REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
A SUCCESS STORY*

Prabha Jagota

At the outset, I express my gratitude to the Tuberculosis Association of India (TAI) for asking me to deliver the Lupin- TAI Oration. I am specially grateful to the TAI Chairman, Dr S.P. Agarwal, Vice Chairman, Dr M.M. Singh, Dr. K. Jagannath, Convener of 56th National Conference on Tuberculosis and Chest Diseases and his team.

I would first like to pay my humble tribute to my gurus: Dr D.R. Nagpaul, Dr. Wallace Fox, Dr N.K. Menon, Dr. G.D. Gothi, Dr K.S. Aneja, Dr. B.C. Arora and Dr G.V.J. Baily. I am thankful to Dr G.R. Khatri for his constant guidance and encouragement, ever since he took over as DDG (TB), Dr T.R. Frieden and my colleagues at the National Tuberculosis Institute (NTI), Bangalore.

TB is one of the most ancient diseases and has been referred to in the Vedas and Ayurvedic Samhitas. It continues to be one of the main causes of morbidity and mortality.

The global estimate for TB incidence and mortality, as reported by Raviglione, Snider and Kochi in 1995 were:

<table>
<thead>
<tr>
<th>Year</th>
<th>New Cases No.</th>
<th>Rate (per 100,000)</th>
<th>Deaths No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>7.5 million</td>
<td>143/100,000</td>
<td>2.5 million</td>
</tr>
<tr>
<td>1995</td>
<td>8.8 million</td>
<td>152/100,000</td>
<td>3.0 million</td>
</tr>
<tr>
<td>2000</td>
<td>10.2 million</td>
<td>163/100,000</td>
<td>3.5 million</td>
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Christopher Dye, in 2000, in his review on TB for the decade 2000-2010 mentioned that there would be 8 million new cases and 2 million deaths due to TB per year.

India and its neighbouring countries, China, Pakistan, Bangladesh and Indonesia account for more than half the incidence. India has nearly 30% of the global burden of the disease.

It is estimated that 4 out of every 1000 persons are suffering from bacteriologically positive active disease and that TB decimates nearly 5000 people every day and one person every minute in India. TB is on the increase and there is little hope of reversing the trend unless serious attention is paid to perception of the disease and its therapy by patients and their relatives as well as priority is given at government and international levels.

Research conducted in the 1960s, which facilitated the formulation of National TB Control Programme, included:

2. Application of chemotherapy on domiciliary basis-1960 by Tuberculosis Research Centre (TRC), Chennai.
3. Sociological study of the awareness of symptoms amongst pulmonary TB cases.-1963 by NTI.
4. Potential yield of pulmonary TB cases by sputum microscopy – 1976 by NTI.

Although epidemiological information from the mass BCG campaign carried out since 1951 and Morbidity survey conducted in 1852...
in rural population of Madanapalle by Frimodt Moller had indicated that problem of TB was widespread in rural areas also, yet for a country as large as India, this sample was inadequate. Reliable information on the magnitude and extent of the disease in the various cross sections of the population was required. This was not an easy task. Apart from resources, trained personnel to conduct large scale surveys were not readily available.

A special committee of the ICMR was set up to address the issue of obtaining this information expeditiously and rationally. It was decided that a systematic survey on a country-wide basis should be undertaken. There were many obstacles, technical as well as non-technical. However, through the government’s efforts, all obstacles were removed and the best of people got to work under the auspices of the TB sub-committee of ICMR. A rigorous time schedule was prescribed and the proposed field work was completed in about two years' time. Six teams equipped with mobile X-ray units and laboratory facilities started field work as per schedule in six zones. Seemingly insurmountable impediments were somehow overcome. Despite all odds, the field work was completed during 1955-57. It took one more year to write the report. The NSS revealed that there were 4 bacillary positive cases per 1000 (with range 2-8/1000). The disease, it was found, was equally prevalent in cities, towns and villages.

TRC was established in Chennai in 1956 to carry out research for the development of drug regimens for the treatment of TB. The first study carried out demonstrated that the time honoured virtues of sanatorium treatment such as bed rest, well-balanced diet and good living conditions were remarkably unimportant, provided adequate chemotherapy was prescribed and taken. Further, there was no evidence that close family contacts of patients treated at home had an increased risk of contracting TB. Therefore, it was concluded, it would be appropriate to treat infectious patients in their own homes.

Birth of National Tuberculosis Institute, Bangalore

The findings of NSS and TRC researches revealed that control of TB would require a totally new approach. It was decided that the focus should be on preventive aspects and finding and dealing effectively with infectious cases. Such work should be done on community-wide basis. It was proposed to establish a national institute to formulate the TB Control Programme and train personnel who would translate the decision as envisaged. Thus, was NTI born in 1959.

To establish this institution for the control of TB in the country, the help rendered by the then Government of Mysore, World Health Organization (WHO) and UNICEF was greatly appreciated by the Government of India.

Dr. Benjamin in the editorial of Ind J Tub (1960) wrote, "We believe the NTI will be a landmark in the history of anti-TB movement in this country and probably in some other countries also. Though it was well known for many years that TB is a social problem, efforts to control it were mainly directed towards diagnosis and treatment of the disease, and that too in hospitals and sanatoria. The Institute attempts a departure from this orthodox procedure. This venture is a novel and pioneering one."

One of the main aims of NTI is to give due recognition to (he social aspects of TB. The social awareness study conducted by NTI indicated that TB is not a silent disease since 95% of bacteriologically positive cases are aware of symptoms and 52% seek care at the various General Health Services (GHS), also known as Peripheral Health Institutions (PHIs), indicating that active case finding is not necessary.

The study on potential of case finding demonstrated that technicians in the periphery can perform sputum microscopy effectively with training and regular supervision. This simple primary tool for diagnosis of TB could yield 45% of the total prevalent pulmonary cases in a district, during one year, through District TB Programme (DTP). These two studies were the main pillars in the formulation of the DTP. District was selected as the basic unit of National Tuberculosis Control Programme (NTP). NTP was decentralized through DTP which operates
from District Tuberculosis Centre (DTC). District Tuberculosis Officer was made responsible for TB control activities at the DTC & PHIs. The other constituents of NTP are Central TB Division, in the Directorate General of Health Services, NTI, Bangalore and State TB Centres. Currently, there are 440 DTCs. In urban areas, there are 650 TB clinics with diagnosis and case management services.

**National Tuberculosis Programme**

The ultimate goal of NTP is to reduce the burden of TB gradually till it ceases to be a public health problem. (Nagpaul D.R. District Tuberculosis Programme in concept and outline, *Ind. J. Tub.* 1967,14,186).

The objectives and principles of the programme are:

1. Detection of maximum number of TB patients in the community;
2. Provision of effective treatment to all patients diagnosed;
3. To reduce their suffering and prevent disability and death;
4. To diagnose and treat patients nearest to their homes;
5. To integrate the TB services with the General Health Services(GHS) for the self-reporting patients; and
6. Free services.

**Functions Of DTC**

1. Case finding : (a) Sputum examination, (b) Chest X-ray, if 3 sputum specimens are negative.
2. Treatment : (a) Standard and Short Course Chemotherapy, (b) Follow up of cases.
3. Case Holding of patients : (a) Motivation, (b) Defaulter retrieval actions.
4. Management : (a) Planning, (b) Implementation of various activities, (c) Supervision of DTC and PHIs

**The achievements of NTP :**

1. Establishment of DTCs with facilities for X-ray, laboratory, BCG, treatment and statistics.
2. Posting of 6 key personnel at each DTC for supervision and training.
3. Implementation of TB control activities in the PHIs.
4. Reduction in human suffering and prevention of deaths.

DTP did not achieve the desired epidemiological impact on the magnitude of TB problem, although sociologically it saved a lot of human lives in terms of reducing the death rate from 225/100,000 to 47/100,000.

NTP was reviewed by three agencies; first by ICMR in 1975, by the Institute of Communication, Operations Research & Community Involvement (ICORC1) in 1988 and by Government of India, WHO and SIDA in 1992.9,10. The last review led to the formulation of Revised National Tuberculosis Control Programme (RNTCP) 11.

The 1992 NTP Review highlighted the following shortcomings of NTP: 1. Inadequate allocation of funds, shortage of drugs, lack of political will, 2. Inability of GHS, with which NTP is integrated, to keep up with the population growth, 3. Over-diagnosis by X-ray, and 4. Low treatment completion rates. The strengths of NTP as observed were : Integration with the health services, Felt-need oriented programme, Priority to sputum positive patients, and Free TB services.

In the light of these recommendations, RNTCP was designed which recommended Directly Observed Treatment, Short course (DOTS) strategy, and was implemented in 1993, as the only strategy which had proven to be effective in controlling TB. As stated earlier, the RNTCP is based on principles of TB control which were established in India at the NTI, Bangalore and TRC, Chennai.

The five well known fundamental principles of RNTCP are: 1. Political and administrative will, 2. Good quality diagnosis - Case - finding primarily by microscopy of sputum of patients presenting at health facilities, 3. Good quality

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treatment-Short Course Chemotherapy (SCC) given under direct observation, 4. Adequate drug supply, and 5. Systematic monitoring and accountability for every patient.

The Success of RNTCP is evaluated by:
1. Expansion of RNTCP by the population coverage, 2. Case detection rates, 3. Ratio of smear positive to smear negative patients, and 4. Cure rates.

Starting in October 1993, the RNTCP was implemented in a population of 2.35 million in 5 sites in different states. The programme was expanded to a population of 13.85 million in 1995 and 20 million in 1996. Rapid scale-up began in late 1998 when another 100 million population was covered under RNTCP. Currently, over 425 million Indian population has been covered and the programme is second only to that in China. Despite this rapid expansion there has been no compromise on the quality of services and results remain technically acceptable and in many areas are excellent.

Cure Rate

The objective of revised strategy was to achieve a cure rate of 85% among new smear positive patients through intermittent 3 days a week supervised SCC or DOTS.

Treatment outcomes have been consistently good, with 8 out of 10 patients (80% cure rate) being successfully treated. Treatment success has increased for all types of patients between 1995 and the first two quarters of 1998.

Cohort analysis of the patients put on treatment in the latest quarter has shown an average success rate of 83% and 3 month sputum conversion rate of 88%. It is heartening to note that quality of diagnosis remained excellent.

Funds for RNTCP

As all the 5 principles of RNTCP are based on adequate funding, it has been given due importance. Funding for RNTCP has been made available from a 5 year soft loan of US$ 142 million from the World Bank. Each district with population of 2 million has a District Tuberculosis Control Society which directly receives funds from the Central Government out of the World Bank assistance. State Governments provide the health infrastructure and staff. In rural areas, India's health infrastructure, has larger health centres for each 100,000 population and smaller centres for each 30,000 population.

Treatment regimens used in RNTCP

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of Patient</th>
<th>Regimen</th>
</tr>
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<tbody>
<tr>
<td>Category I</td>
<td>New sputum smear positive, Seriously ill, sputum smear negative, Seriously ill, extra-pulmonary</td>
<td>$2H_3R_3Z_3E_3/4H_1R_1$ - 6 months</td>
</tr>
<tr>
<td>Category II</td>
<td>Sputum smear-positive, relapse, Sputum smear-positive, failure, Sputum smear-positive, treatment after default</td>
<td>$2H_3R_3Z_3E_3S_1/1H_4R_4Z_3E_3/5H_3R_3E_3$ - 8 months</td>
</tr>
<tr>
<td>Category III</td>
<td>Sputum smear-negative, not seriously ill, Extra pulmonary, not seriously ill</td>
<td>$2H_3R_3Z_3/4H_1R_1$ - 6 months</td>
</tr>
</tbody>
</table>
DOTS - Solution to TB Problem

In as early as 1991, Murray et al reported that by using DOTS, cure rates of 86-90% could be achieved and the cost of per year of life saved with ambulatory short-course treatment was US$1. The Advisory Council for the elimination of TB recommended in 1993 that DOTS should be considered for all patients because of the difficulty in predicting as to which patient would adhere to a prescribed treatment regimen.

Frieden et al, in 1995, observed that application of DOT doubled the cure rates and was associated with a decline in TB by more than 15% annually and in the rate of drug resistance. They also reported that TB can be controlled even in populations in which immunosuppression is common and prevalence of drug-resistant organisms is high.

Kumaresan et al in 1998 reported from Bangladesh that "despite being a low income country with high TB incidence, facing poverty, illiteracy and natural disasters, DOTS strategy was successful because of Government commitment, staff training, regular monitoring, decentralization of diagnosis and treatment by utilizing the existing primary health care centres.

Kenyon et al, in 1999, reported from Botswana that DOTS could prevent drug resistant TB in context of a Human Immunodeficiency Virus (HIV) epidemic in low income countries.

In 2000, Zhang and Enarson reported from China that the prevalence of smear-positive cases of TB decreased by 87% between 1979 and 1999 as a result of DOTS. They also reported a decline in mortality from 11.2 to 2.2 per 100,000. It was also reported that DOTS could reduce the number of TB cases and deaths with minimal development of anti-TB drug resistance in a low income country at a low cost.

According to Balasubramanian et al, as reported in 2000 from Kerala, DOTS increased treatment success from 55% to more than 95%. They also observed that 86% of all failures and relapses were among patients who did not receive treatment observation.

In a recent report (May 2001), Olle-Goig and Alvarez demonstrated that by involving the community, DOTS was successful even in scattered rural population with high illiteracy rates and high HIV infection.

DOTS and HIV

HIV is the strongest known risk factor for the development of TB. HIV breaks down the immune system and makes patients highly susceptible to tuberculosis. These patients, in turn, can spread TB to others. There is a rising trend of HIV sero-positivity among TB patients in both urban and rural population in India and the reported figures vary from 0.4% to 15.28%. RNTCP can play a major role in treating patients of HIV with TB and DOTS is as effective among HIV infected TB patients as among those who are HIV negative. It has been reported that patients infected with HIV and TB survive longer, if they are given SCC with Rifampicin containing regimens and still longer, if SCC is given according to DOT. Chum et al from Tanzania reported in 1996 that despite high HIV infection, which was present in up to 1/3rd of TB patients, there was no increase in relapse rates among HIV infected patients.

Dr. S.P. Agarwal, Director General of Health Services, Government of India, Ministry of Health & Family Welfare, has recently emphasized the importance of TB and the urgency of improvement in services in the light of threats of HIV and multi-drug resistance (MDR). He mentioned that TB would inevitably increase if HIV is not controlled and highlighted the need for effective coordination between AIDS and TB control programmes.
DOTS and MDR-TB

Considerable variation in the prevalence of drug resistance has been recorded among 35 countries in 5 continents. WHO has reported that median prevalence of primary MDR-TB was 1.4%, ranging from 0-14%. A higher prevalence of 2.5% has been reported from Nepal and Thailand. Paramasivan et al (2000) observed that the 1988-89 level of 2% MDR-TB in the North Arcot district went up to 4% in the succeeding decade. They also reported that the level of drug resistance to H,R and HR was of the order of 15.4%, 4.4% and 3.4% respectively.

An alarmingly high proportion of acquired resistance has been reported in India, in Gujarat, resistance to Isoniazid was 35-60% and for Rifampicin 3-37%. Reports from Wardha, New Delhi and Tamil Nadu showed a high level of drug resistance to Isoniazid (20.9%, 50.7% and 23.6% respectively) and MDR-TB (9.6%, 33.7% and 23.3% respectively).

WHO in 1996 reported that the emergence of drug resistance is indicative of ineffective TB control programme. Patients infected with MDR strains require longer duration of therapy and may die of tuberculosis or continue to have TB despite optimal therapy. A large number of reports from different arts of the world have demonstrated that effective treatment programmes can prevent the development of drug resistance. Treatment of MDR-TB is difficult, expensive and often unsuccessful. Patients with MDR-TB need additional intervention besides the usual regimen. Espinal et al in 2000 reported that DOTS prevents the emergence of MDR-TB and helps reverse its trend in community in which it has emerged. Studies from a large number of countries have demonstrated that effective treatment can even result in a decrease in drug resistance if it has emerged.

A continuous surveillance of drug resistance will provide information, which will serve as a useful parameter in the evaluation of control programme and is at present being carried out by TRC, Chennai and NTI, Bangalore.

Achievements of RNTCP

1. More than 20 fold expansion of DOTS in last 3 years
   - second largest programme in the world,
   - in 1999 alone, India accounted for more than 1/3rd of the global increase in DOTS coverage.
2. More than 40% of the population has access to DOTS now.
3. Every month around 1,60,000 persons are examined for TB, more than 40,000 patients are put on treatment and till date, more than 1 lakh lives have been saved and more than 15 lakh infections have been prevented.

In September, 2001, TB experts from medical colleges all over India, in a workshop held at NTI, Bangalore, concluded that within its eight years of implementation and three years of large scale service delivery, RNTCP has proved its credibility as the most effective and the only strategy to control TB in India. During this meeting, Dr. J. N. Pandey, Head of the Department of Medicine, AIIMS, concluded that “The RNTCP is one of the most encouraging successes in the field of health in the past many years. Greater involvement of medical colleges will enrich the programme still further, increase the number of patients benefitting, and put India again at the forefront of teaching and research on Tuberculosis.”

India is going in the right direction as far as the pace and quality of implementation of RNTCP is concerned and we hope to succeed in controlling TB epidemiologically as well as sociologically with an impact on the reduction of poverty.

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Born in Milan in 1847, Count Carlo Forlanini, a surgeon practising in Pavia, Italy was stricken by pulmonary tuberculosis at the prime of his life and career. All his thoughts and efforts, therefore, turned towards his damaged lung. At that point in time, almost nothing was known about the disease except a host of folk prejudices wrapped around an overriding stigma. Time and again, he felt the damaged lung inside him, and decided that whatever caused the damage, the lungs had to be given rest, short of interfering with respiration. He recalled the case of a workman who had had a lung injury because of a broken rib and was brought to him in respiratory distress. To reduce his suffering, he had collapsed (rested) the lung by inserting a tube between the lung and the broken rib and then introduced a litre of nitrogen gas into the created space. But the patient died before the effect of rest could be observed. He decided to repeat the experiment in a similar case who, fortunately, survived. This strengthened his resolve to treat his own tuberculous lung similarly, and, thus, discovered a method for treating pulmonary tuberculosis.

Carlo Forlanini’s discovery came to be known as Artificial Pneumothorax and began to be used, soon after 1882, after the discovery of tubercle bacillus by Robert Koch. As recognition of his services to medicine, Carlo Forlanini was invited to hold the chair of Clinical Medicine at the University of Pavia. In 1906, Forlanini published a book on artificial pneumothorax which reflected his obsession with the great need for scientific studies and education of the people about tuberculosis, if the scourge of tuberculosis had to be controlled.

Eugenio Morelli, his pupil, took over from him both the chair of Clinical Medicine as well as the struggle to control tuberculosis by establishing the world famous Carlo Forlanini Institute in come as a homage to the great benefactor who provided to the profession the only effective therapeutic measure before the advent of chemotherapy of tuberculosis.