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**ECONOMIC BENEFITS OF DOTS STRATEGY TO PATIENTS WITH TUBERCULOSIS
AFTER IMPLEMENTATION OF RNTCP**
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Abstract

DOTS (directly observed treatment, short-course), is the name given to the tuberculosis control strategy recommended by the World Health Organization. According to WHO, "The most cost-effective way to stop the spread of TB in communities with a high incidence is by curing it. The best curative method for TB is known as DOTS." 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. The 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.

Key Words: *Tuberculosis Control, World Health Organization, Revised National Tuberculosis Control Programme and DOTS Strategy.*

Introduction

India has approximately two to three million people infected with Tuberculosis. This public health problem is the world's largest tuberculosis epidemic. India bears a disproportionately large burden of the world's tuberculosis rates, as it resides to be the biggest health problem in India. It remains one of the largest on India's health and wellness scale. India is the highest TB burden country with World Health Organisation (WHO) statistics for 2011 giving an estimated incidence figure of 2.2 million cases of TB for India out of a global incidence of 8.7 million cases. Compared to Canada, there are about 1,600 new cases of TB every year, which does not largely sum up, even closely, to the amount India suffers through. Citing studies of TB-drug sales, the government now suggests the total went from being 2.2 million to 2.6 million people nationwide. Tuberculosis is the biggest health issue that lies around India, but what makes it worse is the newly and recently discovered global phenomenon of TDR-TB - Totally Drug-Resistant Tuberculosis. This issue of drug-resistant TB started off with XDR-TB, and moved on to MDR-TB.

Gradually, the lowest but most dangerous and strongest of them all has situated itself in India as TDR-TB.

"Within India, the Journal—using government data obtained through the Right to Information Act—has reported that India's drug-resistance rate is likely much higher than the 2% to 3% of TB cases reported to the WHO"

Tuberculosis is one of India's major public health problems. According to WHO estimates, India has the world's largest tuberculosis epidemic. Many research studies have shown the effects and concerns revolving around TDR-TB, especially in India; where social and economic positions are still in progression. In Dr. Zarir Udhwadia's report originated from the Hinduja Hospital in Mumbai, India explicitly discusses the drug-resistant effects and results. An experiment was conducted in January, 2012 on four patients to test how accurate the "new category" of TDR-TB is. These patients were given all the first-line drugs and second-line drugs that usually are prescribed to treat TB, and as a result were resistant to all. As a response, the government of India had stayed in denial, but WHO took it as a more serious matter and decided that although the patterns of drug-resistance were evident, they cannot rely on just that to create a new category of TDR-TB.

"Paul Nunn, coordinator of WHO's STOP TB department in Geneva, described the cases as "a wakeup call for countries to accelerate provision of proper care, particularly for multi drug-resistant patients".

Tuberculosis

Tuberculosis, commonly known as TB, is a bacterial infection that can spread through the lymph nodes and bloodstream to any organ in your body. It is most often found in the lungs. Most people who are exposed to TB never develop symptoms because the bacteria can live in an inactive form in the body. But if the immune system weakens, such as in people with HIV or elderly adults, TB bacteria can become active. In their active state, TB bacteria cause death of tissue in the organs they infect. Active TB disease can be fatal if left untreated.

Because the bacteria that cause tuberculosis are transmitted through the air, the disease can be contagious. Infection is most likely to occur if you are exposed to someone with TB on a day-to-day basis, such as by living or working in close quarters with someone who has the active disease. Even then, because the bacteria generally stay latent (inactive) after they invade the body, only a small number of people infected with TB will ever have the active disease. The remaining will have what's called latent TB infection -- they show no signs of infection and won't be able to spread the disease to others, unless their disease becomes active. Because these latent infections can eventually become active, even people

without symptoms should receive medical treatment. Medication can help get rid of the inactive bacteria before they become active.

TB was once a widespread disease. It was virtually wiped out with the help of antibiotics developed in the 1950s, but the disease has resurfaced in potent new forms, multidrug resistant TB and extensively drug-resistant TB. Today, these new and dangerous forms of the disease resistant to some of the commonly used drug treatments have created a public health crisis in many large cities worldwide.

DOTS (Directly Observed Treatment, Short-Course)

Entire Country covered under DOTS in March 2006

Tuberculosis (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 treatments are 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.

Dots is a Systematic Strategy which has Five Components

Political commitment with increased and sustained financing

Clear and sustained political commitment by national governments is crucial if basic DOTS and the Stop TB Strategy are to be effectively implemented. Political commitment is needed to foster national and international partnerships, which should be linked to long-term strategic action plans prepared by NTPs. Strategic action plans should address technical and financial requirements and promote accountability for results at all levels of the health system; they should include TB-related and other relevant indicators, and - where appropriate - political commitment should be backed up by national legislation. Local partnerships with many potential contributors will help improve TB care in terms of access, equity and quality. Adequate funding is essential. Current resources are inadequate, and further effort is required to mobilize additional resources from domestic as well as international sources, with a progressive increase in

domestic funding. The global financing and partnership resources now available for poverty reduction, health systems improvement and disease control offer new opportunities for TB control programmes. Even with adequate financing, critical deficiencies in human resources in the health sector will impede progress in many low- and middle-income countries, especially in Africa. Political commitment is required to support the overall structural and financial changes needed to improve the availability, distribution and motivation of competent health workers. Special efforts, including good strategic planning, will be needed to ensure the availability of adequate and competent human resources for health care in general and TB care in particular.

Element 2

Case detection through quality-assured bacteriology

Bacteriology for diagnosis. Bacteriology remains the recommended method of TB case detection, first using sputum smear microscopy and then culture and drug susceptibility testing (DST), as indicated below.

Strengthened laboratory network. A wide network of properly equipped laboratories with trained personnel is necessary to ensure access to quality-assured sputum smear microscopy. This is likely to require additional investments in the laboratory network in many countries. In addition, every country should have a well-resourced and fully functioning national reference laboratory.

The laboratory network should be based on the following principles:

- adoption of national standards in accordance with international guidelines;
- decentralization of diagnostic services, with high proficiency levels maintained;
- communication among members at various levels of the network; and
- functioning internal and external quality management, including supervision.

Culture and DST services should be introduced, in a phased manner, at appropriate referral levels of the health system. Their functions should include diagnosis of sputum smear-negative TB, diagnosis of TB among HIV-positive adults and children, diagnosis and monitoring of response to treatment of MDR-TB, and testing related to periodic surveys of the prevalence of drug resistance. Maintaining the quality of the laboratory network depends on regular training, supervision and support, and motivation of laboratory staff. Best use should be made of existing public and private laboratories.

Element 3

Standardized treatment, with supervision and patient support

Treatment services. The mainstay of TB control is organizing and administering standardized treatment across the country for all adult and paediatric TB cases - sputum

smear-positive, smear-negative, and extrapulmonary. In all cases, WHO guidelines on patient categorization and management should be followed. These guidelines emphasize use of the most effective standardized, short-course regimens, and of fixed-dose drug combinations (FDCs) to facilitate adherence to treatment and to reduce the risk of the development of drug resistance. Separate WHO guidelines are also available for management of patients with drug-resistant TB.

Supervision and patient support. Services for TB care should identify and address factors that may make patients interrupt or stop treatment. Supervised treatment, which may have to include direct observation of therapy (DOT), helps patients to take their drugs regularly and complete treatment, thus achieving cure and preventing the development of drug resistance. Supervision must be carried out in a context-specific and patient-sensitive manner, and is meant to ensure adherence on the part both of providers (in giving proper care and support) and of patients (in taking regular treatment). Depending on the local conditions, supervision may be undertaken at a health facility, in the workplace, in the community or at home. It should be provided by a treatment partner or treatment supporter who is acceptable to the patient and is trained and supervised by health services. Patient and peer support groups can help to promote adherence to treatment. Selected patient groups, for example prisoners, drug users, and some people with mental health disorders, may need intensive support including DOT.

Improving access to treatment. Locally appropriate measures should be undertaken to identify and address physical, financial, social and cultural barriers - as well as health system - barriers to accessing TB treatment services. Particular attention should be given to the poorest and most vulnerable population groups. Examples of actions that may be appropriate include expanding treatment outlets in the poorest rural and urban settings, involving providers who practise close to where patients live, ensuring that services are free or heavily subsidized, offering psychological and legal support, addressing gender issues, improving staff attitudes, and undertaking advocacy and communication activities.

Element 4

An effective drug supply and management system

An uninterrupted and sustained supply of quality-assured anti-TB drugs is fundamental to TB control. For this purpose, an effective drug supply and management system is essential. A reliable system of procurement and distribution of all essential anti-TB drugs to all relevant health facilities should be in place. The TB recording and

reporting system is designed to provide the information needed to plan, procure, distribute and maintain adequate stocks of drugs.

Anti-TB drugs should be available free of charge to all TB patients, both because many patients are poor and may find them difficult to afford, and because treatment has benefits that extend to society as a whole (cure prevents transmission to others). Legislation related to drug regulation should be in place, and use of anti-TB drugs by all providers should be strictly monitored. The use of FDCs of proven bioavailability and of innovative packaging such as patient kits can help to improve drug supply logistics as well as drug administration, promote adherence to treatment and prevent development of drug resistance. The Global Drug Facility and the Green Light Committee offer countries with limited capacity the benefit of access to quality-assured TB drugs at reduced prices and also facilitate access to training on drug management.

Element 5

Monitoring and evaluation system, and impact measurement

Recording and reporting system. Establishing a reliable monitoring and evaluation system with regular communication between the central and peripheral levels of the health system is vital. This requires standardized recording of individual patient data, including information on treatment outcomes, which are then used to compile quarterly treatment outcomes in cohorts of patients. These data, when compiled and analyzed, can be used at the facility level to monitor treatment outcomes, at the district level to identify local problems as they arise, at provincial or national level to ensure consistently high-quality TB control across geographical areas, and nationally and internationally to evaluate the performance of each country. Regular programme supervision should be carried out to verify the quality of information and to address performance problems.

Enhanced recording and reporting. Both developed and developing countries now have additional diagnostic information at their disposal, including sputum culture, DST and HIV test results, all of which can be used to guide patient management. TB programme managers also need to monitor records and reports from public and private care providers not directly linked to the NTP. Special attention must be paid to ensuring the confidentiality of patient information. (*Advice on what additional data should be routinely collected and how these data should be compiled, collated, analyzed and used to inform TB control can be found here.*) Use of electronic recording systems (*now available*) will be considered where appropriate.

Making the best use of data at all levels will mean many countries having to train staff in the analysis and interpretation of data, as well as in the use of the computer

software that can greatly facilitate this work. As electronic recording systems become more widely available, consideration should be given to storing individual patient data, which will make more detailed analyses of aggregated data possible.

Economic Impact of RNTCP

A study on the economic impact of scaling up of RNTCP in India in 2009 shows that on an average each TB case incurs an economic burden of around US\$ 12,235 and a health burden of around 4.1 Disability adjusted life years (DALYs). Similarly, a death from TB in India incurs an average burden of around US\$ 67,305 and around 21.3 DALYs. A total of 6.3 million patients have been treated under the RNTCP from 1997-2006. This has led to a total health benefit of 29.2 million DALYs gained including a total of 1.3 million deaths averted. In 2006, the health burden of TB in India would have risen to around 14.4 million DALYs or have been 1.8 times higher in the absence of the programme. The RNTCP has also led to a gain of US\$ 88.1 billion in economic wellbeing over the scale-up period. In 2006, the gain in economic wellbeing is estimated at US\$ 19.7 billion per annum equivalent on a population basis to US\$ 17.1 per capita. In terms of TB patients, each case treated under DOTS in India results in an average gain to patients of 4.6 DALYs and US\$ 13,935 in economic well being.

Achievements of RNTCP

- Since inception, RNTCP has evaluated over 55 million persons for TB and initiated treatment for over 15.8 million TB patients.
- Prevention of mortality has been biggest achievement of RNTCP saving more than 2.8 million lives.
- Having achieved national coverage, with special emphasis to areas classified as Tribal and/or Backward, RNTCP is well on track to achieve the Millennium Development Goal (MDG) of halting and beginning to reverse the spread of the disease.
- The RNTCP and National AIDS Control Programme have significantly expanded joint TB/HIV services, which are currently available in 18 states with the aim to cover all states by 2012.
- A national lab scale-up plan with secured funding to establish a network of culture and DST laboratories is in place. By 2010, MDR-TB services were available in 132 districts in 12 states and the programme had diagnosed and provided treatment to almost 4217 MDR-TB patients till quarter ending March 2011, with a vision for nationwide coverage by 2012.
- Medical college involvement has been largely successful. Efforts to engage the private sector have revolved around outreach, directly via public-private mix (PPM)

schemes and through intermediary groups such as the Indian Medical Association (professional organization) and Catholic Bishop Conference of India (CBCI, a faith based organization).

- A major initiative to expand the role of civil society and affected communities in TB care and control is currently underway for 2010 - 2014, supported by a grant from the Global Fund directly to civil society partners.
- Repeat ARTI surveys suggests the Annual Risk of TB Infection in the country has reduced from the national average of 1.5% to 1.1% since 2002-03 to 2007-10 showing a decline of 3.5% annually. With successful implementation of RNTCP the decline in ARTI is indicative of reduction in incidence of TB in India. If we apply this ARTI for incidence estimation, it suggests that the incidence of New Smear Positive TB cases has reduced from 75 per lakh population to 55 per lakh population. While the incidence of all types of TB cases is then estimated to be around 121 per lakh population.
- While the indirect estimate of prevalence of the disease by WHO suggest that around 3 millennium TB cases are prevalent in India currently. The trend in estimated prevalence of TB suggest >50% reduction from its 1990 level of 583 per lakh population to around 250 per lakh population.

TB Control Programme

Every year about 18 lakh persons develop TB in India. In our State, every year about 1.4 lakhs persons develop Tuberculosis, among which 48,000 have TB Bacilli in their sputum. There are 8 TB Hospitals in Tamil Nadu - 2 under the control of the Directorate of Medical and Rural Health Services, 4 under the control of Directorate of Medical Education and 2 Private. There are 3091 beds in the State exclusively for in-patient Treatment of acutely ill patients. All the other patients are under DOTS Treatment in the nearest health facility of the Patient. A State level Officer in the rank of Additional Director of Medical and Rural Health Services is acting as State Tuberculosis Officer to coordinate and supervise the RNTCP Programme. At the District level, the Deputy Director of Medical Services is the Manager of the Programme. The Government of India with the World Bank Assistance is providing 100% expenditure for drugs and establishment cost of all District TB Control Societies headed by District Collectors. The State Government meets the entire expenditure on running all the District TB Centres and Government TB Hospitals.

The Revised National TB Control Programme (RNTCP) is implemented in all the Districts through 142 TB Units (one for every 5 lakh population), 782 Microscopic Centres (one for every one lakh population) and about 11,000 DOT Centres. The RNTCP Programme also has a good partnership with NGOs, Private Hospitals and Private Doctors, Railways,

Port Trust and Military Hospitals. Under this programme, 5.5 lakh persons were examined and about 83,199 were diagnosed as TB patients during the year 2008-09.

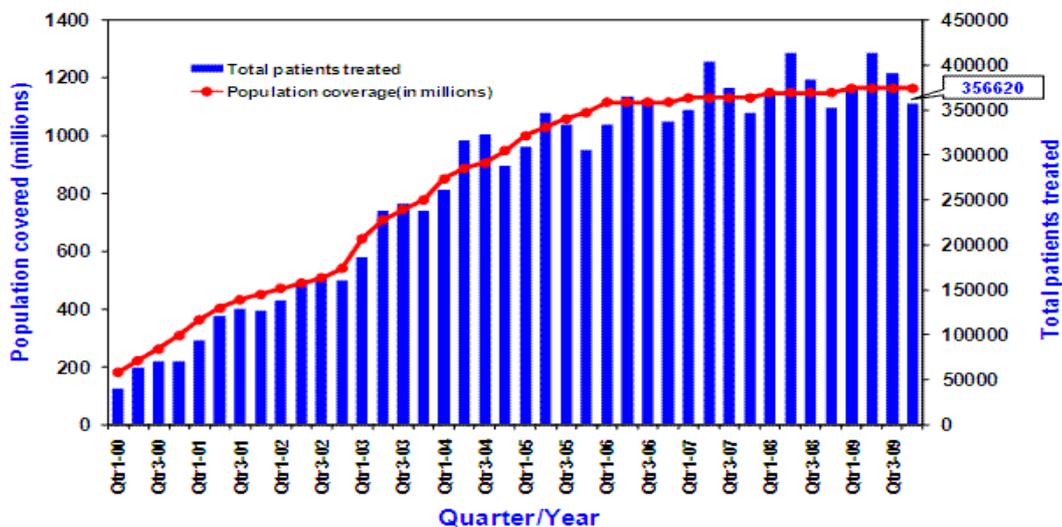
Dots Expansion in India

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, the 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 its technical and operational feasibility, a soft loan of US dollar 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.

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Revised National TB Control Programme and its recent progress in DOTS expansion have 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



Conclusion

The scale-up of TB control in India has resulted in a total health benefit of 29.2 million Disability Adjusted Life Years (DALYs), including 1.3 million deaths averted. In 2006, the burden of TB measured in terms of DALYs lost would have been 1.8 times higher in the absence of the programme. The total gain in economic well-being from TB control is estimated at US\$88.1 billion over the 1997-2006 10-year periods. Total public expenditure on TB control over this period amounted to US\$768 million, with the RNTCP accounting for

US\$299 million and other health sector costs accounting for US\$469 million. The cost of TB control averaged just US\$26 per DALY gained over 1997-2006 and generated a return of US\$115 per dollar spent. Social impact still remains a huge challenge that needs to be addressed. RNTCP is a well-structured program that has covered a large population in a short span of 10 years. The finding from this study that social impact is perceived by nearly two-thirds of TB patients should be taken into consideration, and specific, focused, and intense social support services, awareness generation, and counseling to patients and families need to be built into the program.

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