

RNTCP: Past, Present and Future of TB Control Programme in India

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Tuberculosis is one of the oldest diseases known to affect mankind as shown by the findings of tuberculous spinal disease in Egyptian mummies. The Greeks called the disease *phthisis* ("consumption"), emphasizing the dramatic aspect of general wasting associated with chronic untreated disease. It has also been referred to in the Vedas and 'Ayurvedic Samhitas' as the '*Kshaya Rog*'. The infectious aetiology was debated until Robert Koch's discovery of the bacillus in 1882. Effective anti-tuberculosis drugs were available in the middle of last century, but in Europe and the United States, mortality rates began to decrease decades before the introduction of antimycobacterial drugs due to improvement in socio-economic conditions thereby establishing the fact that TB and poverty are closely related.

BURDEN OF DISEASE

Mycobacterium tuberculosis remains the single most serious pathogen worldwide and a major global public health problem in much of the developing world. Globally it is estimated that 8-9 million people develop active disease every year of which nearly 4 million cases are sputum smear-positive, the majority of

whom are in the developing countries. TB also accounts for nearly 1.7 million deaths annually¹. This is due to the failure to cure a high proportion of sputum smear-positive cases, population growth, HIV-epidemic and other socio economic and demographic factors (poverty, migration, etc). Globally the HIV epidemic is worsening the TB situation, increasing the number of tuberculosis cases and accelerating the spread of the disease. One third of the world's AIDS cases are suffering from TB. HIV increases a person's susceptibility to TB infection and co-infected more likely to break down to TB disease than HIV non-infected in their life time. HIV is now considered the most powerful risk factor for the progression of TB infection to disease.

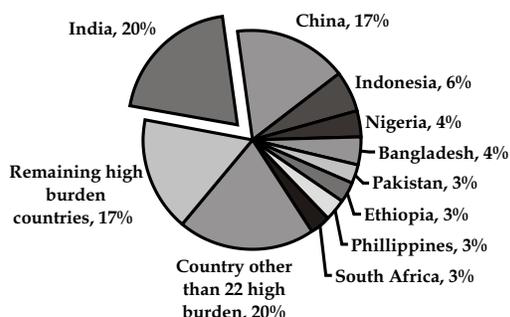


Figure 1: Estimated Incidence of TB, 2002

Source: WHO Report 2004: Global TB Control²

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Tuberculosis kills more adults than all other infectious diseases. More children are orphaned because of tuberculosis than because of any other infectious disease. Tuberculosis (TB) was declared a global emergency by W.H.O in 1993, and countries round the world have intensified their measures towards TB control programmes. In fact, the threat of HIV/ AIDS alerted them to potential danger of TB resurgence.

It is estimated that there were 8.9 million new cases of TB in 2003 (140/100,000 population) of which 3.9 million (62/100,000) were smear-positive, and 674 000 (11/100,000) were infected with human immuno-deficiency virus (HIV). There were 15.4 million prevalent cases (245 /100,000), of which 6.9 million were smear-positive (109/100,000). An estimated 1.7 million people died from TB in 2003, including those co-infected with HIV (229,000)¹.

Each year, 1.8 million new cases of TB occur in India, of which about 0.8 million are infectious new smear-positive pulmonary TB cases i.e. 75 lakh new smear positive cases per lakh population. Based on the Model DOTS project in Thiruvallur, Tamil Nadu and the National ARTI survey it was estimated that the TB burden in the country (baseline year 2000) is 8.5 million, of which 3.8 million are bacillary pulmonary cases, 3.9 million are abacillary pulmonary cases and 0.8 million are Extrapulmonary (EP) cases². More adults die from TB than from any other infectious disease in India - more than 2 every 3 minutes, over a 1000 every

day and about 370,000 every year³. There are over 5.1 million HIV positive patients in the country. The prevalence of HIV in TB cases is estimated at around 5.2% in the country and this pool of TB-HIV co-infected needs to be accorded due priority. With nearly 40% of the Indian population already infected with the TB bacillus and 10% of the infected eventually developing the disease in their life time, this large pool of infected people means that TB will continue to be a major problem in the foreseeable future. Data from recent studies conducted by TRC and NTI, have found MDR-TB levels in India is between 0.5% to 3% in new cases and 12% in re-treatment cases. Although, the prevalence of MDR TB amongst new TB cases is low, but when translated into absolute numbers it is significant resulting in significant morbidity, mortality and economic burden.

The economic and social burden due to TB is also immense. On an average, 3-4 months of work time are lost if an adult has TB, resulting in the loss of 20-30% of annual household income. An average of 15 years of income is lost if an individual dies of the disease. The annual cost to the country has been estimated at US \$ 300 million in direct costs and at US \$ 3 billion in indirect costs. TB kills more women than any other infectious disease, and more than all causes of maternal mortality combined. Moreover, women with TB are stigmatized and more than 100,000 women are rejected by their families each year because of TB. The disease also has an adverse impact on children it leads to a large number of

children becoming orphans, and every year in India alone, 300,000 children leave school on account of their parents' TB³.

GOALS AND TARGETS OF TB CONTROL

The World Health Assembly (WHA) adopted the Directly Observed Treatment, Short-course (DOTS) strategy as a cost-effective tool for combating the scourge of TB across the world. It had declared TB as a global emergency in 1993 due to the enormous morbidity, mortality and socio-economic burden caused by the disease⁴. The WHA in its resolution targeted for 100% coverage under DOTS, achieve 70% case detection of infectious TB cases and to treat successfully 85% of such identified cases by 2000 later extended to 2005⁵.

Supplementing the WHA 2005 global targets, are the G8 Okinawa targets of 50% reduction in prevalence and mortality of TB by 2010 and the Millennium Development Goal (MDG) Goal 6-Target 8 of halting and reversing the incidence of TB by 2015⁶.

The long term goal of the TB control programme is to decrease the mortality and morbidity due to TB and cut the transmission of infection until TB ceases to be a major public health problem. This is to be realized through the twin global TB control objectives. The government of India is committed to achieving the MDG through the implementation of quality assured diagnostic and treatment services under DOTS strategy free of cost to all TB patients across the country.

HISTORICAL PERSPECTIVE OF TB CONTROL ACTIVITIES IN INDIA

The evolution and progress of anti-tubercular efforts in the country has been need-based relating to the problems of a technical, operational and managerial nature that arose over time in the country. As in most of the countries, the first anti-TB measures taken in India were of an unplanned and ad hoc nature confined mainly to the establishment of hospitals and Sanatoria. Attempts to tackle the problem of TB through organized efforts actually had their origin in late 1930s. The chronology of important landmarks in the history of tuberculosis (TB) control can be divided into three phases: the four decades prior to the tuberculosis control programme; the three decades of national tuberculosis control programme and the current phase of Revised National Tuberculosis Control Programme (RNTCP)⁷⁻⁹.

Phase 1: The Early Days (1910-1960)

Before the discovery of antituberculosis drugs, tuberculosis treatment consisted of attempts to strengthen the patients' resistance to the disease. The 'sanatorium movement' which originated in England, in the absence of chemotherapy, recommended a balanced diet, fresh air and regulated exercise.

Around the time India gained independence, effective drugs against TB began to be available (Streptomycin since 1944, Para-aminosalicylic Acid (PAS) in 1946, Thiacetazone 1950, Isoniazid 1952 and Rifampicin 1966). The very notion that there could be effective drugs against

the tubercle bacilli was so revolutionary that researchers began to experiment on the effective dosages and combinations of drugs to be used.

The cost for large scale establishment for TB control was not feasible at that point in time, hence attention was directed to prevention of TB by way of BCG vaccination, which was felt to be feasible operationally and economically. The International Union Against TB (IUAT) gave assistance to the BCG vaccination programme in the country. TB demonstration and training centres were developed for the training of the required personnel. The BCG campaign was introduced on a small scale in Madanapalli in 1948 and was extended on a mass scale in 1951¹⁰. BCG campaign helped in raising awareness of the disease as a public health problem not only in the minds of the medical community but also the message of health promotion and prevention of disease to the remotest part of the country and its population.

National Sample Survey (1955-58)

From 1955 to 1958, under the auspices of the ICMR, a large-scale sample survey was conducted in 6 zones of the country, covering both urban and rural populations, to obtain as precise information as possible about the magnitude of TB problem in the country. The survey confirmed the impression of high prevalence of TB morbidity in the rural areas that had earlier been suggested by the large scale tuberculin testing. It was estimated that of the 8 million suffering from TB disease, about

80% were in the rural areas¹¹. With this revelation, the need for the development of a nationally applicable control programme to tackle the problem of TB was strongly felt.

Phase II Development of the National TB Control Programme (1960-1990)

The TB Chemotherapy Centre (TCC), now known as the TB Research Centre demonstrated that the efficacy of domiciliary treatment provided adequate chemotherapy was prescribed and fully taken. Further, there was no evidence that close family contacts of patients treated at home incurred an increased risk of contracting TB¹². The available tools for control of TB consisted of BCG vaccination for prevention, chest radiography and sputum microscopy for case finding, and ambulatory domiciliary chemotherapy for treatment. The probability of formulating a comprehensive TB programme to combat the disease on a community wide basis now seemed possible.

The development of the National TB Control Programme (NTP) was based on a number of factors related to the epidemiological, sociological, operational, technical and administrative aspects related to TB control in India. NTI conducted operational research studies keeping in mind an average Indian district, its population and health facilities available to enunciate suitable methods for the large-scale application of TB control measures. The NTP was pilot tested in Ananthpur district of Andhra Pradesh in 1961, the first model District

TB centre (DTC). Based on the experiences of the pilot, the National TB Control Programme was launched in 1962, in a phased manner through out the country. A District TB Centre (DTC), which functioned as the nodal / referral centre for TB in the respective District was established in nearly all the Districts.

Phase III The Revised National TB Control Programme (1992 onwards)

Despite the NTP having been in existence since 1962, no appreciable change in the epidemiological situation in the country had been observed. The HIV-AIDS epidemic and the spread of multi-drug-resistance TB were threatening to further worsen the situation. In view of this, in 1992, the GOI with WHO and SIDA, reviewed the TB situation and the performance of the NTP¹³. The observations revealed that the NTP, suffered from managerial weaknesses, inadequate funding, an over-reliance on X-ray for diagnosis, had frequent interrupted supplies of drugs, and low rates of treatment completion and lack of supervision. In 1993, to rectify these lacunae, the government decided to give a new thrust to TB control activities by revitalizing the NTP, with assistance from the international agencies.

In the light of the recommendations and concerns expressed by the Central Health Council, steps were taken since 1993 to implement the Revised National TB Control Programme (RNTCP) in selected areas with World Bank assistance. The Revised National TB Control Programme (RNTCP) thus formulated, adopted the

internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, as the most systematic and cost effective approach to revitalize the TB control programme in India.

DOTS is a systematic strategy which has 5 components¹⁴. These are as follows:

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum smear microscopy
- Uninterrupted supply of good quality drugs
- Directly observed treatment (DOT)
- Systematic monitoring and accountability

Political and Administrative Commitment

Since tuberculosis can be cured and the epidemic reversed, it warrants the topmost priority, which has been accorded by the Government of India. This priority must be continued and expanded at state, district, and local levels.

Good Quality Diagnosis

Case detection is done primarily by sputum microscopy among chest symptomatic patients attending health facilities. This policy allows effective diagnosis in the periphery and appropriate prioritization of efforts.

Good Quality Drugs

An uninterrupted supply of good quality anti-TB drugs must be available. One of the unique innovations under RNTCP

has been the development of Patient-Wise Boxes, earmarked for every patient registered, which contain the full course of treatment for one individual patient, ensuring that treatment of that patient cannot be interrupted due to a lack of drugs. Hence, in RNTCP the treatment never fails on account of non-availability of medicines.

Short-Course Chemotherapy given in a Programme of Direct Observation

RNTCP uses the best anti-TB medications available but unless patients adhere to treatment, it will fail. This is why the heart of the DOTS programme is “directly observed treatment (DOT)” in which a health worker or another trained person who is not a family member, watches the patient swallow the anti-TB medicines in his/her presence.

However, directly observed treatment (DOT) is not just supervised swallowing but a service to the patient. It helps to develop a human bond between the patients and the treatment observer, which increases the probability of the patient completing treatment. With short-course chemotherapy it is easier to prevent drug-resistance by using directly observed treatment, and achieve high cure rates.

SYSTEMATIC MONITORING AND ACCOUNTABILITY

RNTCP has effectively decentralized supervision via the sub-district TB Units, with in-built systems for monitoring and evaluation. There are two means of monitoring the success of treatment.

First, sputum is examined during the course of treatment to monitor the progress and cure of patients. Second, a revised recording and reporting system rigorously monitors and evaluates the outcome of every patient treated at the different levels of the health system, and if any area is not achieving 90% sputum conversion rate at the end of 3 months and 85% cure rate, supervision is intensified. For effective programme implementation, having well-trained and motivated staff is essential.

Goal and objectives of RNTCP

The goal of RNTCP¹⁵ is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem. The goal of RNTCP is achieved through the following objectives.

- To achieve and maintain a cure rate of at least 85% among newly detected infectious (new sputum smear-positive) cases, and
- To achieve and maintain detection of at least 70% of such cases in the population

Clearly, both good outcomes and high case detection rates are essential. But it was felt that it is essential that the system is geared up to reliably cure patients, before any attempts are made at expanding case detection. In fact, experience clearly shows that reliably curing patients' results in a “recruitment effect” wherever effective services are offered and thus case detection rates steadily increase. Cured patients act as

one of the best motivators promoting case detection and patient adherence to treatment. *'Every cured patient is a pamphlet'*

The only effective means by which 85% cure rate or more has been shown to be achievable on a programme basis is by application of the **DOTS strategy**. It should be noted that the principles of diagnosis of TB by sputum microscopy, ambulatory treatment, and direct observation of treatment were first established in India at the Tuberculosis Research Centre, Chennai and the National TB Institute, Bangalore, in the 1950s and 1960s.

RNTCP Structure and Service Delivery Mechanisms

The structure of RNTCP comprises of 5 levels¹⁶ i.e. National, State, District, sub-District and Peripheral Health Institutions. The Central TB Division (CTD) in the Ministry of Health & Family Welfare is responsible for developing technical policies, procuring drugs, preparing training modules, programmes and financial monitoring, quality assurance, advocacy, operational research priorities, and mobilizing funds. The Deputy Director General Health Services (DDG) -TB supervises all activities of the CTD.

The RNTCP is integrated with the general healthcare delivery systems in the states. The State TB Cell (STC) is responsible for the supervision and monitoring of the programme throughout the state, with the District TB Centre (DTC) being the key organizational unit responsible for

the implementation of the programme in the respective districts. The DTC is supported by sub-district TB Units (TUs) established for every 500,000 population to serve as a link between the district level and the periphery. The TU is the lowest reporting unit under the RNTCP. At the TUs, a special cadre of dedicated TB supervisory staff, the Senior Treatment Supervisor (STS) and the Senior Tuberculosis Laboratory Supervisor (STLS), have been appointed on a contractual basis for carrying out supervisory work in the field under the charge of a 'Medical Officer-TB Control'. To further decentralise the diagnostic and treatment services, RNTCP Designated Microscopy Centres (DMCs) have been established for every 1,00,000 population. Norms for the establishments of TUs and DMCs are relaxed to 250,000 and 50,000 population respectively in hilly/difficult and tribal areas. In addition a vast network of DOT centres (treatment centres), all with trained DOT providers, have been established in all RNTCP areas so that patients can have easy access to TB treatment.

In addition, there are 17 State TB Training and Demonstration Centres (STDCs) which act as technical support units to the respective STC. Responsibilities of the STDCs include assisting the STC in training, supervision and monitoring of the programme, quality assurance of the RNTCP sputum microscopy services, advocacy and IEC, and operational research. The level of involvement of the STDCs, however, varies from state to state. Plans to strengthen the STDCs are

underway at the central level.

PROGRAMME IMPLEMENTATION, COVERAGE AND ACHIEVEMENTS

Starting 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). Rapid scale-up began in late 1998, when another 100 million population was covered under RNTCP. Since 1998, the RNTCP has been rapidly expanding and has achieved complete nation wide coverage in March 2006, covering over a billion populations. In 2005 alone, nearly 1.3 million patients were initiated on treatment under³. Over 100,000 patients are now being placed on treatment each month.

Since the start of RNTCP, with the expansion of the programme, larger numbers of patients were initiated on treatment every successive year. Over 5.4 million patients have been initiated on treatment and nearly a million additional lives have been saved from the beginning of the programme. The cure rate was consistently above 80% and in the last few years has exceeded the global benchmark

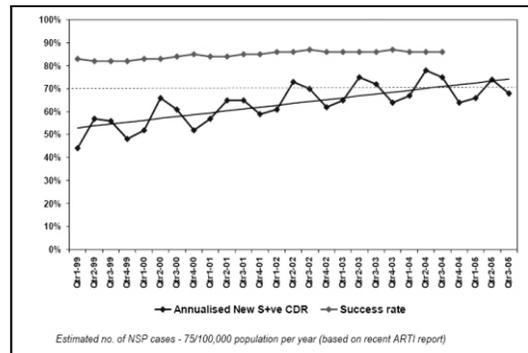


Fig. 3: Case detection rate (NSP) and treatment success rate in DOTS areas, 1999-2005

of 85%. Over the years the case detection rate increased gradually and was 66% in 2005². The trends in population coverage, patients initiated on treatment Fig. 2, cure rate and case detection rates are shown in Fig. 3.

- **Effective and accountable delivery system:** Decentralized diagnostic and treatment services are made available through a network of over 11,000 laboratories and over 4 lakhs DOT centres, supervised by over 2000 TB Units and more than 600 District TB Centres/ reporting units.
- **Human resource capacity building:** Standardized modular training is provided to all levels of health staff. The training modules have been developed at CTD and regularly updated to incorporate new initiatives and developments. The State/district programme managers, the faculty of Medical colleges and master trainers identified in the states are trained at the national level. Further training is undertaken at the state and district level using

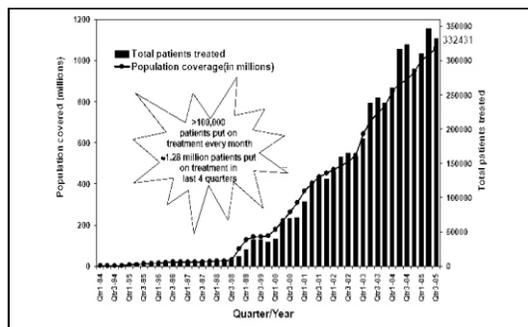


Fig. 2: Population covered under DOTS and total TB patients put on treatment in each quarter

standardized modules developed for different categories of staff. Over 5 lakh health staff has been trained under the programme.

- **Patient wise boxes (PWB):** RNTCP was the first programme in the world to design and use PWB for ensuring uninterrupted supply of anti-TB drugs. This ensures availability of full course of drugs for individual patients. Additionally it simplifies drug procurement and logistics.
- **Supervision and Monitoring strategy:** Innovative tools, checklists, records and indicators identified for monitoring the performance of programme at all levels. The programme has introduced standardized recording and

reporting formats. The reporting from districts to the state and centre are done electronically, and the performances of the districts/states are monitored closely by routine feedbacks, review meetings and evaluations.

- **Involvement of other sectors including Medical Colleges:** The programme proactively involves different health care providers, public and private under innovative models of Public Private Mix DOTS (PPM DOTS). The programme was one of the first to have formal schemes for PPM DOTS. Task force mechanism established for involvement of medical colleges. The programme has successfully involved over 2000

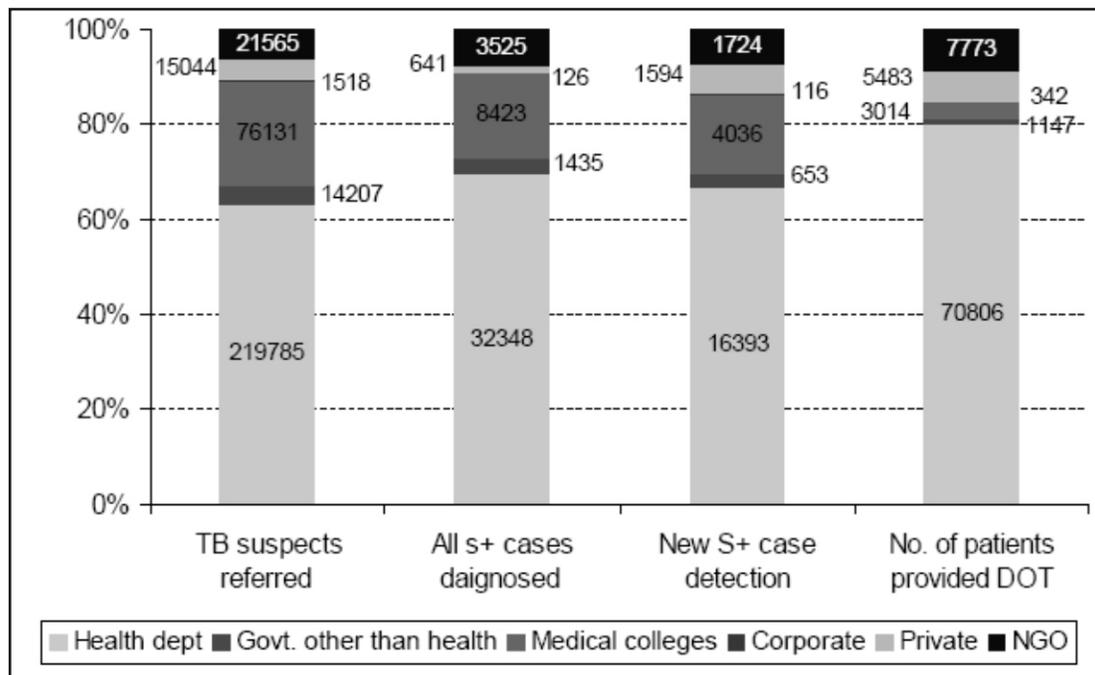


Fig. 4: 14 intensified Urban PPM districts Summary of contribution by different health sectors in 12 months period (4q04 to 3q05)

NGOs, 10000 PPs, 200 Medical Colleges, 100 corporate houses, and health units of ESI, Railways, ports, Mines etc.

Analysis of contribution of private sector and medical colleges in the 14 intensified PPM sites have shown that the government sector contributes to most of the case detections (~60%-70%), followed by the medical colleges (~15-20%).

- **Internationally recommended External Quality Assessment (EQA)** protocol for sputum smear microscopy adapted to country setting and implemented.
- **TB HIV Collaboration:** A Joint RNTCP-NACP (National AIDS Control Programme) action plans for TB-HIV were developed and is being implemented in 14 states. RNTCP-NACP service linkages at various levels, including VCTC-DMC cross referrals have been established. State and district coordination committees were formed to coordinate activities. Staffs from both the programmes are being trained using the new TB-HIV modules, jointly prepared by CTD and NACO.
- **Streamlining of financial management:** The financial management under RNTCP has been decentralized and simplified through the establishment of state/district societies. Comprehensive financial guidelines have been developed and disseminated. Funds are released from the center to the state societies

for onward disbursement to the district societies.

- **Operational Research:** A Central level research committee and a medical college task-force mechanism established to promote and guide operational research. Tuberculosis Research Centre at Chennai and the National TB Institute at Bangalore have conducted pioneering research in TB control and continue to facilitate evidence based revision of technical and operational guidelines. National Operational Research agenda has been developed and disseminated to promote research in the field of TB control.

From 1999 to 2003, the *National Sample Survey to Estimate the Annual Risk of Tuberculous Infection (ARTI)* was conducted by NTI, in collaboration with TRC, Chennai, and with assistance from the concerned states, in four zones of the country. The result of this investigation is critical in estimating the epidemiological situation of TB in India and for assessing the impact of the programme implementation. From the pooled zonal estimates, the national ARTI level has been calculated to be 1.5%. The ARTI in urban areas (2.1%) was found to be higher than that in rural areas (1.3%)¹⁷.

The TRC, in collaboration with NTI, has initiated *Drug Resistance Surveys* in different parts of the country using WHO/ IUAT guidelines. Multi-drug

resistant TB levels were observed to be below 4% among the previously untreated patients.

Impact assessment studies to measure the trends in incidence, prevalence, mortality and drug resistance are being undertaken to record the progress of India towards Millennium Development Goals and ultimate goal of TB control.

- A network of **RNTCP-WHO Consultants** has been established to provide technical assistance, supervise and monitor activities and progress at the state/district level.

A joint GOI-WHO RNTCP review in September 2003, acknowledged that the RNTCP had expanded faster than any other effective TB control programme in the history of DOTS, and its visibility had increased both nationally and internationally. The RNTCP was found to be highly economical, costing on an average less than Rs 2 (US 5 cents) per capita per year¹⁸.

The rapid expansion of RNTCP in India, whilst maintaining quality services and results, has demonstrated that it is operationally feasible to run a technically sound TB control programme based on the DOTS strategy in a populous country, with wide regional and cultural diversities, such as India. However, to make an epidemiological impact of the burden of TB in India, the good results obtained to date needs to be both maintained and improved on over the coming decade or more.

PHASE II RNTCP

The phase II of RNTCP has been recently approved by the government for a period of 5 years, from Oct 2005 to Sept 2010. As the programme has moved from the preparatory/expansion phase to maintenance and consolidation phase, RNTCP endeavors to provide high quality and cost effective diagnostic and treatment services. To further improve the quality of services, earlier strategies have been fine tuned and strengthened and several new initiatives have been initiated viz. case finding, treatment and case holding; quality assurance protocol for sputum smear microscopy; monitoring, supervision and evaluation to improve quality of programme implementation; human resource development through a standardized quality modular training for all levels of health staff; and streamlining procurement of quality assured drugs and other equipments. These would be achieved through further strengthening inter-sectoral collaboration involvement of medical colleges; and IEC activities to widen and increase the reach of the programme. Special emphasis has been laid to intensify efforts to reach the marginalized, hard to reach and tribal populations in the country. A tribal action plan has been framed for the purpose. Effective collaboration with HIV/AIDS control programme is required to address TB/HIV co-infection and improve co-ordination.

In order to achieve the ultimate goal of TB control in the country, the programme will have to be sustained for many years

to come. Continued decentralization of programme management and implementation, ensuring financial support for the RNTCP, and mobilizing community participation in TB control efforts would facilitate the process.

NEWER INITIATIVES

Strengthening of Intermediate Reference Laboratories and implementation of DOTS Plus Under RNTCP Phase II, it is planned to first establish a network of RNTCP accredited quality assured Intermediate Reference Laboratories (IRL), providing culture and DST services for RNTCP, besides monitoring quality assurance protocol of RNTCP. Concurrently a network of DOTS Plus sites, as per international guidelines, capable of enrolling and providing care and management for MDR-TB cases would be established. A total of 24 DOTS Plus sites are being planned across the country over the next five years, with a view to have in place RNTCP DOTS Plus services that are capable of enrolling on treatment at least 5000 "new" MDR-TB patients every year by 2010. The first DOTS Plus sites will be established in the states of Gujarat and Maharashtra and will be ready to enroll the first patients during 2006.

Assessment of Impact: Several surveys are planned to assess the impact of RNTCP on the burden of TB. Repeat ARTI surveys and TB prevalence surveys study the trends in incidence and prevalence of TB, Drug Resistance Surveys to monitor effectiveness of TB control activities and inform on appropriate treatment regimens, and

mortality surveys to study the progress towards MDGs.

MESSAGE FROM THE PROGRAMME

The DOTS strategy has been proven to be a highly cost effective treatment option for tuberculosis. India has done much pioneering work in the field of tuberculosis and it continues to lead the global TB control efforts. In spite of the impressive gains achieved so far, some of the challenges facing the national tuberculosis control programme and envisaged to be addressed in the coming years include: Maintaining quality of services over the next several years; Quality improvements in poorly performing States and Districts; Addressing issues on equity through serving the migratory and underprivileged population groups such as tribes and slum dwellers; Human Resource Development; Addressing health system weaknesses in some large States (e.g. Bihar, UP); Establishment of State level Intermediate Reference Laboratories; Implementation of DOTS-Plus; and, Future impact of HIV and implementation of TB/HIV collaborative activities.

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