality anti-TB drugs** must be available. In the RNTCP, a box of medications for the entire treatment is earmarked for every patient registered, ensuring the availability of the full course of treatment the moment the patient is initiated on treatment. Hence in DOTS, the treatment can never interrupt for lack of medicine.
- **Supervised treatment to ensure the right treatment,** given in the right way. The RNTCP uses the best anti-TB medications available. But unless treatment is made convenient for patients, it will fail. This is why the heart of the DOTS programme is "directly observed treatment" in which a health worker, or another trained person who is not a family member, watches as the patient swallows the anti-TB medicines in their presence.
- **Systematic monitoring and accountability.** The programme is accountable for the outcome of every patient treated. This is done using standard recording and reporting system, and the technique of 'cohort analysis'. The cure rate and other key indicators are monitored at every level of the health system, and if any area is not meeting expectations, supervision is intensified. The RNTCP shifts the responsibility for cure from the patient to the health system.

The new Stop TB Strategy published by WHO in 2006 has DOTS in the core with additional components to address TB/HIV and MDR-TB, health system strengthening, involvement of all care providers, engaging people with TB and affected communities, and enabling/promoting research. RNTCP is already implementing/ plans to implement the activities recommended under the new Stop TB Strategy.

### **DOTS in India**

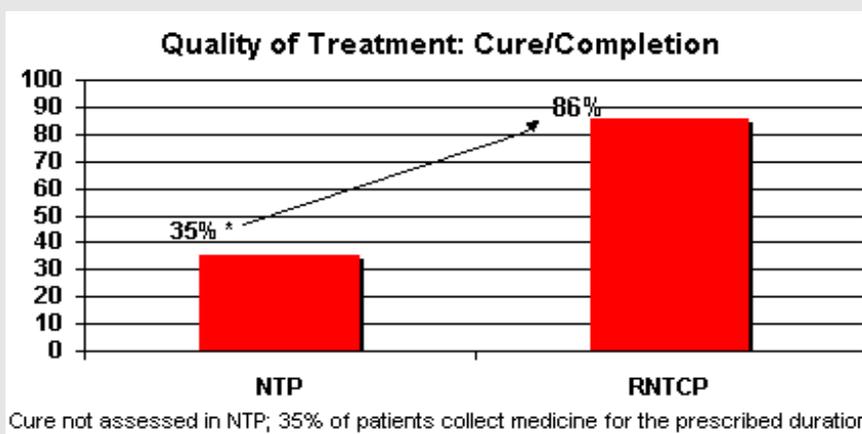
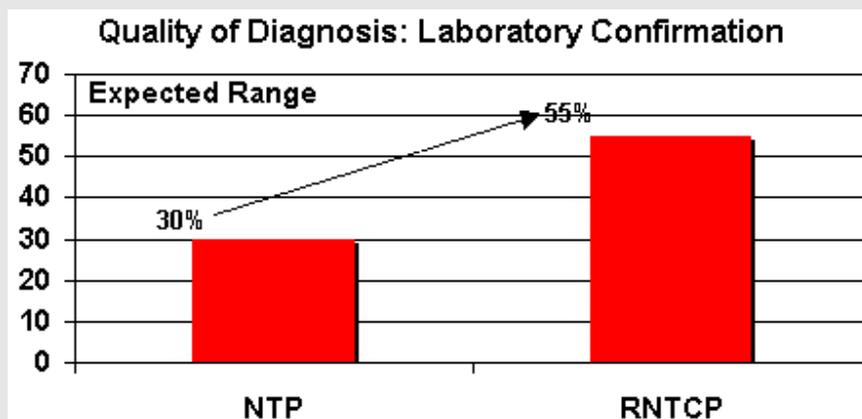
Controlling TB in India is a tremendous challenge. The TB burden in India is still staggering. Every year, 1.8 million persons develop the disease, of which about 800,000 are infectious; and, until recently, 370,000 died of it annually —1,000 every day. The disease is a major barrier to social and economic development. An estimated 100 million workdays are lost due to illness. Society and the country also incur a huge cost due to TB—nearly US\$ 3 billion in indirect costs and US\$ 300 million in direct costs.

The Revised National Tuberculosis Control Programme (RNTCP), based on the DOTS strategy, began as a pilot in 1993 and was launched as a national programme in 1997. Rapid RNTCP expansion began in late 1998. By the end of 2000, 30% of the country's population was covered, and by the end of 2002, 50% of the country's population was covered under the RNTCP. By the end of 2003, 778 million population was covered, and at the end of year 2004 the coverage reached to 997 million. By December 2005, around 97% (about 1080 million) of the population had been covered, and the entire country was covered under DOTS by 24th March 2006.

Every day in India, under the RNTCP, more than 15,000 suspects are being examined for TB, free of charge. The diagnosis of these patients and the follow-up of patients on treatment is achieved through the examination of more than 50,000 laboratory specimens. As a result of

these examinations, each day, about 3,500 patients are started on treatment, stopping the spread of TB in the community. In order to achieve this, more than 600,000 health care workers have been trained and more than 11,500 designated laboratory Microscopy Centres have been upgraded and supplied with binocular microscopes since the inception of the RNTCP.

As a result of rapid expansion in diagnostic facilities, the proportion of sputum- positive cases confirmed in the laboratory are double that of the previous programme and is on par with international standards. Despite the rapid expansion, overall performance remains good and in many areas is excellent. Treatment success rates have tripled from 25% in the earlier programme to 86% in RNTCP.



### DOTS Expansion in India

In 1992, the Government of India, together with the World Health Organization (WHO) and Swedish International Development Agency (SIDA), reviewed the National TB Programme and concluded that it suffered from managerial weakness, inadequate funding, over-reliance on x-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes. Programme review showed that only 30% of patients were diagnosed and only 30% of those treated successfully. Based on the findings and recommendations of the review in 1992, the GOI evolved a revised strategy and launched the **Revised National TB Control Programme (RNTCP)** in the country. Starting as pilots in October 1993, the RNTCP was implemented in a population of 2.35 million in 5 sites in different states (Delhi, Kerala, West Bengal, Maharashtra, and Gujarat). The programme was expanded to

a population of 13.85 million in 1995 and 16 million in 1996. Having proved both its technical and operational feasibility, a soft loan of US \$ 142 million was negotiated with the World Bank in December 1996 and the credit agreement was signed with IDA in May 1997. In 1997 RNTCP was launched as a national programme. It was envisaged to implement RNTCP in 102 districts of the country covering a population of 271 million in a phased manner. Another 203 SCC districts with a population of 447 million were envisaged to be strengthened as a transitional step for introduction of revised strategy at a later stage. Having started in 1997, rapid scale-up began in late 1998, when another 100 million populations was covered under RNTCP. Over the years RNTCP has expanded rapidly as shown below:

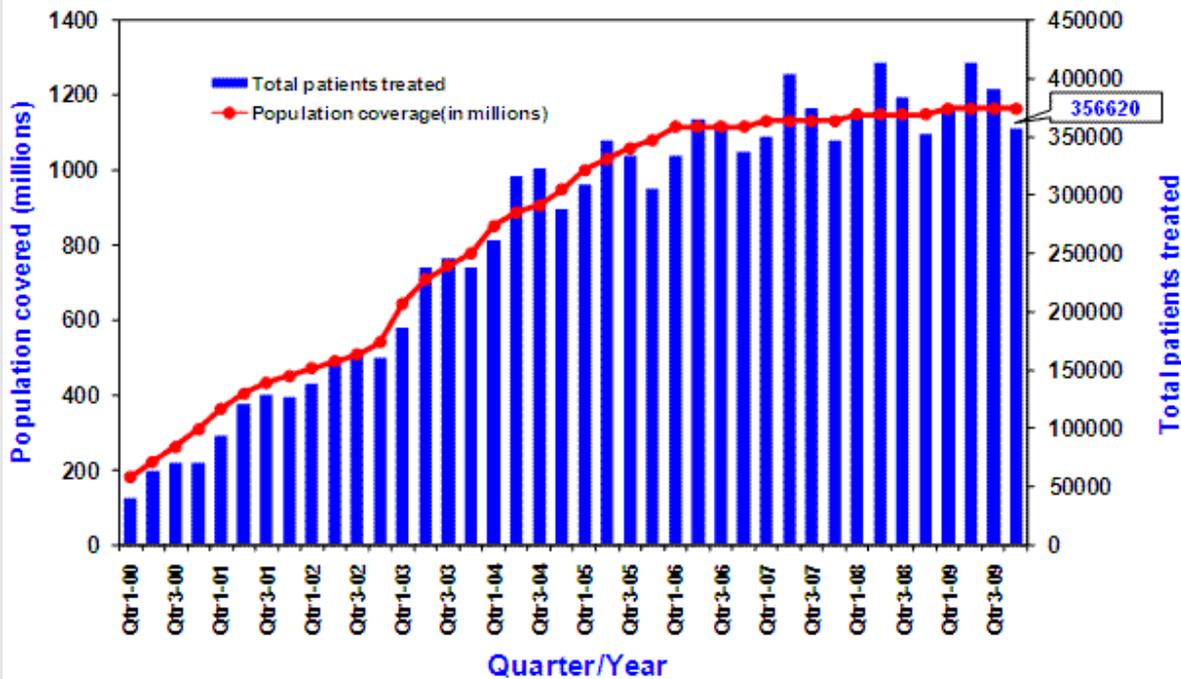
| Year                      | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | March 2006 |
|---------------------------|------|------|------|------|------|------|------|------|------------|
| Population Covered *      | 18   | 130  | 287  | 450  | 530  | 775  | 947  | 1080 | 1114       |
| * cumulative, in millions |      |      |      |      |      |      |      |      |            |

Starting in 1997, the project was implemented in a phased manner to ensure that quality of services is maintained. By March 2006, entire country has been covered under the programme.

Revised National TB Control Programme and its recent progress in DOTS expansion has been encouraging. As per Global TB Report 2003, 2/3rd of the additional sputum positive cases reported under DOTS in 2001, were found in India. In 2002, over 620,000 cases were placed on treatment of which nearly 250,000 were new smear positive cases. In the year 2003, more than 900,000 cases were placed on treatment. In the year 2004 alone more than 1100,000 cases were placed on treatment, and in the 2005, more than 1290,000 cases were placed on treatment - **largest cohort of cases, more than any other country in the world** . By December 2009, more than 11 million patients have been initiated on treatment, saving more than 2 million additional lives. The success of DOTS in India has contributed substantially to the success of TB control in the world.

RNTCP has consistently achieved treatment success rate of more than 85%, and case detection close to the global target. However, in 2007 RNTCP for the first time has achieved the global target of 70% case detection while maintaining the treatment success rate of more than 85%.

## Population in India covered under DOTS and Total Tuberculosis Patients put on treatment each quarter



### TB and HIV

TB is the most common opportunistic infection in people living with HIV virus. As the HIV breaks down the immune system, HIV- infected people are at greatly increased risk of TB. Without HIV, the lifetime risk of developing TB in TB-infected people is 10%, compared to at least 50% in HIV co-infected. HIV is also the most powerful risk factor for progression from TB infection to TB disease. TB in turn accelerates the progression of HIV to AIDS and shortens the survival of patients with HIV infection. Thus, TB and HIV are closely interlinked. In India there are an estimated over 5 million HIV-infected persons.

With such large numbers of HIV-positive individuals in India, it is likely that HIV may worsen the TB epidemic in the absence of a robust TB control programme. However, even among HIV-infected people, TB can be cured. Directly Observed Treatment, Short-course (DOTS) is as effective among HIV- infected TB patients as among those who are HIV negative.

### Multi-drug-Resistant Tuberculosis (MDRTB)

MDRTB refers to strains of the bacterium which are proven in a laboratory to be resistant to the two most active anti-TB drugs, isoniazid and rifampicin. Treatment of MDRTB is extremely expensive, toxic, arduous, and often unsuccessful.

DOTS has been proven to prevent the emergence of MDRTB, and also to reverse the incidence of MDRTB where it has emerged. MDRTB is a tragedy for individual patients and a symptom of poor TB management. The best way to confront this challenge is to improve TB treatment and implement DOTS.

Beginning 1999, the Tuberculosis Research Centre, Chennai in collaboration with the National Tuberculosis Institute, Bangalore, initiated drug resistance surveys in different parts of the

country using the WHO/IUATLD guidelines. The table below provides information about primary isoniazid resistance and primary multi-drug resistance based on analyses completed to date.

**Table: Primary drug resistance, India (1999-2002)**

| District (Zone)     | Intake period | Number of patients | Primary isoniazid resistance % | Primary multi-drug resistance % |
|---------------------|---------------|--------------------|--------------------------------|---------------------------------|
| North Arcot (South) | 1999          | 282                | 23.4                           | 2.8                             |
| Raichur (South)     | 1999-2000     | 278                | 18.7                           | 2.5                             |
| Wardha (West)       | 2000-2001     | 197                | 15                             | 0.5                             |
| Jabalpur (West)     | 2001-2002     | 273                | 17                             | 1.0                             |
| Hoogly (East)       | 2000-2001     | 350                | 10.3                           | 3.0                             |
| Mayurbanj (East)    | 2000-2002     | 343                | 2.5                            | 0.7                             |

Currently large scale representative drug resistance surveys are on-going in 2 States and 3 (Andhra Pradesh, Orissa, Uttar Pradesh) other States are likely to conduct these surveys.

RNTCP is planning to introduce second line anti-TB treatment for MDR-TB cases, starting in early 2007. For this purpose State level Intermediate Reference Laboratories are being established to provide quality assured culture and drug susceptibility testing facilities. The guidelines for management of MDR-TB under DOTS-Plus strategy have been developed.

### **Second Phase of RNTCP**

In the first phase of RNTCP (1998-2005), the programme's focus was on ensuring expansion of quality DOTS services to the entire country. There are many challenges remaining that are to be addressed in order to achieve the TB-related targets set by the Millennium Development Goals for 2015 and to achieve TB control in the longer term.

The RNTCP has now entered its second phase in which the programme aims to firstly consolidate the gains made to date, to widen services both in terms of activities and access, and to sustain the achievements for decades to come in order to achieve ultimate objective of TB control in the country.

All components of new **Stop TB Strategy** are incorporated in the second phase of RNTCP. These are:

1. **Pursue quality DOTS expansion and enhancement**, by improving the case finding and cure through an effective patient-centred approach to reach all patients, especially the poor.
2. **Address TB-HIV, MDR-TB and other challenges**, by scaling up TB-HIV joint activities, DOTS Plus, and other relevant approaches.
3. **Contribute to health system strengthening**, by collaborating with other health programmes and general services
4. **Involve all health care providers**, public, nongovernmental and private, by scaling up approaches based on a public-private mix (PPM), to ensure adherence to the International

Standards of TB care.

5. **Engage people with TB, and affected communities** to demand, and contribute to effective care. This will involve scaling-up of community TB care; creating demand through context-specific advocacy, communication and social mobilization.
6. **Enable and promote research** for the development of new drugs, diagnostic and vaccines. Operational Research will also be needed to improve programme performance.

The Revised National TB Control Programme now aims to widen the scope for providing standardized, good quality treatment and diagnostic services to all TB patients in a patient-friendly environment, in which ever health care facility they seek treatment from. Recognizing the need to reach to every TB patient in the country, the programme has made special provisions to reach marginalized sections of the society, including creating demand for services through specific advocacy, communication and social mobilization activities.