Review Article

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New Vision for Revised National Tuberculosis Control Programme (RNTCP): Universal access - "Reaching the un-reached"

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The Phase II (2006-2012) of the Revised National Tuberculosis Control Programme (RNTCP) has been successful in achieving its objectives. Tuberculosis (TB) disease burden (prevalence and mortality) in India has reduced significantly when compared to 1990 levels, and India is on track to achieve the TB related millennium development goals. Despite significant progress, TB still continues to be one of the major public health problems in the country, and intensified efforts are required to reduce TB transmission and accelerate reductions in TB incidence, particularly in urban areas and difficult terrains. Achieving 'Universal access' is possible and necessary for the country. RNTCP during the 12th Five Year Plan (2012-2017) aims to achieve 'Universal access' to quality assured TB diagnosis and treatment and elaborate plans are being made. This requires broad and concerted efforts and support from all stakeholders with substantial enhancement of commitment and financing at all levels. This paper describes the new vision of RNTCP and an overview of how this will be achieved.

Key words DOTS - multi drug resistance - RNTCP - tuberculosis - universal access

Introduction

India is the highest tuberculosis (TB) burden country in the world, accounting for nearly one-fifth of the global incidence. In 2009, out of the estimated global annual incidence of 9.4 million TB cases; 2.0 million was estimated to have occurred in India¹. Tuberculosis (TB) continues to be one of the most common infectious causes of morbidity and mortality, which despite being a curable and preventable disease, continues to impose an enormous health and economic burden on India.

The Revised National Tuberculosis Control Programme (RNTCP), based on the internationally

recommended Directly Observed Treatment Short-course (DOTS) strategy, was launched in 1997, and expanded across the country in a phased manner. Full nationwide coverage was achieved in March 2006. The goal of TB control Programme is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem in India. The twin objectives of the Programme were to achieve and maintain a cure rate of at least 85 per cent among new sputum positive (NSP) patients, and to achieve and maintain case detection of at least 70 per cent of the estimated NSP cases in the community^{2,3}.

RNTCP Phase II (2006-2012): Achievements (till December 2011) and challenges

Since its inception, the Programme has initiated over 13.8 million patients on treatment, thus saving more than 2.5 million additional lives in comparison to earlier programme⁴. The Programme has consistently maintained the treatment success rate >85 per cent since inception and NSP case detection of 70 per cent since 2007 after whole country coverage. In 2011, the NSP case detection rate was 71 per cent and treatment success rate 87 per cent. Quality assured sputum smear examination facilities are available through more than 13,000 Designated Microscopy Centers (DMCs) across the country. A network of more than 4 lakh (0.4 million) DOT providers are available to provide quality assured DOT services. All States are implementing the 'Supervision and monitoring strategy's - detailing guidelines, tools and indicators for monitoring the performance from the peripheral health institutions level to the national level.

To improve access to tribal and other marginalized groups the Programme has developed a Tribal Action Plan⁶ which is being implemented with the provision of additional TB Units and DMCs in tribal/difficult areas, additional staff, compensation for transportation of patient and attendant, and higher rate of salary to contractual staff. Innovative public-private mix (PPM) schemes have been formulated by the Programme to encourage non governmental organizations (NGOs) and private practitioners to encourage their participation and contribution to TB control efforts in the country⁷. More than 3000 NGOs, 30,000 private practitioners and 150 corporate health facilities are involved in the provision of RNTCP services. Presently, 291 medical colleges (including private colleges) have been involved in RNTCP. Health facilities in government sectors outside Health Ministry have been involved viz. Employees State Insurance, Railways, Ports and the ministries of Mines, Steel, coal, etc., Intensified PPM activities are being undertaken with Indian Medical Association (IMA) in 16 States and with Catholic Bishop Conference of India (CBCI), a faith based organization (FBO), in 19 States². Under Global Fund Round 9, civil society principal recipient (PR) International Union against TB and World Vision would be leading an undertaking of focused Advocacy, Communication and Social Mobilization (ACSM) activities in 374 districts of the country².

It is estimated that 4.85 per cent of the TB patients are human immunodeficiency virus (HIV) infection

positive⁸. NACP (National AIDS Control Programme) and RNTCP have jointly developed "National framework of joint TB/HIV collaborative activities" and these are being implemented in the country. In 2011, around 6,91,658 TB suspects were referred from Integrated Counselling and Testing Centers (ICTC) to RNTCP and of them, about 83,887 were diagnosed as having TB and initiated on DOTS. In the same period about 6,00,000 TB patients (67% of registered TB patients in State implementing intensified TB-HIV package) were tested for HIV, and of them about 44,000 were diagnosed as HIV positive and offered access to HIV care including co-trimoxazole preventive therapy (CPT) and anti retroviral therapy (ART).

The drug resistance surveys estimate the prevalence of multidrug resistant TB (MDR-TB) to be about 3 per cent in new cases and 12-17 per cent in re-treatment cases and also indicate that the prevalence of MDR-TB is not increasing in the country¹⁰. Regardless, India is one of highest MDR-TB burden countries in the world with an estimated 99,000 incident MDR-TB cases¹¹. The Programme is in the process of accelerating the establishment of a network of about 43 accredited Culture and Drug Susceptibility testing (DST) Laboratories by the end of 2013 across the country in a phased manner for diagnosis and follow up of MDR-TB patients, with the support of the Foundation for Innovative New Diagnostics (FIND-India) and other partners². Presently there are 37 accredited culture and DST laboratories under RNTCP. These include four National Reference Laboratories, 15 State level culture and DST Laboratories, and 18 laboratories in other sectors. The Programmatic Management of drug-resistant TB services were initiated in the States of Gujarat and Maharashtra in 2007 and by the end of 2011 it was expanded to all States, over 6,994 MDR-TB patients have been initiated on treatment².

As a result of the implementation of RNTCP in the country, prevalence of all forms of TB has been brought down from 338 per 100,000 population (1990) to 249 per 100,000 population in 2009 and TB mortality in the country has reduced from over 42 per 100,000 population in 1990 to 23 per 100,000 population in 2009 as per the WHO global TB report 2010¹. These India estimates by WHO are based on mathematical modeling, get altered every year and debatable. Repeat population surveys conducted by Tuberculosis Research Centre (TRC, now National Institute of Tuberculosis Research, NITR), Chennai in Chengleput, Tamil Nadu, indicated that since RNTCP implementation a 12 per

cent annual decline in prevalence has occurred, much greater than the decline observed in the preceding decades in the same area¹². The Programme has initiated surveys to assess the impact of RNTCP and progress towards TB related millennium developmental goals. These include: Disease prevalence surveys at seven sentinel sites and the National annual risk of TB infection survey. The results of these surveys will be used to realistically estimate the disease burden in the country in consultation with both national and international technical experts.

Despite this progress, TB incidence and mortality are still very high, and in 2009 an estimated 280,000 people died of TB in the country¹. A vast proportion of TB cases continue to be initially managed in the private sector, frequently inadequately and without subsidy for diagnosis and treatment that patients can frequently ill-afford. Nearly 50 per cent of the retreatment cases notified under RNTCP are treated in other sectors before reaching RNTCP, suggesting inadequate treatment and possible amplification of drug resistance (unpublished data from Central TB Division, GoI). The most serious challenge to TB control is in urban areas. Urban areas still experience intense levels of TB transmission, where urban primary health care systems tend to be weaker and private health care predominates. MDR-TB/XDR-TB occurs due to misuse of anti-TB drugs and interrupted treatment, largely in the private sector, and then can be spread in the community unless it is correctly diagnosed and treated. Linking HIV-infected TB patients to HIV care and support and implementing measures to prevent TB in HIV care settings need further strengthening. Public private mix efforts though beneficial, remain a very small proportion relative to the large numbers of private sector providers; hence the impact of these efforts has so far been relatively limited¹³.

Vision and targets for RNTCP during the 12th Five Year Plan (2012-2017)

The vision of the Government of India is for a "TB-free India" with reduction in the burden of the disease until it is no longer a major public health problem.

To achieve this vision, the Programme has now adopted the new objective of aiming to achieve 'Universal access' for quality diagnosis and treatment for all TB patients in the community¹⁴. This entails sustaining the achievements of the Programme to date, and extending the reach and quality of services to all persons diagnosed with TB. In particular, by end-2017,

the Programme aims to achieve the following targets: (i) Early detection and treatment of at least 90 per cent of estimated TB cases in the community, including HIV-associated TB; (ii) Initial screening of all retreatment smear-positive TB patients for drug-resistant TB and provision of treatment services for MDR-TB patients; (iii) Offer of HIV counselling and testing for all TB patients and linking HIV-infected TB patients to HIV care and support; (iv) Successful treatment of at least 90 per cent of all new TB patients, and at least 85 per cent of all previously-treated TB patients; and (v) Extend RNTCP services to patients diagnosed and treated in the private sector.

Programme activities necessary to achieve RNTCP (2012-2017) targets

In particular, by end-2017 the programme aims to achieve following targets:

Strengthening and improving the quality of basic DOTS services

Core programme functions remain the first priority, including ensuring sanctioned posts are filled and all staffs appropriately trained, ensuring and improving quality diagnostic services, maintaining quality drug supply for first-line treatment, strengthening supervision and monitoring by States and districts. Bringing diagnosis and treatment services closer to the patient at the community level, notably through the network of ASHA community health workers, will remain a priority. Supervision for the greater number of treatment delivery sites in the community and the accumulation of MDR-TB cases on treatment will require enhancement of Programme supervision capacity. National averages of key performance indicators mask considerable regional differences, and much work remains to improve the quality of DOTS services in weaker States and districts. The existing well-functioning Management Information System needs to be enhanced and strengthened by transitioning to an online case-based reporting system. The Programme will make increased use of performancebased payment and incentive strategies to improve the quality and effectiveness of services.

Further strengthen and align with the health system under National Rural Health Mission (NRHM)

Under RNTCP currently, all diagnostic and treatment services are integrated into the general health system while supervision and monitoring has remained

distinct from other major health programmes. For 2012-2017, the Programme will aim to improve integration with the health system by aligning TB supervision oversight with the block-level supervision structures under NRHM.

Deploying improved rapid TB diagnostics to the field level

There are challenges in diagnosing many cases with sputum-smear microscopy and improved diagnostics are required to achieve the Programme's universal access targets, particularly in HIV-infected patients with TB and paediatric TB as well as effective scale-up of MDR-TB and XDR-TB services. The past few years have seen the development of rapid molecular tests for TB that perform nearly as well as the time-consuming bacteriologic techniques used for many decades¹⁵. The validation and rapid deployment of these improved TB diagnostics to all levels of the health system is a key priority for the Programme.

Expand efforts to engage all care providers

Achieving 2012-2017 Programme targets will require much more successful engagement of the private sector at a scale commensurate with the importance of private health care provision in India. Previously, the emphasis with engagement of care providers has been on sensitization of providers to generate referrals to RNTCP for diagnosis and/or treatment, but this has had limited success. Increased resources will be required to finance scale-up of innovative approaches to engage the private sector, with flexible development of strategies from State to State. Efforts are required to make TB a nationally notifiable disease and mechanisms are needed to ensure that all TB cases treated under other sector are notified to RNTCP.

Strengthen urban TB control

Despite the successes of the Programme, TB burden and transmission remains highest in the urban areas, which have the largest and most dense concentrations of vulnerable populations. Improved TB control will be a key outcome in national efforts to strengthen urban health care infrastructure. Stopping TB transmission in cities will require early diagnosis, which necessitates large-scale engagement of private providers and deployment of improved diagnostics across all points of care.

Expand diagnosis and treatment of drug-resistant TB

Expansion of MDR-TB services is costly, in terms of laboratory investment, drug cost, and in supervision

of patients for 24-27 months (instead of the usual 6-9 months). Important activities during the 2012-2017 period will be investment in public sector laboratory capacity, development of systems for quality-assuring and purchasing additional laboratory services from the private sector, assurance of reliable supply of drugs for second-line treatment, deployment of information systems, expansion of collaboration with private providers and improved regulation and promotion of rational use of second-line drugs in the private sector.

Improve communication and outreach and social mobilization

For both basic DOTS services and control of drug-resistant TB, achieving the ambitious universal access objectives of the Programme will require additional development of focused strategies with more focused targeting on hard-to-reach groups as well as addressing socio-economic-related barriers to care. The Programme will also expand the use of innovative communications strategies to generate demand from patients and improve co-operation from the private sector. Community and civil society mobilization on an unprecedented scale is required to ensure that quality TB services from all health sectors are accountably delivered, and that community-based organizations and institutions are engaged and actively supportive of the country's TB control mission.

Promoteresearch for development and implementation of improved tools and strategies

New diagnostics, drugs, and vaccines for TB are in the development pipeline, and hold the possibility of greatly facilitating TB control efforts. The Programme is in the process of rapidly evaluating these improved tools or strategies, collect evidence for scale-up, and if indicated deploy them quickly so that TB control advances may quickly save lives and benefit the country.

Funding requirements and gaps

Effective implementation of all these components will require allocation of huge funds. The estimated funding requirement worked out by a group of experts for 12th Five Year Plan period is approximately 1.26 billion US \$ (`5,825 crores). Currently there is assured funding of up-to 254.3 million US \$ or ₹ 1170 crores from various donors/funding sources. A preliminary estimate suggests a gap of 1011 million US\$ or ₹4,654 crores will have to be financed. Government of India is committed towards controlling TB till it ceases to be

a public health problem (<1 incident cases per million populations), and will seek complete financing for this amount from government and other sources.

Conclusion

RNTCP Phase II has been successful in achieving and sustaining its stated objectives. The burden due to TB has been reduced significantly due to effective implementation of the various components under the Programme with the co-operation and support of all stakeholders. Achieving 'Universal access' is possible and necessary for controlling TB in the country. Ambitious plans have to be made under RNTCP (2012-2017), and executing these requires concerted efforts and support from all stakeholders with significant enhancement of budgetary support and community participation.

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