The role of private health sector engagement in TB control in India

Lal, S.S.

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By

Lal Sadasivan Sreemathy

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Leiden University Medical Center
Department of Public Health & Primary Care

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Promotors

Prof. dr. B.J.C. Middelkoop

Prof. dr. L.G. Visser

Co-promotor

Dr. M. Dechesne

Leden van de promotiecommissie

Prof. dr. R. Reis

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Dr. M. van Cleeff, KNCV Tuberculosefonds

Prof. dr. F.G.J. Cobelens, Amsterdam UMC, location AMC

Prof. dr. mr. J. A.A. Adriaanse

Prof. dr. N.H. Chavannes

Contents

CHAPTER 1

Research Problem and Research Questions

1.1Tuberculosis: A global public health problem

Tuberculosis workers in India found this ‘prescription slip’ with ‘Rifampicin X 2 weeks’ written on it, in the custody of this villager.

He would have bought and consumed Rifampicin for just two weeks without knowing what it was and why he was advised to take this drug. This prescription would have been obviously written by a health care provider. Rifampicin, a mainstay anti-TB drug which has to be consumed by TB patients only along with other drugs in a specific

combination in the correct doses and for a definite period and unmistakably in conditions that can ensure treatment completion. However anti-TB medicines including Rifampicin, can even be bought over-the-counter from private pharmacies in many countries. Irrational use of anti-TB antibiotics is accelerating the generation of mycobacterial resistance to the very few drugs available to cure TB. The world is facing an imminent global emergency of multi-drug resistant tuberculosis epidemic. In a progressing world, about 10.4 million people become TB patients every year of whom about 40% are not notified to the national programmes. At least 1.3 million people lost their lives due to TB which is a curable disease. Where did we go wrong? Can we improve TB control to end the enormous human suffering and the devastating social impacts due to TB? What should we do for that?

Globally, tuberculosis (TB) is a major public health problem. According to the World Health Organization's (WHO) latest estimates, about 10.4 million people have fallen ill with TB in 2016[1]. TB is the ninth leading cause of disease worldwide and ranks above HIV/AIDS as the leading cause of death from a single infectious disease[1]. A tenth of the new TB cases in 2016 also had HIV infection further complicating the diagnosis, treatment and recovery. Growing incidence of drug-resistant TB is additionally muddling the situation with estimated 490 000 new cases of multidrug-resistant TB (MDR-TB) in 2016. Despite the existence of reliable tools to diagnose, and effective drugs to cure TB, estimated 1.3 million people died of TB in 2016[1].

1.1.1 Global Efforts to control TB

WHO has been spearheading the global efforts to control TB which gained momentum in early 90's since the adoption of Directly Observed Treatment, Short-course regimen (DOTS) strategy[2]. WHO's current efforts to control TB are based on the WHO's new 'End TB Strategy' with a vision of 'A world free of tuberculosis – zero deaths, disease and suffering due to tuberculosis' and a goal 'to end the global tuberculosis epidemic by 2035'[3]. The End TB Strategy targets reductions by 95% and 90% respectively in the number of TB deaths and TB incidence rate by 2035 compared with 2015[1]. The strategy also targets Zero TB-affected families facing catastrophic costs due to TB by 2020[1]. Because of the global and country-level interventions in the past more than two decades, TB mortality and prevalence rates fell respectively by 47% and 42% between 1990 and 2015[4]. Currently, the TB mortality rate is falling at about 3% per year while 16% of the TB cases still die from the disease. Similarly, globally, TB incidence is falling at about 2% per year[1]. Various international donors and technical agencies are supporting global as well as country level efforts in controlling TB.

1.2 TB control in countries

Control of TB in virtually all countries is aligned to the global TB strategies developed by WHO together with its partners. TB control in countries are usually implemented by the National TB control Programmes (NTP). NTPs in general are under Ministries of Health (MoH) of governments and therefore are essentially public-sector

entities. However, in many countries, health care providers operating outside the NTP also provide services to TB patients.

1.2.1 Health care sectors in countries

As far as TB control is concerned, the health care sectors can be broadly divided into three major types. These are 1) public health sector under MoH 2) public sector other than MoH 3) private sector. Public sector other than MoH includes governmental ministries, organizations or facilities that provide governmental services, for example; services provided by the armed forces, police, public academic institutions, and public ministries such as transport, education, health, justice and welfare[5]. Similarly, private sector includes organizations, businesses or individuals, mission hospitals, nongovernmental organizations and faith-based organizations. It comprises individual formal and informal private practitioners, for-profit private hospitals and academic institutions, the corporate sector, and voluntary or non-profit sector, which includes charitable or nongovernmental organizations (NGOs)[1,5]. In this thesis, for convenience, public or private health-care providers or institutions that are not directly under the NTP are labelled as non-NTP providers. Such providers include 'public sector other than MoH' and 'private sector' providers.

1.2.2 TB control in public health sector

As has already been stated, NTPs, essentially public health sector organizations, are the primary instruments of the governments to implement TB control in a country. NTPs in general are under MoH.

Public sector organizations other than MoH such as railways, industries or medical colleges may have their own health care facilities which are practically outside the purview of the NTP. In most such situations, NTPs will not have direct control over the TB management practices of these non-NTP public sector health care providers. Similarly, TB cases managed by such providers are often not notified to the NTPs. Therefore, it becomes the responsibility of the NTPs to make additional efforts to ensure standardization in the management of TB in non-NTP sectors and notification of all TB cases diagnosed or treated by them.

Especially in many high TB burden countries, over the past many decades, it had become a reality that NTPs alone cannot manage TB control entirely. This has been mainly due to the presence numerous health care providers under multiple health sectors, gradual weakening of the public health sector and the growth of the private sector. Decrease in the allocation of resources to public health facilities and the resultant weakening of the public sector continued and the public sector in turn failed to cope with the increasing demand of health care. Lately the private sector has overgrown the public sector especially in terms of technology, expertise, range of services and the efficiency in delivery of services[6].

1.2.3 TB control in private health care sector

In many high TB burden countries, private sector is a major player in health care[1]. Majority of poor countries in the world have a large and growing private medical sector[7]. Consequently, private health sector

provides care to significant proportions of TB patients[1,4,7-14]. In many countries, people prefer to first approach private health sector when they are sick[7]. Patients often prefer private health sector even where public health sector facilities are available in their neighbourhood[15]. The common reasons for not accessing government facilities for treatment of TB were dissatisfaction with the services, non-availability of government facilities in the neighborhood, long waiting time and financial constraints[15]. Nevertheless, private health sector also has its own weaknesses that affect effective TB control. Private health sector in many high TB burden countries are largely disorganized and unregulated providing services of variable quality [11,16,17]. In addition, significant proportions of the TB cases seen by private sector are not notified to the NTPs[1]. Delays or failure in diagnosing TB cases will lead to longer periods of infectiousness and increased rates of deaths[18]. Similarly, inappropriate or inadequate treatment of the diagnosed TB cases will accelerate the emergence of multidrug-resistant TB (MDR-TB)[19]. It is assumed that the TB cases that missed notification might have sought care from the private sector while the information was not communicated to the NTP[1]. There are estimated 4.1 million TB cases that missed notification in 2016[1]. There is also a higher likelihood of suboptimal care received by the TB patients that seek care especially from small scale private providers[11,14,16,17,20-22]. Therefore, engaging all health care providers outside the NTPs, especially the private sector, has been identified as a necessity in effectively controlling the TB epidemic[3].

1.2.4 Public-Private Mix for TB Care and Control

The traditional way of thinking was that the respective NTP would manage TB control entirely in a country. However, engaging non-NTP health care providers became a necessity in many countries because of the large number of TB cases managed by them, especially the private-for-profit health sector, with variable quality in diagnosis and treatment. Moreover, most of these cases were not notified to the NTPs. Therefore, NTPs have been making efforts to engage non-NTP care providers that are outside the authority of the NTP. This was to ensure that TB cases are managed by all care providers according to standard guidelines and practices in the country. Gradually, these efforts evolved as a global strategy called Public-Private Mix (PPM) for TB Care and Control. According to the WHO, PPM means all partnership mixes between organizations, businesses or individuals that are part of the public sector or private sector. PPM off late represents a comprehensive approach for systematic involvement of all relevant health care providers in TB control to promote the use of International Standards for TB Care to achieve global TB control targets[23]. The partnership can hence be public–public (between NTP and other public-sector care providers such as general hospitals, prison or military health services and social security organizations), public–private (between NTP and the private sector) or even private–private (between an NGO or a private hospital and the neighborhood private providers)[23,5].

In a broader sense, at global level, the name ‘public’ is often used to represent the NTP services under MoH while ‘private’ covers all

other health sectors outside MoH[23]. The name 'private' broadly includes a wide range of providers from small scale informal providers practising systems other than modern medicine to state-of-the-art health care facilities practising modern medicine. However, among all the non-NTP providers, for-profit private health sector is the most significant sector as far as global TB control is concerned. This is because large proportions of the 'missing cases' are due to underreporting from this private sector[1]. In the chapters of this thesis, the category 'private sector' is mostly used to denote the for-profit private sector whose engagement is important due to the large number of providers and their diverse and disorganized nature. Similarly, in this thesis, the engagement of private sector providers practising modern medicine is given more emphasis.

The goal of PPM approaches has been to increase TB case notification from the non-NTP care providers, especially the private sector, by timely and quality-assured diagnosis, as well as to improve the quality of treatment and care to achieve high levels of treatment success of TB patients. As a principle, global TB control community believes that both public and private sectors have their own strengths and weaknesses. PPM therefore uses complementary strengths and capacities of both public and private health sectors to achieve better TB control. Table 1 summarizes some of the strengths and weaknesses of the public and private health sectors.

Table 1.

Strengths and weaknesses of public and private health care providers [15, 24, 25]

Health Sector	Strengths	Weaknesses
Public Sector	• Qualified staff • Follows international/national guidelines • Services are usually free of cost • Infrastructure and staff available for home visit of patients, follow up during treatment and retrieval of patients who interrupt treatment	• Failure to satisfy patients' needs • Non-availability in the neighbourhood of patients, inconvenient location • Often overcrowded • Long waiting time • Lack of privacy leading to stigma • Lack of people's faith in the system
Private sector	• Better and more flexible access • Convenient timing • Friendly behaviour towards patients • Shorter waiting time • Greater confidentiality • and greater sensitivity to user needs • People trust the providers	• Multiple types of providers • Unqualified/informal providers and traditional healers who follow different systems of healing • Need not necessarily follow standard guidelines • Likelihood of advising unnecessary investigations and prescribing • Higher cost • Inability to perform public health functions

International donor agencies have been funding NTPs to implement PPM projects in the relevant countries. The Global Fund to fight AIDS, TB and Malaria being the biggest international donor in TB control has been supporting PPM initiatives through its grants. Despite the PPM interventions for about twenty years, the success has been modest especially in engaging the non-NTP care providers and in notifying additional TB cases. In addition, in the developing countries, over the period, quality of services provided by the public health sector has been deteriorating while the utilization of private health care services by patients has been growing[6].

1.3 PPM in TB control of India

India has the highest TB burden accounting for over 27% of the estimated global incident TB cases and with more than 40% of the TB cases not notified to its Revised National TB Control Programme (RNTCP)[1]. In addition, private health sector is very large in the country which is accessed by 60-70% of the people as the first point of care when they fall sick[8-10,16]. India has been in the forefront in experimenting PPM pilot projects since the inception of RNTCP. Encouraged by the success of the pilot projects, RNTP in 2003 implemented a national intensified PPM project and subsequently in 2008 started to scale up PPM at national level[26].

RNTCP faced various challenges during the implementation of PPM especially due to resistance from the private health sector arising mainly from the lack of proper understanding of the RNTCP concepts. In the initial years of RNTCP, private practitioners in

general were skeptical about RNTCP's evidence base, scientific validity and feasibility in the Indian context. The important areas of conflicts were around four areas; 1) scientific aspects 2) patients' confidentiality and stigma issues 3) lack of trust in the government systems 4) potential additional burden to private care providers Private health sector also had apprehensions about possible adverse impacts of RNTCP on their interests especially related to losing clientele to public sector[25]. To address this challenge, RNTCP engaged the Indian Medical Association (IMA) that acted as an interface for RNTCP to establish collaborations with the private health sector[26]. RNTCP continued to engage the private sector also by developing special schemes that included monitory compensation for the engagement of private and NGO health sectors[26]. RNTCP in course of time has been accepting the private sector as a reality and therefore continued to adopt measures to work with the private sector[27,28]. Lately, considerable review and refinements of policies have been undertaken by RNTCP to accommodate the private health sector's attributes especially with a patient-centered approach in TB control[28].

1.4 The problem

TB continues to be a global public health problem disproportionately affecting the developing world and the poor people[4]. In 2016, globally, around 40% (4.1 million) of the estimated TB cases were not notified to the NTPs[1]. There were 490 000 incident MDR-TB cases of which only a quarter were notified and treated. Results of the

recent TB prevalence surveys in high TB burden countries indicate that the actual incidence of TB could be even higher than the current estimates[1]. The End TB strategy with the goal of ending TB by 2035 has set very ambitious targets. However, despite the global efforts to control TB and concurrent implementation of PPM strategy, reaching the End TB targets for 2035 appears to be a challenging task. In addition, achieving desired progress towards universal health coverage (UHC) will be essential for ending the TB epidemic as envisaged by Sustainable Development Goals (SDG)[29]. The two key UHC financing indicators namely total government spending on health as a proportion of gross domestic product and out-of-pocket expenditures as a share of total health expenditures will be key to meet the ambitious milestones on route to end TB[30]. The government expenditures on health were less than the WHO benchmark of at least 6% in 150 of 191 countries (79%) in 2014. Out of pocket expenditures represented over 45% of overall health expenditures in 46 countries in 2014[4].

In the background described above, there are new questions that emerge. Are the current PPM efforts adequate for achieving the goal and the targets of the End TB strategy? Are there even better ways of doing things in TB control? Is PPM the right strategy at all to achieve the End TB Strategy's goal and targets? Is there a need to think of modified or newer approaches? This thesis takes the reader through its distinctive but closely linked chapters to ultimately arrive at the discussion and recommendations on how India and the world should address the private sector engagement in TB control in the coming

years to achieve the goal and targets of End TB Strategy and thus end the TB epidemic globally.

1.5 Research questions

The overarching research question in this thesis is "In what manner and under which conditions can the private sector be engaged in health care as to increase the chances of an effective End TB Strategy that will achieve its targets for 2035?"

The specific sub questions that are discussed in detail in the following chapters are the following:

- How did the TB control program of India try to engage the private sector in TB control and what has been the effect of the early PPM pilot endeavors?

In Chapter 3, 'Improving tuberculosis control through public-private collaboration in India: literature review', we are reviewing the characteristics of public-private mix projects in India and their effect on case notification and treatment outcomes for tuberculosis by analyzing the data from 14 PPM projects across India.

- How did India scale up the pilot projects on private sector engagement in TB control to national level and what has been the learning?

In Chapter 4, 'Intensified scale-up of public-private mix: a systems approach to tuberculosis care and control in India', we are analyzing

the processes and outcomes of the systems approach adopted in the intensified scale-up of PPM implemented by RNTCP covering 50 million population in 14 major cities.

- What has been the role of the Indian Medical Association in the engagement of the private sector in TB control and what is its relevance? What are the lessons for India and other countries to learn from the unique endeavor of engagement of medical professional associations in TB control?

In Chapter 5, Role of professional bodies in TB control: An untold story of the Indian Medical Association in fighting TB, we are investigating the history and the process of the engagement of the Indian Medical Association (IMA) in TB control in collaboration with the RNTCP.

- What has been the landscape of funding from the Global Fund, the biggest international donor in TB control, for the engagement of the private sector in TB control?

In Chapter 6, Global Fund financing of public–private mix approaches for delivery of tuberculosis care, we investigate the extent and scope of PPM interventions in TB control programmes supported by the Global Fund. We are examining the evolution of support to PPM for TB care and control in the Global Fund-supported TB grants as reflected in its official documents and studying the distribution and characteristics of PPM initiatives within the Global Fund-supported

programs. We are reviewing the data from 14 countries that reported to WHO for the Global TB control report of 2010.

- Do prisons that house around 10 million detainees, among whom TB is a leading cause of morbidity and mortality, get adequate funding for TB control?

In Chapter 7, Global Fund financing of tuberculosis services delivery in prisons, we examined the Global Fund grants database to identify TB and HIV/TB grants and activities that monitored the delivery of tuberculosis treatment and support activities in prisons.

In Chapter 8, based on the findings of the previous chapters, we are examining the possibilities of PPM to achieve the goals and targets of End TB Strategy worldwide.

CHAPTER 2

Tuberculosis:
The Disease and Its Control

2.1 Tuberculosis

TB is an infectious disease caused by bacteria called *Mycobacterium tuberculosis*. TB mostly affects lungs (pulmonary TB) though it can affect any part of the body. Common symptoms of active pulmonary TB disease are cough that lasts for three weeks or more, coughing up blood or sputum, pain in the chest, weakness, weight loss, fever, loss of appetite and night sweats[31]. TB is spread when a patient with active pulmonary TB expels bacteria into the air by coughing, sneezing, spitting or speaking. The bacteria expelled into the air can be inhaled by an apparently healthy individual who can get infected[31].

People who have been infected by TB bacteria but are not yet ill with the disease, are considered to have latent TB infection (LTBI). One-third of the world's population is latently infected with TB. Individuals with LTBI do not manifest any symptoms and they cannot spread TB to others. However, these individuals will have 10% lifetime risk of becoming a TB patient[31]. Conversion from the latent TB stage to active TB disease occurs when the dormant mycobacteria arouse out of dormancy, become active and multiply in the infected person's body when there is decreased level of immunity often associated with HIV infection[31].

When a person develops active TB disease, the symptoms may be mild for many months. This can lead to delays in seeking medical care and thus result in transmission of the bacteria to others. Delays

in suspecting, diagnosing and treating TB in a patient can lead to increased disease transmission in the community. World Health WHO estimates that patients with undetected active TB can infect 10-15 people in a period of one year[31]. TB is essentially curable if the disease is promptly diagnosed and appropriately treated. Unless timely and appropriate treatment is provided, on average, 45% of HIV-negative people with TB and nearly all HIV-positive people with TB will die due to the disease in about three years[31,32]. Tuberculosis generally affects adults in the most productive age groups[31]. TB decreases people's capacity to work and adds to treatment expenses, exacerbating their poverty[1]. Thus, TB continues to pose difficult barriers to social and economic development of populations especially in the developing nations and disproportionately burdening the poor people across the globe[1].

2.1.1 Multidrug-resistant tuberculosis (MDR-TB) adds to the burden of disease

Inappropriate, interrupted or inadequate treatment of TB usually leads to drug-resistance when the bacteria stop responding to the common anti-TB drugs. When the bacteria are resistant to both “Rifampicin' and ‘Isoniazid’, the two mainstay drugs in the treatment of TB, the condition is called multidrug-resistant TB (MDR-TB) which is difficult and very expensive to treat. Extensively drug-resistant TB (XDR-TB), which is MDR-TB plus resistance to at least one fluoroquinoline and a second-line injectable drug, is a more severe form of drug resistance against which very few drugs are

effective[31]. WHO estimates for 2015 indicate that 3.9% of new TB cases and 21% of previously treated cases had MDR-TB and the average proportion of MDR-TB cases with XDR-TB was 9.5%[1]. In 2015, in addition to the estimated 480 000 new cases of MDR-TB, there were an additional 100 000 people with rifampicin-resistant TB (RR-TB) who were also newly eligible for MDR-TB treatment[1].

2.1.2 Tuberculosis and HIV coinfection

The probability of developing active TB disease is 20 to 30 time more in people who are infected with HIV than in people without HIV, due to their weakened immune system[31]. As per WHO estimates, people living with HIV accounted for 1.2 million (11%) of all new TB cases in 2015. In addition to the estimated 1.4 million TB deaths in 2015, there were an additional 0.4 million deaths resulting from TB disease among people living with HIV[1].

2.1.3 Non-communicable diseases and Tuberculosis

Many non-communicable diseases (NCD) are risk factors for progression from LTBI to active TB disease and often NCDs can complicate management of active TB[33]. For example, diabetes triples the risk of TB disease and therefore TB rates are higher in people who suffer from diabetes. Diabetes can also worsen the clinical course of TB while TB can in turn affect the control of glucose levels in diabetic patients[33]. Similarly, malnourished people have increased risk of reactivation or progression to TB disease and on the other hand when people get TB disease, they get malnourished[33]. Tobacco smoking greatly increases the risk of TB disease and death. More than

20% of TB cases worldwide are attributable to tobacco smoking which is also associated with poor TB treatment outcomes [33]. Higher levels of alcohol consumption increase the risk of TB and contributes to poor TB treatment adherence and consequently poor treatment outcomes[33]. There are also a few other NCDs such as silicosis that increase the risk of TB disease or complicate the treatment of TB[34].

2.1.4 Social determinants of Tuberculosis

TB cannot be considered a standalone health problem; there are many structural determinants of health that generate or reinforce social stratification in society which in turn gives rise to an unequal distribution of the social determinants of health. According to Hargreaves et al, key structural determinants of TB epidemiology include global socioeconomic inequalities, high levels of population mobility, rapid urbanization and population growth[35]. These conditions give rise to unequal distributions of key social determinants of TB, including food insecurity and malnutrition, poor housing and environmental conditions, and financial, geographic, and cultural barriers to health care access. Similarly, the population distribution of TB reflects the distribution of these social determinants. Though TB can affect people across social and economic barriers, the disease disproportionately affects the poor[35]. Undernutrition is an important risk for developing active TB. WHO has identified poverty as a powerful determinant of tuberculosis[31]. Poverty being usually associated with lower health awareness and health consciousness provide the milieu for increased exposure to risk factors of TB such as HIV, smoking and alcohol abuse[31].

Overcrowding in poorly ventilated small housings resulting from poverty increases the risk of indoor tuberculosis transmission[35].

2.1.5 Diagnosis of tuberculosis

Worldwide the primary routine test for TB is the more than hundred-year-old sputum smear microscopy by Ziehl-Neelsen technique[1]. It is relatively cheap and can be performed in peripheral laboratories by general laboratory technicians trained in smear microscopy. While the specificity of Ziehl-Neelsen technique is very high, the sensitivity is variable (20-80%) due to which many cases can be missed (false negative tests)[31,36,37]. Countries that have developed laboratory capacity are also using culture methods which is the current reference standard. There are superior tests such as liquid culture and nucleic acid amplification tests (NAAT) which are very expensive and require sophisticated laboratories as well as well-trained laboratory staff. Diagnosing MDR-TB and HIV-associated TB are more complex. The new cartridge-based nucleic acid amplification test (CB NAAT) can diagnose TB and detect resistance to Rifampicin in about 90 minutes. The use of 'Xpert MTB/RIF® assay', a rapid molecular test to diagnose TB and drug-resistant TB was recommended by WHO in 2010 for diagnosis of pulmonary TB in adults. Since 2013, it has also been recommended for children and specific forms of extrapulmonary TB and is being increasingly rolled out globally[31, 2, 38].

2.1.6 Treatment of tuberculosis

As per the currently recommended treatment, new cases of drug-susceptible TB are treated with a standard drug regimen of 6-month

course using 4 first-line anti-TB drugs namely isoniazid, rifampicin, ethambutol and pyrazinamide[2]. The current standard global practice is to provide ambulatory treatment for TB patients, except when patients are seriously ill and require hospitalization. Drug consumption by patients in ambulatory care is advised to be under supervision and support by treatment supervisors who can be health workers or trained community volunteers[31]. This is to ensure that patients adhere to treatment and in case of treatment interruption, the treatment supervisor can provide support to bring back the patient to treatment. This is essential to achieve the desired outcomes of treatment and to prevent the emergence of drug-resistance. Drug-resistant TB cases would require treatment using second-line anti-TB drugs for longer periods. Second-line treatment is very expensive, and the drugs are very toxic[31]. There are nine drugs in advanced phases of clinical trials for the treatment of drug-susceptible TB, drug-resistant TB or LTBI. Bedaquiline and delamanid, new drugs, have been rolled out in several countries [31].

2.1.7 Prevention of tuberculosis

Bacille Calmette-Guerin (BCG) vaccine, which was developed almost 100 years ago, is widely used for the prevention of TB. Countries with high TB prevalence give BCG vaccine to children on the first day of their birth. BCG can prevent severe forms of extra-pulmonary TB disease such as TB meningitis and miliary TB especially among children. WHO advises that BCG vaccination should be provided as part of national childhood immunization programmes based on a country's TB epidemiology. In 2015, 163

countries reported providing BCG vaccination as a standard part of these programmes. There are thirteen TB vaccines in Phase I, Phase II or Phase III trials[1]. Protective efficacy of BCG vaccine wanes off as the children grow into adults[39]. Therefore, treating and curing infectious patients remain a practical and crucial intervention to prevent spread of TB[3].

2.2 Global efforts to control TB

Concerted global efforts led by the WHO to address TB as a global public health problem have been underway for a long time. In 1993, WHO declared TB a global emergency which led to enhanced focus on countries with high burden of TB[40]. In 1995, WHO launched Directly Observed Treatment, Short course chemotherapy (DOTS) as a strategy that comprised five components namely (1) Sustained political and financial commitment (2) Diagnosis by quality ensured sputum-smear microscopy (3) Standardized short-course anti-TB treatment given under direct and supportive observation (4) A regular, uninterrupted supply of high quality anti-TB drugs and (5) Standardized recording and reporting[2]. DOTS strategy helped to align national TB programs to a standardized global strategy which improved the practices of TB control globally. It also mobilized additional resources which contributed to health system strengthening and therefore increased TB case notification and improved treatment success rates[41].

In 2006, a more comprehensive strategy called ‘Stop TB strategy’ was launched. The goal of the strategy was to dramatically reduce the

global burden of TB by 2015 envisioned by the Millennium Development Goals (MDG) and the 'Stop TB Partnership' targets. The strategy had six components namely (1) Pursue high-quality DOTS expansion and enhancement (2) Address TB-HIV, MDR-TB, and the needs of poor and vulnerable populations (3) Contribute to health system strengthening based on primary health care (4) Engage all care providers (5) Empower people with TB, and communities through partnership (6) Enable and promote research[42].

Stop TB partnership founded in 2001 gave a major impetus to the global TB control efforts. The partnership consists of around 1500 partners from more than 100 countries[43]. The Partnership's mission is to serve every person who is vulnerable to TB and ensure that high-quality diagnosis, treatment and care is available to all who need it. The partnership operates through a secretariat hosted by United Nations Office for Project Services (UNOPS) in Geneva, Switzerland, and seven working groups whose roles are to 1) accelerate progress on access to TB diagnosis and treatment; 2) research and development for new TB diagnostics, drugs and vaccines; and 3) tackling drug resistant- and HIV-associated TB. Stop TB Partnership produces the Global Plan for every five years. The Global Plan to End TB 2016–2020 is the costed plan for implementing the first five years of the End TB Strategy[43].

Currently the global TB control efforts are aligned to the WHO's 'End TB Strategy' 2016–2035 which was endorsed by WHO's Member States at the 2014 World Health Assembly[3]. The Sustainable

Development Goals (SDG) of the United Nations and the End TB Strategy share a common aim: to end the global TB epidemic. The ambitious End TB Strategy's targets are to reduce TB deaths by 95% and to reduce incidence by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB [3]. It has interim milestones for 2020, 2025, and 2030. The strategy highlights the importance of engaging partners within and beyond the health sector, such as in the fields of social protection, labor, immigration and justice[2,3]. WHO in partnership with other technical agencies, donors and national programs have been periodically revising global TB control guidelines with the emergence of new diagnostic tools, medicines or approaches. WHO continues to seek support from partners to implement End TB Strategy[44].

2.2.1 International Standards for Tuberculosis Care (ISTC)

Despite the organized and widespread efforts to standardize the care of TB patients by WHO and implemented by National TB Control Programmes (NTP), quality of management of TB cases has been varying widely across countries and various health sectors. This is often due to a wide range of issues that include health system constraints and infrastructure limitations within the national programs run by the public sector as well as the non-public health sector players. Reluctance or failure of non-NTP public health sectors, especially private sector, in adopting the national policies and guidelines also contribute to non-standardized provision of services to TB patients. To facilitate standardization of TB care across countries and among all kinds of health care providers, the

Tuberculosis Coalition for Technical Assistance in 2006 developed the 'International Standards for Tuberculosis Care (ISTC)' with support from major technical agencies especially WHO. The purpose of the ISTC is to describe a widely accepted level of care that both public and private practitioners should seek to achieve in managing patients who have, are suspected of having, or are at increased risk of developing tuberculosis. ISTC urges all care providers who manage TB patients to recognize that, they are not only delivering care to an individual, but are as well assuming an important public health function that entails a high level of responsibility to the community and to the individual patient. The standards are intended to promote the effective engagement of all providers in delivering high quality care for patients of all ages and all forms of tuberculosis including MDR-TB, TB/HIV and other co-morbidities[45].

2.2.2 Financing for global TB control

Many multilateral and bilateral donors have been providing large sums of funding for TB control to the needy countries. Of the US$ 6.6 billion available in 2016, 74% was from domestic sources[1]. As per WHO estimates, international donor funding for TB has generally increased year-on-year since 2006, and reached US$ 1.0 billion in 2016. The Global Fund to fight AIDS, Tuberculosis and Malaria dramatically increased the international funding for TB. Founded in 2002, the Global Fund is a financing institution, providing support to countries in the response to the three major infectious diseases. The Global Fund is a partnership between governments, civil society, the private sector and people affected by the diseases which raises and

invests nearly US$ 4 billion a year to support programs run by local experts in countries and communities most in need. Between 2004 and 2013, The Global Fund disbursed TB funding in 105 countries. In the same period, 74% of the international funding was provided by The Global Fund. The remaining (26%) funding came from international donors. The cost per patient treated was US$ 1253 for drug-susceptible TB and US$ 9529 for MDR-TB[1]. As per the WHO's projection, globally, the amount for implementation of prevention, diagnostic and treatment interventions would rise from almost US$ 9.5 billion in 2016 to US$ 14 billion in 2020[1].

2.2.3 Accomplishments of the global efforts to control TB

As per the 2016 WHO global TB report, TB treatment averted 49 million deaths globally between 2000 and 2015. The MDG target to halt and reverse TB incidence has been achieved on a global basis. Globally, TB incidence has been declining at an average of 1.5% per year since 2000 which brings the incidence to 18% lower than the level of 2000. TB mortality and prevalence rates fell respectively by 47% and 42% between 1990 and 2015. The number of people dying from HIV-associated TB has also shown a drop of 32% between 2004 and 2014[1].

2.2.4 Major challenges in achieving End TB Strategy

End TB Strategy targets a global reduction of 95% and 90% respectively in the number of TB deaths and incidence by 2035. As reported by WHO, there were 10.4 million incident TB cases in 2016. Only 6.3 million cases were reported WHO by countries which means

that globally there was a 4.1 million gap between incident and notified cases. Similarly, of the estimated 580 000 MDR-TB cases, only 125 000 were enrolled into treatment. There were major gaps in HIV testing of TB patients with only 55% patients tested and 78% of HIV-positive TB patients receiving antiretroviral therapy. Only 910 000 people living with HIV and only 7% of the eligible children under five were started on preventive TB treatment[1]. In 2016, TB was one of the top 10 causes of death globally with estimated 1.3 million people dying of TB. Among the drug-susceptible TB patients notified in 2015, treatment success was 83%. Treatment success of 54% and 30% were recorded respectively for MDR-TB and XDR-TB cases notified in 2013. As has been already discussed, global TB control faces funding shortage; the funding gap in 2017 was 2.3 billion[1]. There are several other implementation challenges faced by TB control in individual countries due to lack of prioritization, inadequate resource allocation and health systems constraints[1.]

2.2.5 TB control in individual countries

Governments, especially of high TB-burden countries, have been investing increasingly in TB control in the past two decades especially with the advent of DOTS strategy. Consequently, there has been remarkable improvement in the infrastructure and manpower for TB control in countries across the globe. Thousands of health care facilities including laboratories were constructed or refurbished to provide better access and quality for diagnosis and treatment to patients with suspected or confirmed TB. Hundreds of thousands of

TB workers and general health staff all over the world were trained or retrained especially in the evolving aspects of TB control[42]. Though the NTPs in general have a vertical nature in higher level programme management, the basic services especially diagnosis and treatment are usually integrated with the primary health care system. Therefore, any improvement in the health systems in terms of infrastructure or quality of care would benefit the TB care services. Similarly, the global and local efforts in the past years to improve TB care services would have resulted in strengthening the general health systems. With the frequently updated WHO guidelines on each relevant area of TB control, it became handy for the countries to standardize their NTPs and align with the global strategies and guidelines. Global efforts led by WHO to establish standard mechanisms for disease surveillance, monitoring, reporting and evaluation helped NTPs advance in these areas.

2.3 Management of TB cases in the health sectors other than public health sector, especially the private sector

2.3.1 Health sectors other than public health sector

Though the NTPs in countries are mostly led by the public health sector, in many high TB burden countries, there are various other health sectors that cater to health care needs of populations. As has been noted in the Chapter 1, the health sectors are broadly divided into three, namely public health sector under MoH, public sector other than MoH and private sector. In this thesis, as indicated in Chapter 1, the health care providers under health sectors other than

public health sector are labelled as non-NTP providers. These include public sector other than MoH and private sector. Examples of such non-NTP health sectors are health care facilities run by public sector entities other than the public health services (eg. Army, Prisons, Railways), and medical college hospitals, private sector, non-governmental organizations (NGO), mission hospitals, nongovernmental organizations, faith-based organizations and corporate (business) sector[1,5]. Especially regarding TB control, non-NTP health sectors in the developing world are often outside the realm of the NTP that usually implements the national TB program. Among these non-NTP health care sectors, the private sector has continuously been growing, through the roles it plays, its contribution to health care and the influence it enjoys in decision making by governments[7].

Studies have proved that in many high TB-burden countries, the first point of contact for majority of the TB patients is private health sector and therefore significant proportions of TB patients are managed by private health sector[18,8,9,10,11-14]. The private health sector providers are largely disorganized and unregulated[46]. They are disorganized because of the multiplicity of providers practising different systems of healing with competing interests for revenue. They are unregulated because of the weakness and failure of the implementation of regulations. In addition, the private sector is heterogeneous and consists of a large spectrum of health care providers ranging from individual practitioners to tertiary care and multispecialty hospitals.

Similarly, the private sector is very dynamic with large numbers of new care providers starting practice every day. The private practitioners can belong to a wide gamut of providers that could include traditional healers, informal care providers and unlicensed practitioners at one end of the spectrum while on the other end there will be highly qualified doctors working in state-of-the-art super specialty hospitals[6]. Because of this diversity, the quality of diagnostic and treatment practices in the private sector can vary widely. In addition, there have been ideological conflicts and competing interests between public and private health care sectors and among practitioners in each sector[47]. This often arises due to the inherent differences in the motivations that drive each health sector in addition to various other characteristics such as the population they serve and the attitude towards adherence to public health principles in the disease management practices. The behavior of the private health care sector is perceived to be influenced by 'for-profit' motive. This motive to generate income from clients could lead to subjecting the patients to costly diagnostic investigations that are not warranted for confirmation of TB, over diagnosis of TB leading to unnecessary treatment, unwarranted hospitalization of patients who can be managed with ambulatory care, prescription of medicines that are not essential for treating TB and the application of unnecessary or invasive treatment procedures[48]. These practices that are divergent from the guidelines for standardized care for TB could make the treatment exorbitantly expensive for the patients treated in the private health sector[49]. Catastrophic expenses due to TB would make the

already poor patients poorer and the poverty in turn would make the patients and family members more vulnerable to new infections or repeated disease episodes thus repeating the vicious circle of disease and poverty. Low priority and lack of necessary infrastructure in the private sector for undertaking public health functions and actions is a reality which also contributes to suboptimal quality in the management of TB patients. Any deviation by the private sector from the standardized practices of TB care would eventually defeat the bigger public health goals. Thus, the private health sector especially in the developing world is a reality that cannot be overlooked at any cost especially because of the significant proportions of patients that are catered by it as well as the inability of the public sector to cater entirely to the needs of all sections of the population[21]. Moreover, the experience so far proves that the partnerships between the public and private sectors in TB control can be mutually complementary[50].

2.3.2 Engagement of non-NTP health sectors in TB control

Globally, organized and systematic efforts to engaging the private health sector in TB control has been underway for more than the past two decades. These efforts, generally under the broad umbrella of 'Public-Private Mix (PPM)' strategy, consist of various approaches to engage non-public health sector care providers in TB control programs[23]. In the area of PPM, WHO has been providing global leadership and technical assistance to the various initiatives that started as pilot projects in many countries where TB burden is high, and the private sector is a major player in health. Based on the experience gained in countries, WHO working together with the

NTPs has developed various guidance documents and tools to effectively engage the non-public health sectors, especially the private sector in TB control[42]. A WHO-led global Working Group on PPM, established by the Stop TB Partnership's DOTS Expansion Working Group, is engaged in developing global policies on PPM and in assisting countries to develop and implement national policies and guidelines to engage all care providers[43]. Within the Working Group, there is PPM Core Group to guide the Subgroup activities[51]. International donors and technical partners have been supporting global and country level PPM initiatives. In the high TB-burden countries, there have been several successful PPM pilot projects since the second half of 1990 that started along with the reawakening of global TB control efforts with the dawn of DOTS strategy in the early 90s[41]. The erstwhile Stop TB strategy had clearly stated its emphasis on the engagement of private health care providers[43]. In the current End TB Strategy, engagement of private care providers is listed as a component under the Pillar 2 - 'Bold policies and supportive systems'[3].

In many countries, public sector organizations such as prisons, army, railways, ports and government-owned industries have their own network of health care facilities. Large numbers of TB patients are managed by these health care facilities owned by public sector undertakings that are outside the structure and control of general health services and NTP. For example, more than 10.35 million people are held in penal institutions throughout the world according to the latest edition of the World Prison Population List[52]. The world

prison population rate, based on United Nations estimates of national population levels, is 144 per 100,000. Since the year 2000 the total world prison population has grown by almost 20%, which is slightly above the estimated 18% increase in the world's general population over the same period[52]. The estimated prevalence of latent TB infection (LTBI) and active TB disease in prison systems are reported to be much higher than the average estimates in the general population, irrespective of the economic status and the population TB burden of the country[53]. Therefore, engagement of prisons in TB control programmes is of significant importance which will need prioritization and appropriate funding. Similar is the case of other public-sector organizations such as army or ports that cater to large numbers of patients.

In summary, in many high TB burden countries, public and private health sectors operate as independent entities with limited formal interactions. The public health sector care providers, overall regulated by the governments, are expected to adhere to standardized practices in the implementation of the national disease control programmes, However, the private sector often functions outside the vigilance of regulatory or quality assurance mechanisms. The private sector is diverse with multiple players and is principally disorganized within it. Therefore, bigger initiatives from within the private sector to address TB as a public health programme cannot be expected. In addition, private sector mainly focuses on curative care and there will not be much interest to engage with public health services due to reasons such as lack of capacity and infrastructure limitations.

Additionally, the private sector in general lack trust in the public sector due to reasons of social, moral and economic dimensions[54]. Weakening of capabilities and deterioration of quality of care in the public sector and inconsistency in delivering promises is also a reason for the private sector's mistrust in the public sector[25]. Nevertheless, the fact remains that the private sector caters to at least 40% of the TB cases with unknown quality of care. Therefore, it is imperative for the TB control programmes to establish public-private partnerships to impart and ensure quality of care for patients who seek care from the private sector.

2.4 TB Control and PPM in India

2.4.1 India as a case study

India is chosen as a case study due to the following reasons: (1) India has the highest number of incident TB cases (2) Of the 2.8 million estimated incident cases in 2015, around 1.1 million cases were not notified to the national programme (3) Vast majority of these 'missing' cases seek care from the private health sector that don't notify the cases to the national programme (4) India has one of the biggest and diverse private health sectors in the world (5) India was one of the first countries where the national TB control programme made efforts to engage the private health sector in TB control through PPM approaches (6) Ensuring standardized care for TB in the private health sector is crucial to end the TB epidemic in India (7) Ending the global TB epidemic is heavily dependent on the progress in TB

control in India where estimated 27% of the global incident TB cases are estimated to occur.

2.4.2 Health care system in India

India follows a federal system of government which has divided the areas of governance and operations between the national and state governments. Health is a state subject which means the primary responsibility to provide quality health care services to the people lies with State Governments[55]. In addition, the state governments organize and maintain the infrastructure including staff of the health care facilities owned by the state government. The national government is responsible for implementation of national programmes[55].

The health sector in India can be broadly divided into public sector and non-public sector. The public sector can be again subdivided into two; those run by the state government's ministry of health and those run by the national government's ministry of health/other public-sector undertakings. The ministry of health in a state will usually have three categories, namely, the Directorate of Health Services, the Directorate of Medical Education and the Directorate of systems of healing other than modern medicine. Based on the national design, State governments run health care facilities that are expected to provide free care and services[30]. The Directorate of health services manages the state level network of health care facilities that provide primary health and preventive services with curative care usually up to secondary levels. Directorate of medical education, through the

medical colleges, oversees medical education as well as curative health care mostly at tertiary level. The medical education is also regulated by the national medical council of India that gives recognition to the colleges and in maintaining standards of medical education. Currently there are 474 medical colleges in the country [56]. The government department that takes care of systems of healing other than modern medicine is broadly known as AYUSH (Ayurveda, Yoga, Unani, Siddha, Homeopathy, Naturopathy). There are health care facilities owned by public sector organizations under the central government or other national public-sector undertakings that provide health services to specified populations. For example, the Central Government Health Scheme (CGHS) under the national Ministry of Health provides health care to the central government employees, pensioners and their dependents. Similarly, public sector undertakings, for example; Railways, Ports, Prisons and Army, have their own health care services to take care of their employees and dependents. Employees State Insurance Corporation manages a self-financing social security and health insurance scheme for Indian workers belonging to lower income groups[26].

The health care providers owned by the Ministries of Health (MoH) or other government organizations are considered as public-sector entities. Non-public health sector can be broadly divided into private sector, NGO sector, corporate sector and informal care providers. The private health care sector comprises the entire spectrum of providers ranging from individual doctors in their consultation rooms to secondary and tertiary care hospitals. Corporate Industries also

provide health care to their workers and dependents through their health care facilities of varying sizes. There are health care providers under NGOs that usually operate as non-profit establishments or charity missions especially in the areas where public sector care is not easily available. NGO sector also has primary, secondary and tertiary level health care facilities. The different types of heath care providers in India can be summarized as shown in Table 1.

Table 1.

Types of health care providers in India

Public Sector (Government)		**Non-Public Sector**
Ministry of Health (state government)	Other Ministries (central government)	(Non-Government)
1. Directorate of Health (primary health) 2. Directorate of Medical Education (Medical Colleges) 3. Other systems of healing (AYUSH-Ayurveda, Yoga, Unani, Siddha, Homeopathy, Naturopathy)	1. Central Government Health Scheme 2. Railways 3. Employees' State Insurance 4. Mining, Coal, Steel, Ports, Prisons, Armed Forces	1. Private hospitals /practitioners (Modern medicine or AYUSH) 2. NGO facilities 3. Corporate Industries 4. Informal providers (eg. Traditional healers)

Source: Technical and Operational Guidelines for tuberculosis control in India 2016, Revised National Tuberculosis Control Programme, Ministry of Health and Family Welfare, Government of India

The public health care facilities in rural areas of India have been developed as a three-tier system (Table 2) which consists Sub Centres (SC), Primary Health Centres (PHC) and Community Health Centres (CHC); each type serving a defined population. These are established and maintained by the state governments as per national guidelines. PHC is conceived as a basic health unit to provide an integrated curative and preventive health care to the rural population as close to the people as possible, with emphasis on preventive and promotive aspects of health care[57]. PHC is the first point to meet a qualified doctor of the public sector in rural areas for those who directly report or are referred from SCs for curative, preventive and promotive health care. A typical PHC covers a population of 20 000 in hilly, tribal, or difficult to reach areas and 30,000 populations in plain areas[58].

Table 2.

Health care infrastructure in rural India and the population norms

Centre	Population norms	
	Plain area	Hilly/Tribal/Difficult Area
Sub Centre	5,000	3,000
Primary Health Centre	30,000	20,000
Community Health Centre	120,000	80,000

Source: Rural Health Statistics, Government of India Ministry of Health and Family Welfare Statistics Division 2014-15.

National disease control programmes, including TB control programme, are implemented mostly through the PHCs. CHCs are for a population of 80,000 to 120,000 each of which serves as a referral centre for 4 PHCs. The SC is the most peripheral and first contact point between the primary health care system and the community which is meant for a population of 3000-5000. Each Sub Centre is required to be manned by at least one auxiliary nurse midwife / female health worker and one male health worker. As on 31st March 2015, there were 25 308 PHCs, 153 655 SCs, and 5396 CHCs in the country[59].

2.4.3 Health system constraints

The government of India in its 12th five-year plan (2012-17) states that the health system in India suffers from several weaknesses[53]. As depicted in the plan, the availability of health care services from the public and private sectors taken together is inadequate. At the start of the 11th five-year plan, the number of doctors per hundred thousand population was only 45 against a desired number of 85. The quality of healthcare varies considerably in both the public and private sectors. In addition, many practitioners in the private sector don't possess the required qualifications to treat patients. Regulatory standards for private hospitals are either inadequately defined or ineffectively enforced. Affordability of health care is a serious issue faced by large proportion of the population. Absence of an extensive and adequately funded public health service forces large numbers of people to suffer from heavy out-of-pocket expenditures on services

sought from the private sector. This results in considerable financial burden on families during periods of major illnesses. The 12th five-year plan also foresees further increase in health care costs with rising life expectancy, as larger proportion of the population would become vulnerable to NCDs requiring expensive chronic treatments. India would therefore face health problems reflecting the dual burden of communicable diseases and NCDs. Total expenditure on health care in India, taking both public, private and household out of pocket expenditure, was about 4.1 per cent of Gross Domestic Product in 2008–09. However, the public expenditure on health was only about 27 per cent of the total, which is very low by any standard[29].

As discussed in Chapter 1, there has been a steady weakening of the public health sector over the years. This resulted principally from the reduction in the allocation of resources to public health facilities and the inability of the public sector to cope with the increasing demand of health care. In addition, while the SCs, PHCs and CHCs have increased in number in 2014-15, the current numbers are not sufficient to meet their population norm[59]. In addition, doctors and other support staff posted in the PHCs in rural areas often may not live in their place of posting. Absenteeism of staff and limited hours of services at the health centres are also a problem. The services of the health care staff are often limited to the days of their visit and the hours when the facility is open. This poses barriers to the optimal utilization of the government health care services especially in rural areas. At the same time, as most of the private medical practitioners live in the places they work, they are easily accessible at the

convenience of patients. Studies by Bhat show that the doctors at the PHCs don't get enough time to spend with each patient due to their higher patient volumes[6].

2.4.4 Private health sector in India

The private health sector providers in India vary widely in their size, location, package of service delivery, socioeconomic groups they serve and several other characteristics. Private sector also includes providers practising various systems of medicine that can be broadly classified into modern medicine, AYUSH, paramedics and informal providers[30]. Paramedics are those who are trained to support some specific aspects of health care based on the advice of physicians and who are not expected to treat patients independently. Informal care providers include traditional healers or unqualified care providers who possess no formal training.

Evidence from surveys of the informal sector by the National Sample Survey Organization (NSSO) showed that there were an estimated 1 million private health care providers in India in the year 2010-11[60]. Seventy-two percent of all health care enterprises are small Own-Account-Enterprises (OAEs), which are individual or household - run business providing out-patient services without hiring a worker on a regular basis[60]. The remaining 28% is composed of medical establishments like private hospitals or clinics. Among the one million enterprises, only about 50% are in rural areas and the remaining are found in urban areas while close to 70% of Indian population lives in rural areas[60,61]. Similarly, eighty per cent of the

OAEs were located at villages whereas most of the establishments were in the urban areas. In ten years between 2000-01 and 2010-11, the share of enterprises engaged in hospital activities has increased significantly (Figure 1). The number of establishments engaged in hospital activities had more than doubled during the same period[60]. The trend shows that new establishments have been coming up mostly in the urban areas while the number of OAEs have been going down. This indicates that there is a rapid transformation towards organized forms of business growing in urban areas while the OAEs are declining in number[60]. The distribution of health care providers by main activity is given in Table 3. Based on the activities, National Industrial Classification has categorized health care into six sub categories. About two third of these enterprises are either hospitals or medical care facilities practising modern systems of medicine while over one-fifth of all enterprises are engaged in practising AYUSH.

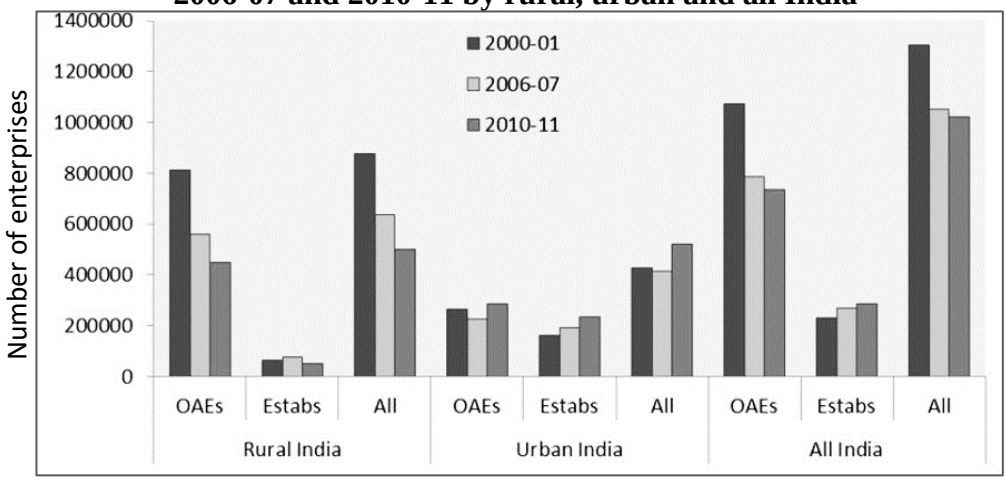
A census conducted in 62 major cities on organized health care sector in 2012 revealed that 95 percent of the total hospital facilities were private hospitals[60]. These private facilities were heterogeneous in nature and it ranged from small nursing homes to big corporate hospitals. Among the different types of hospitals, private hospitals had a share of 71 per cent followed by the nursing homes with 24 per cent. Trusts and charitable (NGO) hospitals contributed to around 3 percent and corporate hospitals 1 percent[60].

In India, private medical practitioners usually serve as the primary contacts for people when they fall sick[7-10]. Therefore, they are the providers of first line care for common illnesses and emergencies.

These practitioners are usually linked to the specialists or higher-level care facilities to where they refer their patients when they are unable to handle the cases themselves. Because the specialists are less in number and they tend to base in towns, patients from villages ultimately come back to the local private medical practitioner for continued care. Among many, availability and proximity of the private medical practitioners are the major reasons for the patients to come back to private practitioners.

Figure 1.

Number of enterprises by type and location in India: 2000-01, 2006-07 and 2010-11 by rural, urban and all India



OAE: Own-Account-Enterprises Estbs: Medical establishments

Source: 57th, 63rd and 67th rounds of NSSO, India (Mukhopadhya, I., Selvaraj Sakthivel, & Sharma Sandeep. (2015). changing landscape of private health care providers in India: Implications for national level health policy)

Table 3.

Distribution of Health Care Providers by main activity by per cent in India

Health care providers	Own-Account-Enterprises (%)			Establishments (%)		
	Year			Year		
	2000-01	2006-07	2010-11	2000-01	2006-07	2010-11
Hospital activities	0.6	1.2	3.6	15.5	14.9	18.8
Medical and dental practices	50.5	47.2	63.3	58.8	47.1	53.4
AYUSH practitioners	27.8	24.2	23.0	13.3	18.1	14.1
Nursing and physiotherapy	14.9	14.4	5.0	1.6	7.3	1.8
Diagnostics/ Pathology	1.3	2.3	2.4	9.3	11.3	9.9
Others	4.9	10.7	2.5	1.6	1.3	1.8
Total	100	100	100	100	100	100

Source: 57th, 63rd and 67th rounds of NSSO, India (Mukhopadhya, I., Selvaraj Sakthivel, & Sharma Sandeep. (2015). Changing landscape of private health care providers in India: Implications for national level health policy.

Usually, the private medical practitioners have lower patient load and they get more time to spend with their patients[6]. The private medical practitioners generally develop good rapport with the patients in the local community which positively influences the trust and therefore

the utilization of services they provide. Studies show that most private practitioners have timing patterns that suit the needs of clients[6] Private sector in India derives part of its appeal from the patients' lack of trust, typically found in developing countries, in public health care facilities. Both the rich and the poor go to the private sector because of proximity, lack of long queues, convenient timing, friendly approach and availability of the service for longer hours of the day[62]. There is also a widespread notion that public-sector drugs that are given free are of cheaper quality and are not effective. Poor people generally prefer the private sector, especially the informal sector, due to similar reasons. Private sector would comply with the interests and preferences as well as cultural perceptions of the people. For example, preference for injections among the villagers are entertained by informal practitioners. Giving intramuscular injections of analgesics, antihistamines, and intravenous drips of glucose and vitamins, often as placebo, are common in villages. These injections are often given on patients' demand. Informal providers would give strong doses and mixture of many medicines and especially for shorter durations and even for a day or a single dose so that the patients can afford the price. There is also preference for herbal drugs in the community due to the perception that herbal products are safer, and the modern medicines are toxic. Private informal providers prescribe herbal medicines and medicines of indigenous systems along with modern medicine drugs to satisfy the demands of patients. These are some of the reasons for patients prefer private sector. In addition, surveys have clearly

demonstrated that private sector is an important source of care even where public services are available[15].

2.4.5 TB epidemic and TB control in India

India has the highest number of incident TB cases and accounts for 27 per cent of the estimated 10.4 million global incident cases in 2015[1]. Revised National TB Control Programme (RNTCP) is one of the biggest national health programmes in the world. RNTCP, based on DOTS strategy, was initially implemented as pilot projects from 1993. Following the success of the pilots, the national scale up started in 1997. RNTCP achieved 100 per cent geographic coverage of the country by 2006. The programme has over the years contributed to commendable improvements in the access for people to TB care services in the country. Nevertheless, RNTCP had realized from the beginning itself that the public sector alone could reach only a portion of patients and the remaining patients will continue to receive care from the non-public health care providers, mainly the private sector. Therefore, the programme, as early as in 1995 made efforts to encourage the private sector to collaborate with RNTCP[26].

2.4.6 Management of TB control programme within the public health sector

National TB Control Programme is one of the oldest disease control programmes of India which started in 1962. With the national roll-out of the DOTS strategy – based RNTCP in 1997, there were major revisions in the structure of the national programme at the national and subnational levels. Newer staff positions were created up to the

peripheral levels dedicated for TB service. Important examples include the introduction of the positions of deputies to the National programme manager, State-level TB officers, creation of sub district level TB management unit with designated staff (e.g. Medical officer-TB Control) and dedicated staff such as Senior TB supervisor and Senior TB Lab Supervisor for a population of 500,000[30]. There are peripheral staff namely TB Health Visitors for each 100,000 population who are dedicated to support the treatment and follow up activities especially in urban areas[63]. In addition, through agreements with the related departments of social welfare, RNTCP received nationwide support from the workers at Anganwadi Centres (a type of rural mother and child care centre) to provide treatment supervision and follow up[27]. Anganwadi workers are part of the health system who, stationed at Anganwadi Centres, provide basic health care in Indian villages. They take care of health care activities which include contraceptive counseling and supply, nutrition education and supplementation, as well as pre-school care. There are 1.34 million operational Anganwadi Centres in India as on December 2014[64]. These workers in the community provide treatment supervision and follow up during TB treatment[27,65]. Accredited Social Health Activists, selected from villages and trained to work as an interface between the community and the public health system, are also engaged in the community level activities to support TB patients[27]. RNTCP engages community volunteers and provides financial incentives to partly compensate for the time they spend for TB work.

2.4.7 TB Control and the non-public health care sectors in India

RNTCP in the early 90's was originally designed for continued operations of the existing National TB control Programme with the revised approaches of the DOTS strategy implemented mainly through the public health services of the state governments. Though a central government-sponsored programme of significant vertical nature, the implementation of RNTCP below the district level was intended to be integrated with the primary health care services provided by the state governments. However, over the years, the primary health care services especially in the rural areas, where masses seek health care, have been facing increasing challenges especially due to weakening of public health and decreasing allocation of resources and the inability of the public systems to cope with the increasing demand of health care[6]. Bigger private sector health care providers like secondary and tertiary care hospitals have been growing substantially especially into the space created by the weakening public health sector and by promptly responding to the needs of the population. In the process, private sector over the period has become a major stakeholder that has partly replaced the public sector mainly in the provision of curative services. Consequently, the private health sector has been managing increasing proportions of patients that include large numbers of TB cases. Alongside the private sector, health care services have been developing extensively under the NGO sector, corporate sector industries and government departments other than the state government health services[6]. While

people would benefit from the multitude of health care providers especially because of easy access and patient-friendly services, the complexity created as a spinoff in the implementation of national health programs is colossal. Compartmental way of functioning and impervious territories of control enjoyed by the individual government departments made it difficult for the RNTCP to get them adopt national programme guidelines. On the other hand, lack of regulatory mechanisms or failure to implement the existing regulatory instruments continue to pose tougher challenges to the engagement of private health sector in RNTCP [66,67].

The ground-breaking study "Treatment of tuberculosis by private general practitioners in India' published by Dr. Mukund Uplekar in 1991 threw light on the unexpectedly low levels of awareness about drug treatment for TB patients among private medical practitioners in Mumbai city of India. While there were a few standard, efficient, recommended regimens, 100 private doctors in the study prescribed 80 different regimens, most of which were both inappropriate and expensive[16]. A repeat study 'Tuberculosis Management by Private Practitioners in Mumbai, India: Has Anything Changed in Two Decades?' conducted after about 2 decades in 2010 found that little seemed to have changed over the years, with a vast majority of private practitioners unable to provide a correct prescription for treating TB. Only 6 of the 106 respondents wrote a prescription with a correct drug regimen; 106 doctors prescribed 63 different drug regimens[17].

Studies show that the private sector is the most preferred source of care even where public services are available[10,15]. Preference for the private medical practitioners is observed in the treatment of TB also[68]. However, there is no accurate information about the number of private care providers, their TB patient load and the quality of care provided to the TB patients that seek care from the private sector. In addition, studies in India have found that more than 75% of the private medical practitioners practice modern medicine whereas only 11% of them had a formal degree in it[69]. This means that large numbers of private medical practitioners, who are not scientifically trained in modern medicine, are managing TB patients which would result in suboptimal quality of care. Delay in diagnosis, missed diagnosis, use of non-standard or inappropriate drug regimens, insufficient doses, treatment for inadequate durations and lack of mechanisms to ensure completion of full course of treatment are the major issues found in the management of TB in the private sector[70-72]. Poor record keeping practices and failure to document treatment outcomes are also issues of concern in the private sector. Private sector in general has no systems to undertake public health responsibilities of TB treatment, for example, to visit the patients' homes to screen household contacts, provide health education, monitor treatment, follow up laboratory tests, retrieve patients interrupting treatment and to organize community support[73].

2.4.8 History of public-private mix (PPM) in India under RNTCP

In the initial years of the RNTCP, even before the concept of PPM was coined internationally, India had paid special attention to

building collaborations with the health care providers. However, the journey has not been easy due to several historic and concurrent reasons. When the previous NTP of India was repackaged into RNTCP, the programme had adopted many approaches in the management of TB patients which were based on the essential principles of the underlying internationally recommended DOTS strategy. Many of these new approaches were different from the practices that had existed in the private sector for many decades. While the doctors working in the public health sector were bound to implement RNTCP as per the national guidelines, private practitioners challenged many of the policies especially by questioning its scientific validity, evidence base in the Indian context, feasibility and practicality. The important areas of conflicts and the issues raised by the private sector can be classified into four main groups namely 1) Scientific aspects 2) Patients' confidentiality and stigma issues 3) Lack of trust in the government systems 4) Perceived additional burden to care providers.

1) **Disagreements on scientific aspects**

a. Smear microscopy: RNTCP policies insisted that sputum smear microscopy should be employed as the primary tool to diagnose pulmonary TB. National programme's reasoning included the arguments that 1) laboratories, technicians and materials are widely available throughout the country especially through the network of PHCs 2) the test is easy to perform 3) the test is cheap and 4) the test is very specific. The private sector pointed out the disadvantages of

smear microscopy; 1) the test has low sensitivity and therefore at least 50% of the cases will be missed due to false negative results 2) private hospitals in general were routinely not performing microscopy diagnosis of TB 3) patients, when referred to public facilities for smear microscopy, had to stand in long queues to meet the doctor and the laboratory technician 4) test needed three sputum samples taken on two different days and the results were given usually on the third day forcing the patient to make multiple visits[74].

b. X-Ray as a primary diagnostic tool: RNTCP policy discouraged using X-Ray as a primary diagnostic tool because its high sensitivity with low specificity could result in a lot of false positive cases diagnosed and unnecessarily treated. RNTCP recommended X-Ray only as a tool in classifying a TB case as a smear negative pulmonary TB case. When the smear was initially negative, and the cough persisted after treatment with a full course of general antibiotics, patients were advised to have chest X-Ray done. If the X-Ray had shadows suggestive of TB, those patients were considered as smear negative pulmonary TB cases. Private practitioners in general did not agree because they have been using X-Ray as a screening tool and if the X-Ray was suggestive of TB, they had advised other investigations to confirm TB. X-Ray was also used to assess the extent of the TB disease and as a follow up investigation to assess progress during treatment. In addition, X-Ray was used to diagnose many conditions other than TB.

c. Other diagnostic tests: RNTCP also advised doctors to avoid unnecessary and expensive investigations such as CT scans unless it is clearly indicated for clinical management. The private practitioners held the opinion that they have been managing many cases other than TB which would need other investigations. For example, there could be other concomitant disease conditions which would need diagnosis as well as clinical staging. Therefore, private sector advocated for CT scans. The Ministry of Health and Family Welfare banned the use of serodiagnostic test kits for diagnosis of tuberculosis because of the inconsistent and improper test results leading to wrong diagnosis. Private practitioners wanted to use serodiagnostic test kits when they had diagnostic dilemma due to negative results in other investigations in a patient who was strongly suspected of having TB.

d. Drug regimens: RNTCP initially had standard types of blister packs of drugs in three categories. In general, Category I for smear positive patients, Category II for patients on retreatment and Category III for smear negative or extra-pulmonary patients who were not seriously ill. These drugs were packed in patient-wise boxes for the entire duration of treatment (6 months for Category I and III and 8 months for Category II). The drugs were of standard doses and had to be consumed by the patients three times a week. However, the private sector was in disagreement with the fixed doses as it didn't allow flexible doses for patients of different weight bands. Treatment with only 3 drugs in the Category III for non-severe cases of extra pulmonary or smear negative cases was another area of disagreement

where the private sector advocated for at least four drugs. In addition, there were no blister packs available for pediatric cases initially. The private sector was also against the use of thrice weekly consumption of medicines instead of daily intake due to the fear that it was inadequate to cure the patients. RNTCP insisted that there was enough scientific evidence to prove effectiveness of thrice weekly regimen. Similarly, RNTCP was against empirical treatment when TB is only clinically suspected and not confirmed by laboratory tests. This was to prevent inappropriate or irrational use of anti-TB medicines, though many private practitioners continue to try empirical treatment[68].

2) Disagreement on issues related to patients' confidentiality and stigma

a. Supervised treatment: RNTCP insisted on directly observed treatment (DOT) where the patient must consume drugs in the presence of a treatment observer who can be a health facility staff, or a community volunteer identified by the RNTCP and agreeable to the patient. Provision of a treatment supervisor was opposed by the private sector alleging that this would affect confidentiality and prevent TB patients from seeking care from the private hospitals[68].

b. Patients' home visit. RNTCP's field staff were expected to make mandatory visits to the patient's homes for initial health education and to establish rapport with the patients to reduce the risk of interruption of drug consumption as well as to make the retrieval easier if the patient interrupts treatment. Private sector was against

this for fear of stigma attached to TB. For the same reasons, private sector objected to the follow up visits by TB field staff to counsel patients to visit laboratory for follow up tests.

3) Issues related to lack of trust in the government systems

a. Private sector in general didn't trust quality of goods and services offered by the public sector. Therefore, the private medical practitioners were reluctant to take the risk of referring their patients to the public-sector facilities.

b. Feedback from the public sector about referred patient: One of the major grievances raised by the private sector doctors, who had referred some of their patients to the public sector, was that they didn't receive regular and prompt acknowledgment and feedback from the public sector. There were also concerns about the loss of patients to the public sector and therefore loss of revenue.

4) Issues related to perceived additional burden on private care providers

a. Reporting burden: Private sector was opposed to the registration of TB patients in the TB register which required collection of many details about each patient for cohort analysis as well as for monitoring and evaluation purposes. The participating health care facilities were expected to keep a variety of forms and registers to facilitate this process. The private sector considered this paper work and record keeping as additional burden which would also require extra

manpower. The private sector also had the fear of interference by the TB staff in their clinical decisions.

b. Patient follow up and retrieval. Private sector generally doesn't have dedicated manpower for follow up with the patient or to retrieve patients if they interrupt consumption of drugs. The financial incentives offered by the RNTCP as per the national policy for ensuring treatment adherence didn't seem to be attractive for the private sector.

In India, the systems to monitor and control the practices of individual doctors is rather loosely implemented. Diagnostic tools and drugs are abundantly available in the market. The mechanisms to scrutinize the use of diagnostic tools or prescription of medicines by doctors do not systematically function. Therefore, it is practically not possible for RNTCP to ensure that the private sector also adopts the national policy or to control their practices. In addition, public sector doctors who engage in private practice after office hours often deviate from the national policies which is also not easy to be controlled by RNTCP.

2.4.9 The role of the Indian Medical Association

In this background comes the importance of the Indian medical association (IMA), the umbrella organization of the medical practitioners of India. With its branches in all the 29 States and Union Territories of the country, IMA has over 250 000 doctors as its members through more than 1650 local branches spread over the

country[75]. IMA in the initial years opposed RNTCP declaring that the program is not in the best interests of the country and that the programme would create major dents in the TB control accomplishments of India. IMA's opposition to RNTCP gained wide dissemination especially among doctors through its publications and other forums. It was inevitable for RNTCP to take IMA into confidence and use it to reach private doctors and community at large to address undesired propaganda about RNTCP. Over the years, the partnership between RNTCP and IMA grew progressively and culminated in a national project funded by The Global Fund. The role of IMA in RNTCP is better expressed in Chapter 5.

Since the initial years itself, RNTCP has been making efforts to engage NGOs that had health care facilities as well as private health care providers. Engagement of Mahavir Hospital, Hyderabad in 1995 and the Ramakrishna Mission hospital, New Delhi in 1997 were the earliest examples of large-scale partnerships with non-public care providers. In addition to the clinical services provided to the patients, these facilities were identified as the headquarters of the sub-district level RNTCP activities with the responsibility of supervising and coordinating with the health care facilities engaged in RNTCP [31]. After these, gradually, many models of PPM that engaged private hospitals came up; the major projects were in Delhi, Kannur, Kollam, Mumbai, Pune, Thane and Tea Gardens of the North-East[26,76,77].

Using the experience gained from the collaborations with NGOs and the private sector, RNTCP published guidelines for the participation

of the NGOs (in 2001) and private practitioners (in 2002)[26]. These guidelines provided the opportunity for many NGOs and private practitioners to formally collaborate with the RNTCP. There were different 'schemes' available in the guidelines providing specific framework for the provision of the RNTCP-approved services, based on the capacity of the provider. Signing of a 'Memorandum of Understanding' between the District TB Control authorities and the health care provider made the partnership formal. Health care providers engaged through the schemes were eligible for financial assistance as a compensation for their time spent in carrying out RNTCP activities[26].

As the RNTCP gradually expanded in its geographical coverage, newer initiatives in general were experimented by more districts in various parts of the country. These PPM initiatives demonstrated increased case notifications and higher rates of treatment success[9,78]. Economic evaluations undertaken on PPM sites in Hyderabad, New Delhi and Bangalore revealed that the cost per patient cured to the society was slightly lower in PPM sites compared to RNTCP. The studies concluded that PPM was cost-effective and reduced the financial burden on the patients as well as the society[79-81].

RNTCP took systematic efforts to engage public sector organizations namely Employees State Insurance (ESI), Central government Health Services and the ministries of Railways, Defense, Prisons, Steel, Coal, Mines, Petroleum & Natural Gas, Shipping, Power and Chemicals & Fertilizers which resulted in respective organizations

sending directives to their own health care facilities to adopt the RNTCP strategy and notify the patients to RNTCP[26]. RNTCP has also been interacting with the large corporate houses and advocating for adoption of RNTCP policies and guidelines in their health care facilities.

The expansion of the RNTCP in the public sector was steadily progressing with the aim of achieving nationwide coverage by 2006. However, the PPM pilot projects remained scattered and isolated thereby covering only marginal percentages of the population that needed service. The programme noticed that the case notification rates remained low especially in large urban areas with high density of population and high TB incidence. Large numbers of private health care providers of variable sizes in urban areas failed to diagnose and treat a lot of TB patients. As a response to this situation, RNTCP decided to implement urban TB project in selected cities.

RNTCP has been periodically updating PPM tools and encouraging initiatives to experiment newer PPM approaches. In addition, many bold and unprecedented steps were taken in the past few years such as declaring TB as a disease requiring mandatory notification, developing a case-based web-based notification system which can be accessed by the private health care providers to notify the cases, developing the Standards for TB Care in India (STCI), banning the of use of certain unreliable commercial serological tests, and controlling over-the-counter sale of TB antibiotics. Moreover, the program started providing drug regimens for daily consumption

replacing the thrice-weekly regimen of RNTCP. In the area of PPM also, RNTCP is committed to Universal access to TB care and the latest technical and Operational Guidelines published in 2016 envisions a broader public-private partnership in the place of PPM[82]. RNTCP has also recently published its National Strategic Plan (NSP) for 2017-23 where PPM is discussed in the backdrop of the success of recent experiments such as online case notification, public-private interface agency (PPIA) and application of newer Information and Communication Technology platforms.

2.4.10 Public private interface agencies (PPIA)

Despite the success of pilot models to engage the private sector, the efforts of RNTCP to replicate or expand these models didn't achieve considerable success. However, there were good components of these models that the programme had identified as potential strategies for improvising newer approaches. The concept of interface agencies came up in this process. An early example of a successful interface agency was 'Mahavir' hospital in Hyderabad that worked between the public and private sectors. IMA played the role of interface agency in the Delhi, Kannur and Kollam models in Kerala and in the scale-up of the Kerala model into a national initiative funded by The Global Fund. WHO also demonstrated the usefulness of an interface agency in the intensified urban TB PPM projects[26].

Learning from the various interface mechanisms, RNTCP decided to formally establish Public Private Interface Agencies (PPIA) to facilitate engagement of the private sector. RNTCP accepted it as a

strategy in the NSP 2012-17[27]. PPIA is conceived as an agency that is available and capable of functioning as an interface agency which will be acceptable to both the public and private providers. Though initial pilots are being funded by donors, RNTCP would eventually be able to find sustainable mechanisms and resources to establish and fund the interface agencies. The PPIA will be ideal to be implemented in settings where the TB burden is very high, for example, densely populated cities and slums where many TB patients receive care from private sector but are not notified to RNTCP. PPIA is perceived to be appropriate where the public sector is strong and committed to engage the private sector. PPIAs are broadly bound by the policies of the national programme and they are expected to align the private sector with the national program guidelines and the STCI. PPIAs work largely under RNTCP's supervision especially by the local functionaries. PPIAs follow the overall Monitoring and Evaluation guidelines of the programme and the data is collected on a mutually agreed framework and is shared with the programme. RNTCP and donors undertake supervisory visits and evaluation missions in addition to audits of the PPIA activities to ensure implementation in broader alignment with the RNTCP. PPIA is discussed in more detail in chapter 7.

2.5 Conclusion

TB, despite being a curable disease, continues to be a major global public health problem that claims millions of lives globally. Accelerated emergence of MDR-TB and HIV coinfection add to the

impediments. Social determinants also contribute to TB making the poor more vulnerable. Despite the concerted efforts to control TB based on global strategies of WHO, at least 40% of the 10.4 million estimated TB cases are not notified to the NTPs. Delayed diagnosis and non-standard treatment received by patients who access care from the private health providers further complicate TB control by increasing the period of infectiousness, likelihood of developing MDR-TB and the chances of death. Experience of several pilot projects in engaging the non-public health sectors especially the private sector led to the development and frequent adaptations of WHO's PPM strategy. PPM strategy, funded by international and domestic donors, has been guiding the PPM efforts in relevant countries. Though the implementation of PPM has been underway for about two decades, overall, global TB control is yet to experience significantly higher rates of case notification, let alone the impact in terms of reducing TB incidence and mortality. Weakening of the public health sector in many high TB-burden countries further contributes to the worsening of the situation. India, the country with the highest number of incident cases globally, has been facing many challenges due to the disengagement of the private health sector in RNTCP. In the initial years, RNTCP faced opposition from the private sector. Due to these reasons, PPM projects in India also witnessed modest results until the new PPI model that demonstrated unprecedented success in terms of TB case notification. While the WHO's End TB Strategy has very ambitious targets, the global TB community and PPM advocates are struggling to find an appropriate

and effective solution to the present situation of 40% of the TB cases missing notification and the accelerated emergence of MDR-TB cases.

CHAPTER 3*

Improving Tuberculosis Control through Public-Private Collaboration in India: Literature Review

*Dewan, P. K., Lal, S. S., Lonnroth, K., Wares, F., Uplekar, M., Sahu, S., Granich, R. & Chauhan, L. S. Improving tuberculosis control through public-private collaboration in India: literature review. BMJ (Clinical research ed.) 332, 574-578, (2006).

3.1 Introduction

More cases of tuberculosis occur in India than in any other country in the world. An estimated 1.79 million new cases of tuberculosis and 352 000 tuberculosis related deaths occurred in 2003, representing one fifth of the global burden of incident cases of tuberculosis and mortality[83]. The Indian Revised National Tuberculosis Control Programme began large scale nationwide implementation of the World Health Organization's global tuberculosis control strategy (DOTS) in 1998 and has since expanded rapidly. Country-wide coverage is anticipated by April 2006. However, almost half of patients with tuberculosis in India may initially seek help from the private healthcare sectors, where diagnosis, treatment, and reporting practices often do not meet national or international standards for tuberculosis[9,71,84]. Subsequent delays in diagnosis and inadequate treatment may result in extended infectiousness, acquired drug resistance, treatment failure, and high rates of relapse—all of which may impair efforts for tuberculosis control in India. Collaborations between the public and private health sectors, or public-private mix, may be an important solution. Public-private mix has been defined by WHO as strategies that link all healthcare entities within the private and public sectors (including health providers in other governmental ministries) to national tuberculosis programmes for expansion of DOTS activities[85]. Published reports of public-private mix projects indicate that the approach is feasible and effective, but previous

evaluations are largely limited to local and individual experiences [13,50,86,87] India has the largest collection of such experiences of public-private mix, few of which to date have been reported[88-91]. We describe the effect of a series of pilot public-private mix projects in India on case notification of tuberculosis and treatment outcomes and discuss the potential role of public-private mix in improving tuberculosis control in India.

3.2 Methods

After early experiences showed the potential value of public-private mix activities[88,92], the Indian Revised National Tuberculosis Control Programme developed formal guidelines to help local programmes structure collaborations with private healthcare providers and non-governmental organizations[93,94]. These guidelines offered a diverse group of plans for the community of private providers, with options to participate in the referral, diagnosis, or treatment of patients with tuberculosis. The Indian tuberculosis programme also made financial incentives available for local programmes to distribute to cooperating providers, although these incentives were not always used. For our review we included all collaborations between the Indian Revised National Tuberculosis Control Programme and private health providers listed in the programme's surveillance records. To allow focus on private practitioners and nongovernmental organizations, we excluded collaborations with medical colleges and government health facilities outside the authority of the Indian ministry of health[95]. We reviewed only collaborations with non-governmental

organizations in which tuberculosis care was delivered to an area with a population of at least 500 000.

For each project the evaluation period was the time frame for which case notification or treatment data were available. These data were collected for each project site in quarterly (three month) increments from the Indian tuberculosis programme surveillance records and WHO public-private mix project evaluation reports. If available, we also collected project area case notification data from the Indian tuberculosis programme before the introduction of a public-private mix project. In some areas data on tuberculosis surveillance before the start of a public-private mix project were not available because projects were started from the onset of expansion of the Indian tuberculosis programme into the region. Since patients who are positive for acid fast bacilli on the basis of a sputum smear test are generally considered to be the main source of *Mycobacterium tuberculosis* transmission, we limited data collection to new cases whose sputum tested positive for acid fast bacilli. We defined a private sector notified patient as a patient diagnosed as having tuberculosis or referred by the private health sector, who was subsequently recorded (registered) by the Indian tuberculosis programme as a tuberculosis case. All other patients registered as having tuberculosis were defined as public sector notified patients. We defined private provider administered DOT as the administration of directly observed antituberculosis treatment to a patient registered as having tuberculosis by a private health provider (including

community volunteers supervised by private providers). Public sector administered DOT was defined as the administration of directly observed antituberculosis treatment to a patient registered as having tuberculosis by the public sector tuberculosis programme. We used standard WHO definitions for treatment outcomes[96]. A treatment success was defined as a new patient with sputum positive for acid fast bacilli who achieved cure or completed treatment. For each public-private mix project we calculated quarterly case notification rates by dividing the number of new case notifications of sputum positive for acid fast bacilli by the estimated population of the project area. To calculate the mean annual case notification rate for each project, quarterly rates were multiplied by 4 and averaged. Population estimates were taken from the 2001 census, or local government estimates if census data were unavailable.

3.3 Results

As of February 2004, 24 public-private mix projects met our inclusion criteria (see bmj.com), and we were able to collect data from 14 (58%) of the 24 projects (table 1)—six of eight (75%) collaborations with private practitioners, one of five (20%) collaborations with large corporate based practitioners, and seven of 11 (64%) collaborations with large non-governmental organizations. In all projects, the Indian tuberculosis programme provided training for private providers to synchronise laboratory, diagnostic, and treatment practices with national guidelines. Costs of training were uniformly borne by local or state tuberculosis programmes. The

public-private mix projects used a variety of methods to link the Indian tuberculosis programme and private providers.

Projects in Kannur and Kollam (Kerala) provided training and support for private laboratories and encouraged referral of patients with sputum smears positive for acid fast bacilli to public sector facilities for treatment[78]. Other projects relied on private providers to refer patients with suspected tuberculosis to public sector facilities for smear microscopy. In 10 (71%) of the 14 reviewed projects, private laboratories provided free smear microscopy, and the Indian tuberculosis programme partially reimbursed these laboratories by providing free slides and reagents. Professional societies, such as the Indian Medical Association, were also essential partners in bringing together public and private providers. Although patients were generally referred to the public sector for treatment, private providers sometimes acted as treatment providers. Treatment providers were responsible for administering directly observed treatment regimens (intermittent dosing, three times a week) supplied by the Indian tuberculosis programme. Staff of the Indian tuberculosis programme routinely supervised all treatment providers, and programme staff were responsible for attempts to restart tuberculosis treatment among patients who interrupted therapy.

Table 1 Characteristics of selected public-private mix (PPM) pilot projects in India (as of August 2004)

	Areas with existing government health infrastructure							Areas without government health infrastructure						
		Kerala			Maharashtra						New Delhi		Tamil Nadu	
Project characteristic	Delhi LRS (New Delhi)	Kannur	Kollam	Mumbai	Thane	Thane Rural	Mahavir (Andhra Pradesh)	Tea Estates (Assam and West Bengal)	SHIS (West Bengal)	Falah-e-Am (Uttar Pradesh)	NDTB	RK Mission	Leprosy Rural Relief	St Mary's Leprosy
Population	0.1	2.4	2.6	4	1.2	1.6	0.5	4.6	1.2	0.5*	0.2*	0.6*	0.5	0.5
Primarily urban or rural area served by project	Urban	Mixed	Mixed	Urban	Urban	Rural	Mixed	Rural	Rural	Urban	Urban	Urban	Rural	Urban
Supplemental funding	GOI	No	No	WHO	No	No	No	No	No	No	No	No	No	No
Third party coordinating organisation	DMA	None	IMA	NGO	None	None	None	ITA	None	None	None	None	None	None
No of collaborating private providers														
Referring private providers	Unknown	Unknown	Unknown	1018	95	94	334	226	35	Unknown	Unknown	Unknown	15	21
Microscopy centres	3	31	25	0	2	1	6	3	5	1	1	1	1	1
DOTS treatment providers	3	33	Unknown	192	98	138	36	222	625	2	Unknown	Unknown	400	493
Medical colleges	0	1	0	4	1	0	0	0	0	0	0	0	0	0
Service charges to patients by private providers														
Sputum acid fast bacilli microscopy	Free	Charge	Charge	Free	Charge	Charge	Free	Free	Free	Free	Free	Free	Free	Free
Drugs for DOTS treatment	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Primary supervision of private providers														
Private microscopy centres	RNTCP and DMA	RNTCP	RNTCP	RNTCP	RNTCP RNTCP	NGO and private providers	RNTCP	NGO	NGO	NGO	NGO	NGO	NGO	NGO
PPM DOTS treatment providers	RNTCP and DMA	RNTCP	RNTCP	RNTCP and NGO	RNTCP RNTCP	NGO and private providers	Corporate and private providers	NGO	NGO	RNTCP and NGO	NGO	RNTCP and NGO	RNTCP and NGO	RNTCP and NGO

Population in millions according to 2000 census.

LRS=Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases; SHIS=Southern Health Improvement Samity; NDTB=New Delhi Tuberculosis Centre; RK=Ramakrishanan; RNTCP=Revised National Tuberculosis Control Programme; NGO=non-governmental organisation; DMA=Delhi Medical Association; IMA=Indian Medical Association; ITA=Indian Tea Association; GOI=Government of India. *Estimated.

Table 2 New case notifications of tuberculosis on basis of sputum smears positive for acid fast bacilli among public-private mix pilot projects in India, 1999-2004

Public-private mix project (state)	Before public-private mix project		After public-private mix project		% change in mean case notification rate	Public-private mix contribution to case notification in project areas	
	Evaluation period	Mean (95% CI) tuberculosis case notification rate*	Evaluation period	Mean (95% CI) tuberculosis case notification rate*		Total No of new case notifications	No (%) of new case notifications from private sector
Private practitioners							
Delhi LRS (New Delhi)	Jan 1999 to Dec 2000	51.3 (34.8 to 64.2)	Jan 2001 to Mar 2002	101.6 (83.0 to 120)	98.0	127	28 (22)
Kannur (Kerala)	Jan 2000 to Jun 2001	28.3 (25.0 to 31.7)	July 2001 to Dec 2002	33.8 (30.5 to 37.1)	19.4	1225	307 (25)
Kollam (Kerala)	Jul 2001 to Jun 2002	36.6 (31.0 to 42.2)	July 2002 to Dec 2003	41.0 (36.4 to 45.5)	11.9	1588	264 (17)
Mumbai (Maharashtra)	Jan 1999 to Jun 2001	29.7 (25.3 to 34.1)	July 2001 to Dec 2003	54.3 (50.1 to 58.5)	82.7	3544	910 (26)
Thane Municipal (Maharashtra)	Jan to Dec 2001	50.5 (38.3 to 62.7)	Jan 2002 to Mar 2003	64.7 (53.9 to 75.6)	28.0	971	61 (6)
Thane Rural (Maharashtra)		NA†	Jul 2001 to Jun 2003	41.6 (31.0 to 46.0)	NA	3530	64 (2)
Corporate and non-governmental organisation							
Mahavir (Andhra Pradesh)		NA†	Jan 1999 to Dec 2003	46.5 (41.8 to 51.2)	NA	1162	1162
Tea Estates (Assam and West Bengal)		NA†	Jan 2001 to Jun 2003	66.6 (58.0 to 72.7)	NA	3327	3327
SHIS (West Bengal)		NA†	Jul 2003 to Mar 2004	31.6 (24.5 to 38.8)	NA	285	285
Falah-e-Am (Uttar Pradesh)		NA†	Jan 2001 to Jun 2003	101.6 (79.1 to 124.1)	NA	1270	1270
NDTB (New Delhi)		NA†	Jan 1999 to Dec 2003	105.8 (88.0 to 123.6)	NA	1058	1058
RK Mission (New Delhi)		NA†	Jan 1999 to Dec 2003	80.6 (73.5 to 87.7)	NA	2417	2417
Leprosy Rural Relief (Tamil Nadu)		NA†	Oct 2000 to Dec 2003	42.1 (34.1 to 50.2)	NA	722	722
St Mary's Leprosy (Tamil Nadu)		NA†	Jul 2000 to Dec 2003	44.7 (41.2 to 54.5)	NA	888	888

NA=not available. See table 1 for other definitions.
*Mean annual case notification rate over evaluation period.
†Tuberculosis surveillance data not available before public-private mix evaluation period, as local Indian tuberculosis programme not yet implemented.

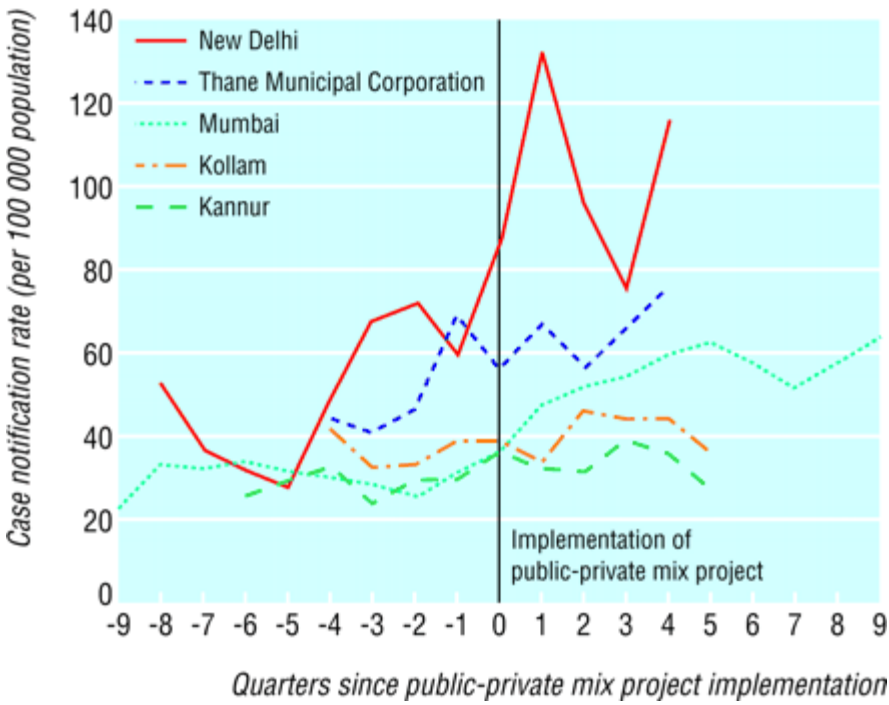
3.3.1 Contribution of public-private mix projects to case notification under DOTS

The six public-private mix projects that primarily involved private practitioners were evaluated for a median of 18 months (range 15-30 months). During this time, 10 985 new cases of tuberculosis on the basis of sputum smears positive for acid fast bacilli were reported in the project areas, of which 1631 (15%) were from the private sector (table 2). This represented 2-26% of case notifications for each of those individual projects. In each of the five projects involving private practitioners with data available from before and after implementation of a public-private mix project, the average quarterly number of positive case notifications increased by between 12% and 98% after initiation of the project (figure).

The eight public-private mix projects that involved collaborating partners from the corporate sector or nongovernmental organizations were evaluated for a median of 30 months (range 9-48 months). During this time 11 129 new cases positive for acid fast bacilli were notified in these areas. Since public-private mix projects were the sole source of Indian tuberculosis programme services here, all case notifications were attributed to the private sector. As local data for tuberculosis surveillance were not available before these projects, no comparison could be made between notification rates before the start of the project.

Figure 1.

Tuberculosis Case Notification Rate Before and After Implementation of Public-Private Mix Project



Tuberculosis case notification rate before and after implementation of public-private mix project, for collaborations with private practitioners in India, 1999-2004. Projects represented are those with data available before implementation of public-private mix project

3.3.2 Treatment outcomes with private provider administered directly observed treatment

In nine (75%) of 12 public-private mix projects with available data on treatment outcome, private provider administered directly

Table 3 Treatment outcomes of new patients with sputum smear positive for acid fast bacilli treated by private practitioner administered directly observed treatment in public-private mix pilot projects, India 2000-02

Public-private mix project (state)	Evaluation period*	Total No of new case notifications	Cured (%)	Completed treatment (%)	Died (%)	Failed treatment (%)	Defaulted (%)	Transferred (%)	Treatment success (%)†
Private practitioners									
Delhi LRS (New Dehli)	Jan to Mar 2001	20	18 (90)	0	0	1 (5)	1 (5)	0	90
Kannur (Kerala)	Jan 2001 to Jun 2002	85	78 (92)	0	2 (2)	1 (1)	4 (5)	0	92
Mumbai (Maharashtra)	Apr to Dec 2002	296	181 (61)	58 (20)	7 (2)	15 (5)	35 (12)	0	81
Thane Municipal (Maharashtra)	Jan 2001 to Mar 2002	215	168 (78)	0	10 (5)	14 (7)	22 (10)	1 (0)	78
Thane Rural (Maharashtra)	Jul 2001 to Jun 2002	63	55 (87)	0	4 (6)	0 (0)	3 (5)	1 (2)	87
Corporate and non-governmental organisation									
Mahavir (Andhra Pradesh)	Jan 1995 to Dec 1999	161	143 (89)	1 (0)	3 (2)	6 (4)	8 (5)	0	90
Tea Estates (Assam and West Bengal)	Jan 2001 to Mar 2002	1925	1604 (83)	17 (1)	126 (7)	99 (5)	77 (4)	2 (0)	84
Falah-e-Am (Uttar Pradesh)	Jul 2001 to Jun 2002	1040	979 (94)	4 (0)	26 (3)	2 (0)	30 (3)	0	94
NDTB (New Dehli)	Jan 1999 to Dec 2001	584	508 (87)	1 (0)	14 (2)	29 (5)	28 (5)	4 (1)	87
RK Mission (New Delhi)	Jan 1999 to Dec 2001	1429	1217 85)	0	40 (3)	64 (4)	68 (5)	40 (3)	85
Leprosy Rural (Tamil Nadu)	Jul 2000 to Dec 2002	472	420 (89)	0	28 (6)	16 (3)	4 (1)	4 (1)	89
St Mary's Leprosy (Tamil Nadu)	Jul 2000 to Dec 2002	623	514 (82)	49 (8)	51 (8)	4 (1)	4 (1)	0	91

See table 1 for definitions.
*Patients included if notification as case of tuberculosis and initiation of treatment occurred in specified evaluation period.
†Proportion of patients documented as cured or completed treatment.

observed treatment met or exceeded the Indian tuberculosis programme target of 85% treatment success (table 3). In two projects where treatment outcomes of public sector administered, and private provider administered directly observed treatment were compared, no significant differences were found [78,90].

3.4 Discussion

Collaboration between the Indian Revised National Tuberculosis Control Programme and private practitioners in India improved the case notification of tuberculosis while maintaining good treatment outcomes. Compared with historical surveillance data from the same project areas in a limited number of projects involving private practitioners, higher mean case notification rates were observed after implementation of the public-private mix project. Furthermore, limited data from non-governmental organizations and private industry medical services showed their ability to work with the Indian tuberculosis control programme and successfully diagnose and treat large numbers of patients with tuberculosis. A strong public sector tuberculosis control programme proved critical for provision of necessary advocacy, training, and supervision. These findings highlight the feasibility of building public-private collaborations and the considerable potential they hold for improving tuberculosis control in India.

Concomitant efforts by the Indian tuberculosis programme to increase case detection through educational campaigns and improvement of public sector clinical services likely also played a

part. Indeed, national case notification rates from areas without public-private mix projects increased over the same general period as the evaluated projects, as would be expected in the setting of an expanding tuberculosis programme making active efforts to improve case detection. Even accounting for this limitation, to the Indian tuberculosis programme the benefits of public-private mix have proved sufficiently substantive to warrant inclusion into the overall Indian tuberculosis control strategy.

Local tuberculosis programmes made substantial investments in the training and supervision of private providers. These investments may be justified, as recent economic analyses of public-private mix projects in Hyderabad and New Delhi support the perception that public-private mix is cost effective[79]. Furthermore, public-private mix reduces treatment costs for patients, as drugs are provided free of charge by the Indian tuberculosis programme. Programmes should, however, avoid diverting resources from public sector tuberculosis control for public-private mix, as any erosion in effectiveness from public sector tuberculosis control might neutralise the positive benefits of public-private mix activities.

As a result of India's active engagement with these public-private mix projects, the scene is set for a broad scale-up of public-private mix into routine practice for tuberculosis programmes. Policies and operational guidelines are in place to guide local programmes and private providers in implementing such public-private mix activities.

At the central government level, the Indian tuberculosis programme has pursued and formalised agreements with other large government institutions. The programme has also sponsored national workshops and developed specific procedures for collaboration with medical colleges, which treat large numbers of patients with tuberculosis and play a crucial part in the management of complicated cases[95]. Consensus recommendations have been developed for the management of tuberculosis in adults and children in partnership with professional societies, medical colleges, and international experts [97,98]. Urban areas tend to have large numbers of private providers and hence are being targeted for intensified public-private mix scale-up. Plans are under way for expansion and replication of strategies associated with sustained success.

Tuberculosis programmes should recognise public-private mix as a public health intervention within their control mandate and engage both public and private healthcare providers to ensure equitable availability of services[99]. Providers who treat patients with tuberculosis should recognise that they have a responsibility to patients and their communities to adhere to standards of care, including prompt and accurate diagnosis, reporting, and effective treatment in accordance with DOTS[100]. Furthermore, coalitions with third party coordinating organizations may also promote ongoing involvement of the community; here public-private mix projects using third party interface organizations showed particularly large contributions to tuberculosis case detection.

What is already known on this topic
India has almost one fifth of the world's burden of tuberculosis, and as many as half of patients with tuberculosis see private providers first Collaboration between public tuberculosis programmes and private healthcare sectors is an important strategy to ensure equitable access to quality tuberculosis diagnosis, treatment, and care
What this study adds
In a series of pilot projects in India, tuberculosis case notification improved after implementation of public-private collaboration The Indian tuberculosis programme is scaling up efforts to collaborate with private providers and improve access to directly observed treatment, particularly in urban areas

The diverse public-private mix projects we describe highlight the feasibility and challenges of implementing public-private collaboration in tuberculosis control. Similarly, these public-private mix concepts could be applied to other diseases of public health importance, including HIV and malaria, which increasingly require linkages between governments, private providers, and community-based organizations. The lessons of Indian public-private mix projects have been and continue to be instrumental in shaping the global agenda for public-private mix activities in DOTS expansion

and may accelerate the achievement of goals for global tuberculosis control.

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CHAPTER 4*

Intensified Scale-Up of Public-Private Mix: A Systems Approach to Tuberculosis Care and Control in India

* Lal, S. S., Sahu, S., Wares, F., Lonnroth, K., Chauhan, L. S. & Uplekar, M. Intensified scale-up of public-private mix: a systems approach to tuberculosis care and control in India. *Int J Tuberc Lung Dis* **15**, 97-104, (2011).

4.1 Introduction

In general, public health interventions are planned and designed by the public health sector. On the ground, however, significant numbers of patients seek care from a variety of care providers that are often alienated from organized public health programmes[62]. To address the non-involvement of different care providers, who are a thriving part of many health systems, the World Health Organization's (WHO's) Stop TB Strategy has made 'engaging all care providers' an essential component of global tuberculosis (TB) control[101], using the public-private mix (PPM) approach. PPM entails a public sector programme taking the leadership and providing support to facilitate systematic involvement of non-programme providers in TB control. The multiplicity of care providers is nowhere as starkly obvious as in India, where a plethora of different types of providers operate in large, parallel health care sectors (Table 1).

A fifth of the global burden of incident TB cases occur in India; in 2007, there were an estimated 3.3 million prevalent TB cases, almost 2 million new cases and around 330 000 deaths due to TB[102]. Conscious of the ground realities, the Government of India's Revised National Tuberculosis Control Programme (RNTCP), along with phased DOTS expansion, set up several PPM projects across the country. Private providers contributed on average 16% of cases, with a treatment success rate of 86%[103]. The cost-effectiveness of such PPM initiatives has been demonstrated[79,81]. To help scale-up PPM, the RNTCP developed national schemes to suit the capacity of

different providers to contribute and that of the RNTCP to support them[93].

The RNTCP adopted a systems approach for phased scale-up of PPM activities that incorporated 1) local mapping of all care providers in a systematic manner; 2) prioritization of providers most likely to contribute to TB case notification and treatment; 3) agreement on the provider-specific task-mix; 4) setting up of a surveillance system to measure the contribution of the different providers; and 5) implementation and evaluation of the results of collaboration prior to further expansion.

The objectives of PPM scale-up were to study the extent and nature of participation by the different health care provider categories and its effect on case notification and treatment success rates. This paper describes the processes and outcomes of this systems approach for PPM scale-up in 14 major Indian cities.

4.2 Methods

The intervention

The Central TB Division (CTD), the head office of the RNTCP within the Ministry of Health and Family Welfare, launched the intensified PPM scale-up project in 14 major urban districts* from July to September 2003, covering a total population of about 50 million (ranging from 600 000 to 6 million per city). The same national

* Ahmedabad, Bangalore, Bhopal, Bhubaneswar, Chandigarh, Chennai, Delhi, Jaipur, Kolkata, Lucknow, Patna, Pune, Ranchi and Thiruvananthapuram. With the exception of Pune in Maharashtra, these are the capital cities of the respective major states in India.

schemes for engagement with different providers were applied in these 14 cities as in the rest of the country. Additional human resources were provided in the form of one dedicated PPM medical consultant and two peripheral field supervisors per city, whose tasks were to assist the district programme managers by advocating for PPM, conducting situational analysis with mapping of the health care providers, developing action plans, facilitating reporting, sensitising and training providers, supervising and monitoring the activities and sending monthly progress reports to the CTD.

Local action was backed by the advocacy activities of the CTD, which also started collaborative activities with the Indian Medical Association (IMA). A concise version of the RNTCP training module and an advocacy kit were developed for private medical practitioners. CTD then formally communicated with those non-Ministry of Health public sector agencies that had health care facilities. To facilitate the involvement of medical colleges, task forces were established at national and state level. The CTD, assisted by the WHO Country Office TB team, conducted regular meetings with the PPM consultants, organised training, undertook monitoring and frequent supervisory visits, and planned the evaluation. The roles and responsibilities to be assumed by the public and private health care providers were clearly identified and differentiated. Training, supervision, provision of quality-assured free drugs, supplies and honoraria, tracing of treatment defaulters and notification of TB cases remained the responsibility of the RNTCP, while referral, diagnosis,

treatment of TB cases as per RNTCP policy, and providing information to the public sector about TB patients and treatment interruption were responsibilities assigned to the non-public health services that became involved with PPM[93,104]. Unique features of this intervention were the existence of national policy and broad guidelines, availability of training materials and focused advocacy and dialogue [93,104-106]. Although no monetary incentives were given to the providers, they received increased social recognition and credibility due to improved documented treatment success of their patients.

4.2.1 PPM surveillance system

To monitor the contributions of the different providers to key TB control indicators in the 14 cities, the RNTCP developed a PPM-focused surveillance system. Providers were grouped into six categories, each of which was assigned a code (Table 1). In addition to certain process indicators (Table 2), the system was designed to measure the extent of contributions to referral of TB suspects, TB diagnosis, notification of new smear-positive pulmonary TB (PTB) cases, treatment support, and treatment outcomes.

Table 1.

Coding of different provider categories in PPM-focused surveillance system

Code	Description
H	State-level public sector health facilities (under the health department of the respective state governments, e.g., hospitals, health centres, dispensaries, etc.)
G	Public sector health facilities outside the purview of the state government department of health (ministries/departments under central government, e.g., railways, social insurance organization, etc.)
M	Medical college hospitals (under the medical education department: public and private medical colleges)
C	Corporate sector health facilities (health facilities attached to industries, factories, etc.)
P	Private health facilities (private-for-profit sector: individual practitioners or hospitals; practitioners of homeopathy and indigenous Indian systems of medicine and traditional healers; community volunteers engaged in supervision of treatment)
N	Voluntary NGOs (non-profit NGO sector: clinics, dispensaries, hospitals)

PPM = public-private mix; NGO = non-governmental organization.

The surveillance system used routine RNTCP recording and reporting formats with minor modifications to enable disaggregated data from the different provider categories to be captured. The laboratory request form for sputum examination was used for non-programme providers to refer TB suspects to the RNTCP. When the

TB suspect reported to a designated microscopy centre (DMC), the laboratory technician recorded the name of the referring provider on the laboratory form and the laboratory register. The RNTCP supervisors reviewed the laboratory register and treatment cards, and copied the appropriate provider code into the TB register to note the source of referral and place of treatment. Quarterly district reports were generated from the 14 cities.

4.3 Results

4.3.1 Extent of participation by different providers

Table 3 summarises the extent of involvement of the different provider categories. The majority of the H, G, M, and N sector facilities were involved in some activity (referral, diagnosis or treatment). The number of cases notified per staff member trained was much higher for H and M providers than for the other categories, and was lowest for G and P. Although 15 740 providers were listed, only a small proportion expressed interest in undergoing training after the sensitization efforts by the RNTCP.

4.3.2 Effect on overall case notification rate

In the 14 cities, case notification rates for new smear-positive (NSP) cases and all new cases increased from 52 to 58 and from 146 to 171 per 100 000 population, respectively. During the same period, in other cities of the country, the NSP case notification rate dropped slightly from 54 and returned to 54, while the notification rate for all

new cases dropped from 136 to 132/100 000. Trends from 1999 to June 2007 are shown in Figure 1

4.3.3 Contribution to case notification by different provider categories

The contribution of the different provider categories to notification of NSP cases from April 2004, when data first became available, is shown in Figure 2. Health department facilities contributed on average 67% of the NSP cases during this period, medical colleges 16%, private practitioners 6% and NGOs 7%, while other public providers and the corporate sector contributed only 3% and 1%, respectively. Assuming that one third of the cases from medical colleges were notified by private medical colleges, the private sector, including NGOs, contributed about 18% of all notified NSP cases.

Table 2.

PPM evaluation indicators

Output indicators

1. **Referral of TB suspects:**
   Contribution of the respective health care providers in referring TB suspects to RNTCP DMCs, as recorded in the laboratory registers.
2. **Diagnosis of all smear-positive PTB cases:**
   Contribution of the respective health care providers to overall smear-positive PTB case diagnosis, measured by counting the number of smear-positive PTB cases diagnosed in DMCs located at the health facilities of the respective health providers.
3. **New smear-positive PTB case notification:**
   Contribution (based on source of referral) of the respective health care providers to the notification (cases registered in the RNTCP) of new smear-positive PTB cases.
4. **DOT provision to TB patients:**
   Contribution of the respective health care providers to DOT among patients treated under the RNTCP, as ascertained from the TB treatment registers.
5. Treatment outcome disaggregated by the type of provider providing DOT.

Process indicators

1. **Provider sensitization:**
   Number of facilities listed, contacted and sensitized as a proportion of all providers listed.
2. **Training**:
   Number trained as proportion of providers listed.
3. **Involvement of different PPM facilities**:
   By formal or informal agreement, in various tasks such as referral, diagnosis (laboratory), treatment (DOT provision), and both (diagnosis + treatment).
4. **Supervision:**
   Number of supervisory visits made to PPM partner facilities or sites by type of supervisor and supervised facility.

PPM = public-private mix; TB = tuberculosis; RNTCP = Revised National Tuberculosis Control Programme; DMC = designated microscopy centers; PTB = pulmonary tuberculosis; DOT = directly observed treatment.

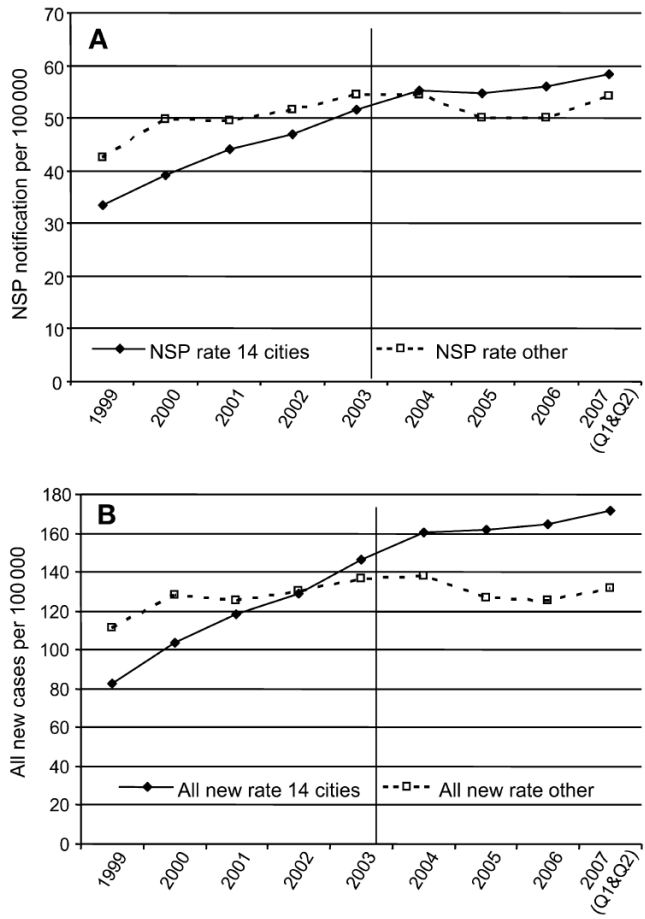
Table 3 Participation in RNTCP by the different provider categories

Provider*	Facilities listed† *n*	Staff trained‡ *n*	Involved in referral† %	Involved in diagnosis† %	Involved in treatment† %	NSP cases notified per year *n*	Cases all forms treated per year *n*	Yearly notification per no. trained
H	1611	2976	8	21	86	17042	55797	5.7
G	299	653	42	18	52	741	1254	1.1
M	85	759	24	48	59	4297	3644	5.7
C	54	49	35	13	9	135	373	2.8
P	15740	1426	25	0.4	14	1643	5626	1.2
N	782	1105	22	9	44	1811	8240	1.6

*See Table 1 for details.
†Not mutually exclusive for the role of referral, diagnosis and treatment.
‡Staff in the facilities who underwent training.
RNTCP = Revised National Tuberculosis Control Programme; NSP = new smear-positive pulmonary tuberculosis.

Figure 1

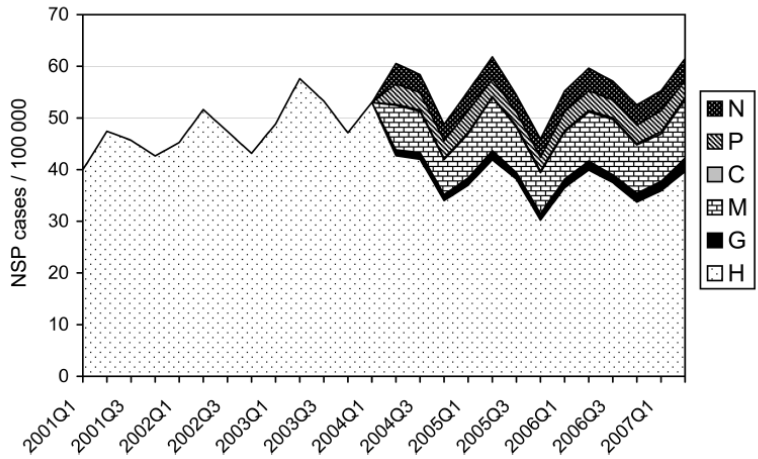
Trend in case notification rates of NSP (A) and all new cases (B) in the 14 cities with intensified PPM scale-up and in other areas.



The vertical line separates the periods before and after intensified PPM scale-up. Case notification/100 000 for 2007 annualized from quarter (Q) 1 and 2 data. NSP= New Smear Positive.

Figure 2.

Contribution by different provider categories (see Table 1 for details) to case notification in the 14 cities



NSP = new smear-positive

4.3.4 Inter-city differences

Substantial variations were observed in case notification trends and contributions by the different providers across the 14 cities. In Bangalore, for example, there was a continued increase due to gradually increasing contributions by medical colleges and some increase in contribution by private practitioners (Figure 3).

Some PPM sites achieved case notification rates that were above the national and state level figures. In the CTD records, certain common factors were identified in these sites, including strong RNTCP administration, evidenced by the district TB officer and other district and sub-district level key staff in place, adequate numbers of supervisory visits, appropriate use of resources and promptness in

reporting. Similarly, the administration took a proactive role in initiating steps such as inviting partners for meetings, sending communications requesting them to become involved with the RNTCP and sensitising their key staff. The involvement of large non-public health sector facilities, such as medical colleges, which cater to a significant percentage of the population, was also a common factor.

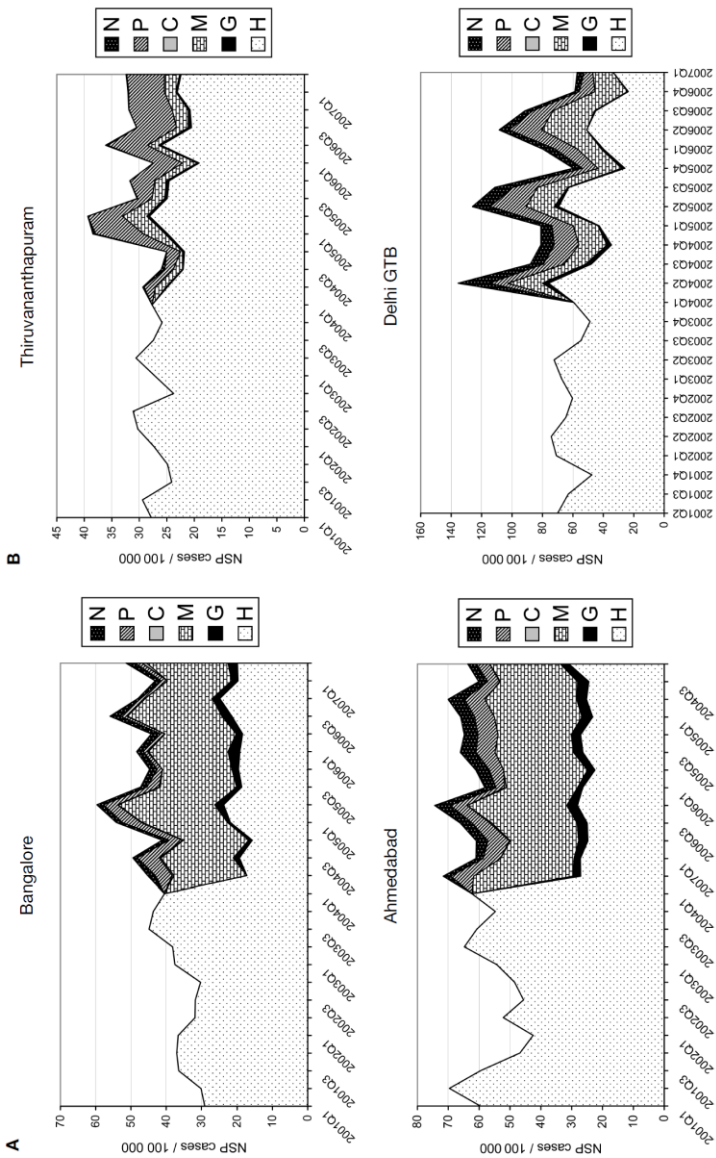
4.3.5 Task-specific contributions by providers

Contributions to referral, diagnosis, NSP case notification and treatment are shown in Figure 4. The H sector was the dominant contributor to all indicators. Medical colleges (M) were very active in identifying suspects and diagnosing patients, while they played only a minor role in treatment provision (4%).

4.3.6 Effect on treatment outcomes

Treatment outcomes for all cohorts combined from April 2004 to June 2007, disaggregated by treatment provider category, are summarised in Table 4. The treatment success rate was above the 85% target for all sectors combined, and individually for the H, P and N sectors. Analysis of treatment outcome trends showed that, except for the medical colleges and corporate sector, high cure rates were maintained throughout the intervention period. The cure rate in medical colleges declined from 86.5% in 2004 to 67.3% in 2006, due to a new RNTCP policy decision to register TB cases admitted to medical college hospitals in the local TB registers even if the patients were residents of other districts. This resulted in a higher percentage

of ‘transferred out’ patients. For the corporate sector, the number of cases was relatively small, and therefore a few ‘transferred out’ cases, as in the case of Ranchi, reduced the cure rate considerably.



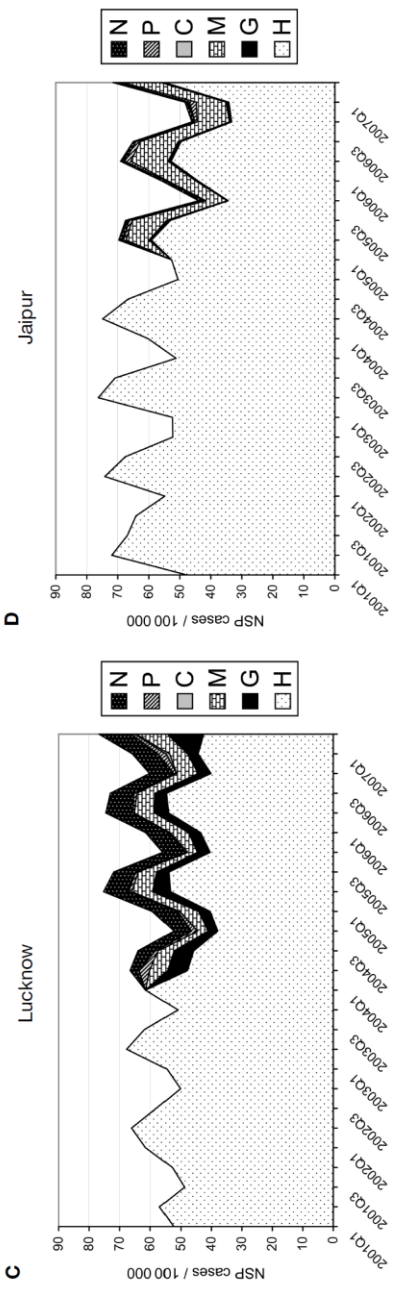
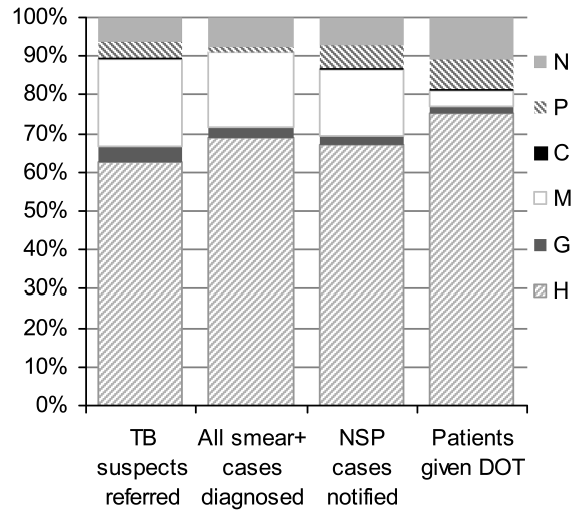


Figure 3 Variation in contributions to case notification by different providers across cities. Examples where substantial contributions were made by **A**) medical colleges, **B**) private providers and **C**) NGOs; and **D**) examples of very limited overall contribution and very small NGO and private sector contribution. NGO = non-governmental organisation.

Figure 4.

Contribution by the different providers to referral, diagnosis, NSP case notification and treatment, 2004–2007



TB = tuberculosis; DOT = directly observed treatment; NSP = new smear-positive

4.4 Discussion

It is evident that the systems approach to the phased scale-up of PPM activities—listing all care providers, sensitising a wide number with subsequent training of a selected group using standard training materials, and prioritising and engaging those who expressed an interest through appropriate schemes—was productive in the 14 cities. Overall, the intensified PPM initiative was associated with a 12% increase in notification of NSP cases in the 14 cities, with a high treatment success rate across all provider types. However, there were large variations between cities in relation to case notification trend,

and the different types of providers varied in their involvement with the RNTCP across the different settings. However, we acknowledge the fact that populations visiting the various types of providers may have different TB prevalence rates.

The public health sector remained the largest contributor to all indicators, and strong public-sector implementation was observed to be required for successful PPM activities in all sites. The finding that all providers who engaged in treatment provision had good treatment outcomes endorses the RNTCP policy of engaging RNTCP providers only if they can ensure directly observed treatment. As the medical colleges contributed a sizeable proportion of cases, the CTD focused on these and involved nearly all of them, particularly in the PPM sites. However, due to their large catchment areas and limited outreach capacity, medical colleges are less suitable for long-term ambulatory treatment. They have therefore been encouraged to send cases after diagnosis to other providers closer to the patients' place of residence.

Table 4 Treatment outcome for all cohorts combined from April 2004 to June 2007, disaggregated by treating provider category

	Registered *n*	% of all	Cure %	Treatment completion %	Died %	Failure %	Default %	Transfer %	Treatment success %
H	41384	77	85.2	0.8	3.3	2.7	6.9	1.0	86.0
G	735	1	82.7	1.4	2.7	3.1	8.0	2.0	84.1
M	2390	4	77.5	1.3	3.0	2.6	5.7	9.5	78.7
C	260	1	78.5	1.2	4.2	1.2	7.7	7.3	79.6
P	3649	7	86.6	1.7	3.8	2.5	4.7	0.7	88.3
N	5457	10	83.9	2.1	3.9	3.2	6.5	0.8	86.0
All	53875	100	84.8	1.0	3.4	2.7	6.7	1.4	85.8

The involvement of large numbers of small private providers (mostly single practitioners), each yielding a small number of cases, may not be as cost-effective as the involvement of large institutions such as medical colleges. However, the substantial contribution by private

providers in some of the 14 cities shows great potential, as these represent the majority of health providers in most parts of India[107]. As private providers are commonly the first contact for people with TB, their involvement is of particular importance to reduce diagnostic delay and save costs for patients[80]. The low proportion of listed private providers who were involved (25% in referral and 14% in treatment) was mainly due to the large number of private practitioners generally. Despite sensitisation efforts targeting large numbers of private practitioners, only a small proportion expressed willingness to attend systematic, formal training and to participate in RNTCP activities. A strong, proactive RNTCP administration and the presence of a sizeable non-public health sector are understood to be important factors for establishing collaboration and thus notify more TB cases in PPM sites. Weak regulation, resulting in a private drug market that pushes anti-tuberculosis drugs through private medical practitioners, variable standards of health care provision by the private sector, and a lack of mechanisms for the certification and accreditation of private practitioners, are identified barriers to PPM implementation. According to the consensus understanding of the CTD, even within the RNTCP, at the peripheral level, there was a lack of interest and experience in dealing with other sectors and a lack of faith in their capacity. Similarly, within the private sector, a lack of faith in the public sector health programmes and a low priority for public health programmes worked against wider implementation of PPM activities[73]. Anecdotal evidence suggests that lack of political will at the district level of RNTCP leadership, coupled with

reluctance from the private sector to collaborate for fear of losing patients, have been impediments to PPM. This aspect was not measured by the present study and there is scope for the RNTCP to explore it further. This study suggests that the decision as to whether and what type of providers should be engaged depends more on current delivery trends in a given location than on the type of provider. The proportion of TB notifications by provider appeared to be highly dependent on how predominant the type of provider was in the given city. At the same time, all types of providers were equally successful at treatment. This suggests that an important factor to consider while designing TB control programmes is where people currently receive care. This may be more important than other intrinsic provider characteristics. Systematic and continuous mapping of private providers by local health administrations would facilitate similar interventions for TB and even other diseases, and these results need to be shared with the broader health systems audience in addition to the narrower TB audience. The results and conclusions of this study could be instructive for other disease control programmes and interventions for health systems design generally.

4.5 Conclusion

The different types of health care providers varied in their importance and level of involvement with the RNTCP across the country. The systems approach adopted by the RNTCP in the 14 major cities led to a 12% increase in NSP case notification, with relatively good treatment success rates across all providers. Many challenges and

barriers remain to wide scale-up of PPM TB activities in India. The factors identified as leading to the success of the initiative have been used to inform the further development of RNTCP policy for the wider expansion of PPM TB activities across the country.

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CHAPTER 5

Role of professional bodies in TB control: An untold story of the Indian Medical Association in fighting TB

5.1 Introduction

Tuberculosis (TB) continues to be a major public health threat by claiming millions of lives each year. India has an estimated 2.8 million new TB cases occurring annually which is 27% of the global incidence[1]. India's national TB control programme (NTP) was established in 1962 under the Ministry of Health (MoH). A review by WHO held in 1992 concluded that NTP, despite thirty years of its existence, had not created any significant epidemiological impact on TB burden of the country[108]. Failure in meeting standards in diagnosis and treatment, low rates of treatment completion and lack of adequate documentation on treatment outcomes were reported as the major weaknesses. To address the weaknesses, Revised National TB Control Programme (RNTCP), based on the principles of the WHO-recommended Directly Observed Treatment, Short course chemotherapy (DOTS) strategy, was implemented in the country in 1997[108].

In India, vast majority of qualified doctors, dispensaries and hospitals are in the private sector[109]. As a result, private health sector provides care to significant proportions of TB patients also[15,60]. About 60 to 70% of TB patients in India first seek care from private health care providers[8-10]. There are close to one million qualified and licensed doctors in India, majority of whom work in the private sector [15,60]. Private health care sector in India is very diverse and consists of

multiple types of care providers that are largely disorganized and to a great extent unregulated[46]. While 70% of the Indian population live in rural areas, only a third of government doctors work in rural India[110]. Therefore, rural India is served mostly by private health care providers. Similarly, urban areas have higher numbers of private health care providers where the primary health care network of the government is not utilized by people as much as in rural areas[110]. Unlike the public health sector, private health sector in general lacks systems for ensuring adherence to the diagnostic algorithm designed by RNTCP for early and accurate diagnosis of TB cases. Quality of treatment also varies across private health sector providers due to lack of adherence to standardized treatment guidelines[16,17]. In addition, private health sector is typically not designed to perform public health actions for ensuring treatment adherence and to record treatment outcomes of TB patients. Due to these reasons, TB patients who seek care from the private health care providers would face inordinate delays in being promptly diagnosed[70]. Similarly, TB patients are likely to receive inappropriate, inadequate or interrupted treatment at private health care facilities[8]. While delayed diagnosis results in increased morbidity, mortality or spread of the disease in the community, suboptimal treatment can cause death of patients or accelerated generation and spread of mycobacterial resistance to TB drugs. Multidrug-resistant TB (MDR-TB) is more difficult and expensive to treat compared to drug-susceptible TB[18,111]. Whereas RNTCP achieves high treatment success rates for patients with drug-susceptible TB, without standardized treatment and prompt follow

up, treatment success in the private sector can be as low as 30%[15]. Considering the importance of private sector in health care, RNTCP since its inception, has been making efforts to engage private health care providers[26]. In this regard, the Central TB Division (CTD), RNTCP's national programme management unit, sought assistance from the Indian Medical Association (IMA). IMA, a voluntary organization, is the professional association of the doctors practising modern system of medicine. IMA with its 1650 branches across the country has over 200 000 doctors as its members[75]. In the transition from NTP to RNTCP, while the basic diagnostic tools and drugs remained essentially the same, there has been repackaging of approaches in the diagnosis and treatment based on the principles of the DOTS strategy. However, the modern medicine practitioners in the private health care sector, in general, opposed RNTCP. This was a major reason for RNTCP to seek the help of IMA in engaging private health care providers. This article aims to bring to light the untold story of IMA's engagement in TB control as a close partner of RNTCP. The article also touches upon the operational challenges that IMA faced in the process.

The objectives of this paper are to study 1) the role of IMA in the engagement of private health care providers in TB control and what is its relevance and 2) the lessons for India and other countries to learn from the unique endeavor of engagement of medical professional associations in TB control.

5.2 Methods

We used standard WHO definitions as given in 'Definitions and reporting framework for tuberculosis – 2013 revision (updated December 2014)[112]. Public-Private Mix (PPM) strategy became formalized by the establishment of PPM subgroup of the DOTS Expansion Working Group in 2000[113]. Therefore, the search for literature was for the period from 2000 to 2017. Though there are no peer-reviewed publications specifically on the processes of IMA's PPM projects, information about IMA's engagement is available in many publications of IMA, RNTCP, and other agencies or researchers. The contribution of IMA's engagement as additional TB cases notified is reflected in some published articles. For our study, we considered available published articles on the collaborations between IMA and RNTCP, internal memos and policy documents.

We reviewed the tuberculosis section of the WHO website to collect latest information on TB epidemiology, current TB control situation, policy guidelines and TB control data with focus on India[114]. We also searched 'PPM Resources' at WHO website[115]. WHO also publishes an annual report on global TB control the purpose of which is to provide an annual assessment of the global TB epidemic and the progress made in implementing the global TB control strategy. The latest WHO report published in 2017, which has used information and data from 2016, was reviewed[1]. We also gathered information from various documents available at the RNTCP's website which includes programme guidelines, Technical and Operational Guidelines,

National Strategic Plan and guidelines on the programmatic management of drug-resistant TB (PMDT) and TB/HIV[116]. We reviewed annual performance reports published by RNTCP which contain qualitative information as well as RNTCP's annual performance data[116]. We collected information on IMA-PPM from peer-reviewed articles on PPM. We also looked at articles published by the journal of Indian Medical Association, peer-reviewed articles on other journals, and publications of organizations such as CTD, WHO, American Thoracic Society and the Global Fund. We conducted interviews with officials of IMA especially the ex - IMA national coordinator for RNTCP who was associated with RNTCP since 2000 by starting the first RNTCP-designated microscopy centre in the private health sector at his own hospital[25]. We also interviewed the erstwhile PPM advisor to IMA and a RNTCP consultant of IMA[117,118]. We held discussions with RNTCP's key staff at CTD and in Kerala state[119,120]. We met many present and ex- RNTCP staff.

We considered the projects that qualified as PPM as per WHO definition in which IMA was engaged[115]. We defined a project as IMA-PPM project where IMA formally collaborated with RNTCP. We used two tools namely 'PubMed/MeSH' and 'Google Scholar' for literature search. The search words used were Indian Medical Association AND TB, Indian Medical Association AND TB AND Public Private Mix, Indian Medical Association AND Public private mix, Indian Medical Association AND Revised National Tuberculosis Control Programme, Indian Medical Association AND

Private sector AND TB, Indian Medical Association AND Tuberculosis. Only articles published in English were included.

5.2.1 Online questionnaire survey

An online questionnaire survey was also conducted as part of the study. A list of major reasons of opposition from private medical practitioners to RNTCP was created after discussions with selected experts in TB-PPM in India. The RNTCP policies and the major reasons for opposition grouped under four major categories namely diagnosis, treatment, patient-related and physician-related were listed. This list was produced based on the discussions with selected TB PPM experts of India which was validated by the online survey among PPM experts/stakeholders representing RNTCP functionaries at national and subnational levels, private health sector providers, technical agencies including WHO, donor agencies, academia, researchers, IMA, social activists and people affected by TB in India who have been directly associated with RNTCP and PPM[121]. These experts were selected from the pool of experts used by RNTCP in its various functions. Survey was sent to 28 experts and we received 21 responses which gave a 75% response rate. The results were compiled and analyzed. (see Table 1)

The survey clearly validated the reasons for opposition of the private sector to the policies of RNTCP. All except one reason received agreement by majority of the respondents. In the case of one reason (while RNTCP didn't advise sputum culture as a primary diagnostic test, private medical practitioners often wanted to use culture as a

diagnostic/confirmatory test complementary to other tests), there was agreement from only 42% of the respondents. However, in this case, the percentage disagreed was 47% while 11% was not sure of the response.

In addition to the issues shown in the table below, private medical practitioners had concerns about potential impact of RNTCP on their clientele which used to come out in private conversations with private medical practitioners[118]. This was mainly due to RNTCP's insistence that services provided to presumptive as well as confirmed TB patients by private health care providers had to be as per the RNTCP guidelines and by using laboratory reagents and drugs supplied by the government which the private medical practitioners had to offer free of cost to the patients[18,118]. In addition, private medical practitioners were expected to refer their patients to public health facilities whereas they had the fear of losing their clientele or their patients facing unfriendly treatment at public health facilities[117,118]. Private medical practitioners were also opposed to the supervision by the RNTCP staff. The main reasons for this were alleged policing and harassment by government staff and the reluctance of the private health sector to provide access for government staff to their own registers and records[117,118]. These concerns were not included in the survey because these were often not explicitly expressed by the private care providers. This information came from the in-depth interviews with some of the PPM experts[117,118]. This is the background where RNTCP decided to take the help of IMA to reach the private health sector.

Table 1.

RNTCP policies and reasons for private medical practitioners[25,117,119,120].

RNTCP policies and reasons for opposition from the private health sector	Percent (%) of experts in agreement
Diagnosis-related issues	
One of the main reasons for private medical practitioners not preferring smear microscopy for diagnosing pulmonary TB was low sensitivity of the test	**55**
Multiple visits the patients had to make, long queues and unfriendly behaviour at public sector hospitals were some of the important reasons for the private medical practitioners' lack of preference for sending their patients to public sector hospitals for doing smear microscopy	**95**
private medical practitioners opposed the restrictions by RNTCP on using X-Ray in the diagnosis of pulmonary TB as the private practitioners wanted to use X-ray to rule out conditions other than TB and for clinical assessment of the patient during treatment	**95**
While RNTCP didn't advise sputum culture as a primary diagnostic test, private medical practitioners often wanted to use culture as a diagnostic/confirmatory test complementary to other tests	**42**
Private medical practitioners preferred to use commercial serological tests for diagnosing TB RNTCP discouraged the use of these tests	**95**

Treatment-related issues	
While RNTCP insisted on using RNTCP-supplied drugs packed in patient-wise boxes for the entire duration of treatment of TB, private medical practitioners in general were not keen to use these drugs due to lack of trust in the quality of drugs provided by the government	**63**
While RNTCP insisted that patients had to be treated using one of the three categories of drugs supplied by RNTCP, private medical practitioners were not keen to use them as drugs of same doses had to be given to patients of a wide range of body weights which, they felt, could lead to under dosing or overdosing	**74**
While RNTCP advised 4 drugs for new and 5 drugs for re-treatment patients (first line treatment), private medical practitioners often wanted to prescribe more drugs and not be limited to the RNTCP-recommended drug regimen	**94**
While RNTCP insisted on treatment of 6 months for new and 8 months for re-treatment TB patients, private medical practitioners often wanted to prescribe drugs for longer durations	**68**
While RNTCP advised only 3 drugs for smear negative/Extra pulmonary TB cases, private medical practitioners in general preferred to use more drugs	**95**
While RNTCP drugs were to be consumed by patients only three days a week, private medical practitioners preferred daily drug consumption by their patients	**100**
While RNTCP strictly discouraged empirical treatment with anti-TB drugs and insisted that 'treatment had to be started only if TB was the diagnosis and once started, treatment had to be completed until the last dose', private medical practitioners wanted to try anti-TB drugs (when in doubt) for a few days and withdraw if there was no progress	**89**

Patient-related issues	
While RNTCP insisted directly observed treatment (DOT) for TB patients, private medical practitioners in general were opposed to it due to concerns about patients' confidentiality	89
While RNTCP insisted on smear microscopy as the follow up test to assess improvement and to confirm cure for pulmonary TB patients, private medical practitioners wanted to use X-ray and other tests for the same purpose	89
While RNTCP insisted on notifying all TB cases by designated government staff, private medical practitioners opposed it for confidentiality and stigma issues	68
While RNTCP insisted on patients' home visit by health staff for initial health education and follow up, private medical practitioners opposed it for stigma and confidentiality issues	74
Physician-related issues	
While RNTCP held the view that completion of TB treatment by patients was the responsibility of the doctor who started anti-TB treatment, private medical practitioners didn't accept it due to lack of mechanisms for following up the patients until treatment completion	95
While RNTCP insisted in tracking and bringing back the patients when they interrupted TB treatment, it was not practical for private medical practitioners to do it as they had no mechanism to retrieve such patients	100

5.3 The process of partnership between RNTCP and IMA

Initially, IMA was also skeptical about RNTCP's claims as a better programme compared to the previous NTP[25,117]. In addition, IMA also had concerns about the private medical practitioners' apprehensions about possible impact on their clientele that RNTCP

would cause[25,117]. In the meantime, certain pilot PPM projects had come up in New Delhi (1999), Kannur (2000) and Kollam (2001) where local IMA units played a key role[25,26,78]. The New Delhi project relied on private health care providers to refer patients with suspected tuberculosis to public sector facilities for smear microscopy.

By 2000, when Kerala, a state in the south of India, became the first state to achieve hundred per cent geographic coverage of RNTCP, CTD advised the state to systematically engage private health sector in TB control. Subsequently, Kerala state administration of RNTCP chose Kannur and Kollam districts as pilot districts for private health sector engagement.

Kannur district developed a model based on a private laboratory surveillance network for sputum smear microscopy where free training and quality assurance supervision were provided by RNTCP[78]. The laboratories participated on a voluntary basis and there was no signed agreement between RNTCP and the laboratories. IMA played a major role in developing the model and the project had the advantage of the district TB officer (DTO) of Kannur officiating as the secretary of IMA's Kannur branch. Sensitization workshops were held at IMA branch meetings.

In Kollam district, RNTCP encouraged smaller private hospitals, clinics and individual practitioners to refer presumptive TB patients to RNTCP facilities and simultaneously supported relatively bigger private hospitals with laboratory facilities to set up RNTCP-

designated microscopy centres[25,117]. As PPM activities were slowly picking up in the whole district, Punalur, a sub district, was chosen for intensified PPM activities[25,117]. One of the reasons for picking Punalur was the presence of 'Deen hospital', a private facility, owned by Dr. Asokan RV, the then secretary of IMA in Kerala. Deen hospital was designated as a RNTCP-microscopy centre which, as per RNTCP's basic criteria, had a physician, laboratory for sputum smear microscopy, laboratory technician, space to safely store RNTCP drugs, space with privacy for supervised drug consumption by TB patients, and staff to provide treatment supervision and counseling support to TB patients. RNTCP organized training of staff and provided laboratory consumables, anti-TB drugs and recording and reporting tools. A memorandum of understanding was signed between RNTCP and Deen hospital. Treatment supervision of the patients living in the neighborhood was agreed upon as the responsibility of the Deen hospital while RNTCP staff took care of health education, patient counseling, follow-up home-visits, recording of treatment progress and reporting of treatment outcomes of all patients[25,26,117]. The Director of Health Services of Kerala state inaugurated the Designated Microscopy Centre, which demonstrated political will of the government and RNTCP to partner with private health sector and IMA[122].

WHO's Country Office in Delhi provided technical assistance to both Kannur and Kollam pilots through the WHO-medical consultants posted in Kerala. RNTCP showcased New Delhi, Kannur and Kollam

models as earlier examples of PPM where IMA took a facilitator's role by acting as an interface between RNTCP and the private health sector[78,122,123]. IMA forums and publications gave wide publicity to the project[25,117].

The results of PPM models in terms of increased TB case notification from the private health sector motivated IMA to further expand PPM to the entire state of Kerala based on the model developed in Kollam district which focused on training private medical practitioners and then designating them as a provider of RNTCP services. IMA thus trained around 1150 private medical practitioners using a funding organized by WHO India country office. Seeing the success of this expansion in Kerala state, CTD advised IMA to further expand the model to a few more states of India as a regional project which happened by 2005[124]. The repeated success in engaging private health care providers and notifying additional TB cases prompted CTD to develop a new project to further expand this model which received The Global Fund's Round-6 funding where IMA became a subrecipient of funding to RNTCP[109,125]. IMA simultaneously worked with Eli Lilly Foundation and trained doctors on RNTCP in Himachal Pradesh and Madhya Pradesh states focusing on training of private health sector doctors[25]. In the process of systematic evolution from pilot projects in Kannur and Kollam districts to a national partnership between IMA and RNTCP, relationship between the two organizations became stronger. IMA also advocated among its members for the engagement of private health sector in RNTCP

through its various forums including the Journal of Indian Medical Association[25,126]. IMA summarizes its PPM strategy around four components; profession-based approach, non-financial incentives, one-on-one peer sensitization and adherence to International Standards for TB care[45,127]. IMA called it a profession-based approach because the association engaged only the doctors and health facilities that practise modern medicine. Training, certification and endorsement of private health sector facilities to provide RNTCP services were the examples of non-financial incentives. One-on-one peer sensitization was meant for doctors who couldn't find time for attending training programmes. This was done by meeting doctors at their facilities and providing information about RNTCP.

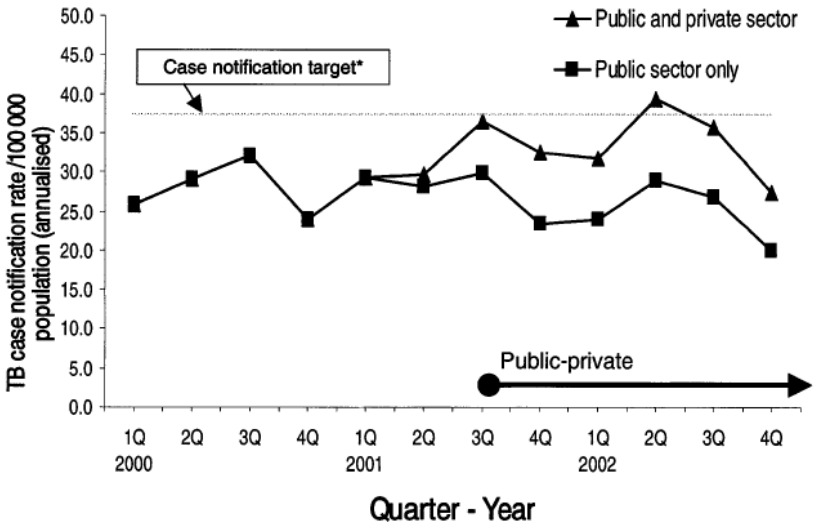
The pilot projects in Kollam and Kannur recorded high percentages of participation of the targeted private health care providers. Within a year, both districts recorded over 20% increase in case notification[25,78]. Figure 1 shows the increase in case notification in Kannur district during the period 2000-2002[78]. Both projects achieved treatment success rates above the RNTCP target of 85% [25,78].

As given in Tables 2 and 3, the IMA-Global Fund project covered 169 districts and 532 IMA branches serving a population of 415 million and over 55 000 IMA members. The project in a period of 8 years from 2007 to 2015 reached 103 254 private medical practitioners practising modern medicine through continuing medical education and trained 163 86 of them. The project also

notified 112 409 TB cases. Over 4000 practitioners signed agreements with RNTCP and close to 5000 'DOTS centres' were established[128]. The project thus demonstrated the potential of IMA in engaging private medical practitioners practising modern medicine and thereby increasing TB cases notified. While the contribution of this project as a successful demonstration model has to be recognized, it has to be remembered that the achievement in terms of numbers is not big especially in India where the number of qualified doctors practising modern medicine is about a million and more than a quarter of TB cases occur. Despite being a very big project that ultimately covered 16 States/Union territory, 25% of the districts and more than a third of the population of the country, it could reach only slightly over 100 000 private medical practitioners while less than 1000 doctors signed a Memorandum of Understanding with RNTCP. In addition, only 112 409 TB patients were notified in the whole duration of the project period.

Figure 1.

Public and private health sector tuberculosis case notification rate, new AFB-positive patients, Kannur District, 2000–2002[78].



There is a seasonal variation observed in India due to which number of cases will be the lowest in the 4th quarter and the highest in the second quarter of the year.

5.4 Lessons learned from the IMA-RNTCP partnership

5.4.1 Lessons for India

IMA's engagement helped RNTCP realize the advantage of engaging professional associations at the initial planning stages of policy development and revisions. RNTCP also realized the importance of addressing the reluctance of private health care providers in partnering with RNTCP for fear of losing their clientele. This learning convinced RNTCP to introduce formal mechanisms for partnerships with private health sector which led to the development

of different RNTCP schemes for partnerships that have the provision of appropriate compensations and incentives to private medical practitioners [26,28]. Absence of a formal agreement between IMA and RNTCP is considered as a gap which has led to situations where lack of ownership from either or both parties has created bottlenecks for the projects. Abrupt ending of funding to the IMA-Global Fund project from the government and the disorderly and unsystematic closure of the project is cited as an example for this gap by the IMA [25]. In addition, the absence of a dedicated focal point for managing this partnership at RNTCP was a major gap [25,117,118].

Table 2.

States and Union Territory covered by the Global Fund project of IMA[129]

Name of State/Union Territory	Number of districts	Number of IMA branches	Number of IMA members	Estimated population (in millions, 2011 Census)
Uttar Pradesh	75	113	10,935	199.3
Punjab	22	59	4,700	27.7
Haryana	22	43	3,124	25.4
Maharashtra	36	162	19,291	112.4
Andhra Pradesh	13	154	16,470	49.4
Chandigarh	1	1	701	1.1
Total	**169**	**532**	**55,221**	**415.2**

Table 3.

Achievements of IMA-Global Fund project from 2007 to 2015 [129]

Indicators	Achievement (Cumulative)
Number of Reviews and workshops held at National and state Level	98
Number of issues of dedicated RNTCP-IMA Newsletter and IMA Journals published and distributed to all IMA members in 15 projects states and a Union Territory	31
Number of Continuing Medical Education sessions organized for doctors	545
Number private medical practitioners reached through continuing medical education	103,254
Number of private providers trained in RNTCP using RNTCP Module for private practitioners and International Standard of Care Guidelines	16,386
Number of private health care providers signed Memorandum of Understanding with RNTCP	923
Number of IMA members from the 15 project states and 1 Union Territory who have signed an Memorandum of Understanding under one of the RNTCP PPM schemes	4,446
Number of private peripheral Health Institutions initiated	1,828
Number of DOTS centres started	4,709
Number of Designated Microscopy Centres approved in the project sites	107
Number of TB patients notified by private medical practitioners	112,409

IMA also realized its limitations as a voluntary organization, without jurisdictive authority, in engaging private health care providers in RNTCP. The important limitations listed by RNTCP are 1) not all private medical practitioners are members of IMA 2) doctors are not legally bound to follow IMA's appeals and 3) IMA is not equally organized in all states of the country. These resulted in variable influence of IMA on its members across states which made it difficult to generate the same level of motivation among all branches of IMA across the country. Though IMA could mobilize private medical practitioners to attend training and capacity building workshops, following up with them to designate their facilities as RNTCP-centres has been a challenge because IMA didn't have the infrastructure and resources for that. At the same time, RNTCP staff who have been already burdened with their routine work were unable to supplement this gap. Increase in case notification from private health sector after the private medical practitioners got access to the RNTCP's web-based notification system has been an indication for the need to expand electronic notification to the private health sector. Absence of a formal agreement stating the respective roles and the frequency of formal review meetings between IMA and RNTCP resulted in reduced levels of interactions between the organizations. Absence of a focal person at CTD for IMA-related matters has also contributed to weakening of the relationship. RNTCP had no earmarked funding for IMA engagement which made the formal interactions rather ad hoc.

RNTCP and IMA learnt important lessons from PPM pilot projects also. For example, the intensified PPM in Punalur sub district provided an important lesson about the risk of too much of decentralization of laboratory services. Recruitment of large number of private health care providers in PPM network resulted in additional workload of supervision which disrupted the routine work of supervisory staff. This in turn impacted the quality of diagnostic and treatment services. This experience informed the policies and RNTCP in turn decided the criteria of at least 60 adult outpatient attendance per day to designate a private health care facility as a microscopy center.

5.4.2 Lessons for other countries

Other countries that have similar situation like India with high TB burden, robust NTP, widespread private health sector and presence of a professional association of physicians can learn from the IMA-PPM model. Moreover, many of the high TB burden countries with private health sector as a major player in health care are facing similar problems in TB control as India does. For example, countries like Pakistan, Bangladesh, Myanmar, Thailand, Vietnam, Indonesia Philippines, Nigeria, Kenya and Ethiopia have significant proportions of TB patients seeking care from private health care providers[1]. Such patients are likely to reach the NTP very late or may not to reach at all resulting in most such patients receiving suboptimal or no care for TB. Large proportions of such cases also wouldn't get notified to the

respective NTPs[1]. In many of these countries, professional organizations of doctors would have prominent presence and considerable influence on private health sector and doctors. Lessons from India could inform the NTP policy makers and the leaders of professional organizations in these countries.

5.4.3 Achievements of IMA-RNTCP partnership

RNTCP using its experience and the lessons learnt from the PPM pilot projects, including those IMA-PPM models, developed national guidelines for the engagement of private medical practitioners[26]. IMA took part in the development of this document to reflect the perspectives of the private health care providers[25]. RNTCP in 2003 sought IMA's support in scaling up PPM at national level following which IMA's president in a declaration endorsed RNTCP and urged all the doctors to extend support to the national program. Incidentally, IMA's national president had already implemented RNTCP at his private hospital which was a RNTCP-designated microscopy centre in Kannur district where PPM was pilot tested from 2000[25,117]. In 2004, RNTCP developed an abridged version of training module for private practitioners, which replaced the previous module which had very descriptive chapters on administrative, programmatic and operational aspects of RNTCP that were not perceived as relevant for private practitioners. In 2006, IMA organized a national workshop on RNTCP which gave birth to the National Working Group of IMA for TB. IMA nominated Dr. Asokan, IMA leader from Kerala, as the National Coordinator of the working group with the responsibility of

leading the partnership with RNTCP. RNTCP in turn coopted IMA into the national working group on private sector. RNTCP also invited IMA to attend its biannual periodic review meetings and the WHO-led joint programme monitoring missions held every third year. In 2007, IMA formed IMPACT (Indian Medical Professional Associations' Coalition Against TB), a consortium of the relevant professional associations of specialist doctors such as pulmonologists, pediatricians and internal medicine doctors[25,109,117].

IMA was invited to the global steering committee that was set up to draft International Standards for TB Care (ISTC) in 2006 which was organized by the Tuberculosis Coalition for Technical Assistance, a global project funded by the USAID[45]. In 2007, IMA endorsed ISTC and urged the doctors to follow the standards prescribed in the document for diagnosing and treating TB patients [25,130]. IMA also endorsed 'Patients' charter for tuberculosis care' which defined TB patients' rights and responsibilities. IMA, together with other partners, assisted RNTCP in the development the Standards of TB Care for India[45].

Upon CTD's recommendation, WHO nominated IMA to the Strategic and Technical Advisory Group for TB which meets every year at WHO's headquarters in Geneva, Switzerland to advise WHO in refining TB control strategies and policies. IMA with support from WHO and Stop TB Partnership launched 'Stop TB Asia Coalition' in 2015 which was followed by signing of a pledge by the Indian Health Minister, global TB leaders and representatives of international

organizations and partners[25]. IMA has lately joined hands with Confederation of Medical Associations of Asia and Oceania with secretariat in Tokyo under Japan Medical Association to be part of the global fight against TB[25].

5.4.4 Long term attainments of the IMA-RNTCP partnership

The lessons learnt from the long-term IMA-RNTCP partnership were also used in the development of strategic guidelines for formal engagement of private health sector providers[131]. IMA's act of endorsing and deliberations on ISTC contributed to visible improvement in awareness among private medical Practitioners about the public health aspects of TB control and their responsibilities towards TB control[25,117]. There has been improvement in the quality of prescriptions of private medical practitioners as increasing numbers of them have been prescribing fixed dose combination drug regimens of reputed pharmaceutical companies instead multiple drugs which had the risk of consumption of inadequate drugs or doses by patients[25,117,118]. IMA's interactions with RNTCP also resulted in RNTCP's amendments of policies to accommodate the interests of the private health sector. One of such adaptations of IMA is the decision to experiment an innovative concept of Public-Private Interface Agency (PPIA) that allowed opportunity for neutral non-government agencies to function as an interface between RNTCP and private health sector. This was a shift in the RNTCP's approaches by creating an environment that promotes flexibility for private health sector engagement and trust among partners in TB control[27]. The

flexibility offered in one of the initial PPIA projects implemented in Mumbai city to use a diagnostic algorithm other than that of RNTCP was welcomed by the private sector. PPIA project in Mumbai city uses X-Ray as the screening tool while Xpert MTB/RIF, an automated diagnostic test, is used for confirmation of TB disease and identifying rifampicin resistance[132]. The National Strategic Plan 2017-25 of RNTCP includes a new scheme to address TB care in private health sector which will have incentives for private health sector providers and patients to improve reporting TB cases to RNTCP[28]. IMA's recommendation to simplify the documentation processes of TB disease events was also considered in the RNTCP's strategy regarding digital tools for recording and reporting. Concern of patients about the lack confidentiality in a system of paper-based registers and reports have been raised by IMA which is addressed by electronic reporting[25,118]. RNTCP's decision to allow private practitioners to access its web-based case-based notification system led to significant increase in case notification from private health sector in the recent years[1]. IMA points out that this model appears to have reduced financial burden on patients due to the availability of RNTCP services to patients who access care from private health care facilities[25].

5.5 Discussion

India is continuing to be the country with the highest number of incident TB cases with a quarter of the share for incident TB cases and unnotified TB cases. The End TB Strategy of WHO has set a very

ambitious goal of ending TB by 2035. Ending global TB will depend greatly on the pace of TB control in India which will in turn depend on the level of engagement of private health sector in RNTCP. As has already been discussed, private health sector in India is a heterogenous entity which is controlled by complex dynamics and undercurrents which are only partly understood yet. By the inherent characteristics and the way of functioning of the for-profit-private health sector, its challenging for a national health programme with social positioning to engage the private health sector in a public health programme that is not overtly aligned to their business model. Therefore, engaging the private health care providers in TB control is not an easy and straightforward task. Therefore, RNTCP will have to resort to multiple mechanisms to engage the various types of players in the private health sector to ultimately reach all the TB patients cared by them. Particularly to reach the patients in the private health sector, RNTCP will need facilitators to interface with the private health sector. It is in this background that an overview of the engagement of IMA, examining the processes, documenting the lessons learned and identifying the challenges became important.

The results from the IMA–RNTCP partnership demonstrates the need for and the value addition due to such a partnership in the larger interest of public health. It's clear from the evidence that though isolated and local IMA-RNTCP collaborations were there, IMA's declaration of nationwide support to RNTCP in 2003 changed the situation within IMA drastically in favour of PPM. This change in the

approach largely reduced the opposition from the private health sector towards RNTCP. In addition, IMA-PPM projects have demonstrated improved participation of private medical practitioners in RNTCP and resultant increase in TB case notification notwithstanding the fact that the achievement in case notification in absolute numbers was marginal compared to the size of the TB problem. WHO-led Joint Monitoring Mission that reviewed RNTCP in 2015 recommended that major initiatives must be undertaken to sensitize and engage private medical practitioners by involving stakeholders like IMA and other professional associations[133].

The IMA-RNTCP partnership had evolved over more than two decades through regular interactions between the two organizations that arose out of the need of RNTCP to engage private health care providers. Even after establishing a national-level partnership, the collaboration faced challenges especially due to administrative delays that became bottlenecks specifically in fund transfers to the project. Absence of a formal agreement signed between RNTCP and IMA was a major gap in addition to the absence of a focal point at CTD for PPM affairs. Absence of adequate documentation of the evolution and history of the partnership reduced the opportunities for the expansion of the model within the country and replication elsewhere. The benefits RNTCP received through this partnership is also inadequately documented. Even the limited documentation of the IMA's role as an interface contributed to the idea of a neutral interface agency between RNTCP and the private health sector for

building innovative models like PPIA. RNTCP's decision to scale up PPIA projects will be an opportunity for further strengthening IMA-RNTCP collaborations.

Absence of comprehensive monitoring and evaluation strategy to measure the impact of IMA-PPM projects stands out as a major gap that would impact future fund mobilization for expanding and replication of the model. In the Global Fund project, there were delays and interruptions in the fund disbursement to IMA. This was mainly because the government was the principal recipient of the Global Fund grant and the transfer of funds to IMA, the subrecipient, was interrupted or delayed due to bureaucratic bottlenecks and slowness of the government systems[25,117,118].

IMA has also taken cognizance of the challenges and has defined solutions to take this partnership forward. IMA has been reviewing its political and geographical strengths and planning to optimize its reach within private doctors in India[25]. RNTCP and IMA has started exploring ways of extending this partnership in the scale up of newer initiatives like PPIA at national level[25,119]. IMA being the common organization of doctors that can greatly influence its members especially in the private health sector will have a continued and enhanced role in helping India move towards ending TB. RNTCP implementation being primarily led by the government, a strong public sector with adequate capacity and willingness to partner with private health sector is required to materialize meaningful partnerships between RNTCP and the private health sector.

5.6 Recommendations

Having examined the IMA-RNTCP partnership in its entire length starting from the pilot projects through the latest developments, the recommendations can be listed as follows.

1. There should be a platform, for example a workshop, to examine the status of IMA-RNTCP collaboration leading to identification of key issues and challenges in the IMA-RNTCP partnership. The challenges identified in the process of the partnership should give insights to IMA in developing solutions aligned with the market practices.
2. MA-RNTCP collaboration must be revamped and a formal signing of agreement between IMA and RNTCP must be done to ensure effective contribution from both the organizations. There should also be clear division of responsibilities between RNTCP and IMA.
3. A focal point should be identified at RNTCP who will have the responsibility of managing the partnership with IMA.
4. The key issues and challenges should be systematically documented.
5. Similar projects in future should have strong monitoring and evaluation systems so that respective partner's contribution can be easily measured.
6. The scope for IMA to engage more proactively in innovative mechanisms like PPIA should be explored.
7. There should be appropriate and practical approaches to address the fear of the private health sector about losing their

clientele by engaging in RNTCP-related activities.

8. Appropriate mechanisms and tools must be established to ensure that feedback about patients received by RNTCP from private health sector is sent to the participating private health care providers.
9. In future occasions of funding by international donors, IMA should play the role of principal recipient of the grant to address the unnecessary bureaucratic delays in receiving the funds from the government as principal recipient.

5.7 Conclusion

Though RNTCP's efforts to engage the private health sector was initially offset by the opposition from the private health care, IMA's engagement facilitated the process and contributed to success in the establishment of partnership with private medical practitioners, increasing case notification and maintaining higher rates of treatment success. IMA acted as an interface for creating partnerships between RNTCP and private health sector in many successful PPM projects. The lessons learnt from the IMA-RNTCP projects should inform the policy decisions on further strengthening IMA-RNTCP collaborations. As donor funding is dwindling, RNTCP should consider increased investments in the private health sector using IMA as an interface with the private health sector. Professional associations like IMA should be engaged more in a strategic manner and involved in all the stages of decision making process. There is scope for further improvement in IMA-RNTCP collaboration through

refinement of the existing models as well as experimenting newer and innovative models. Every effort to increase TB case notification and maintain treatment success in India is a crucial step towards global efforts to ending TB epidemic by 2035.

CHAPTER 6*

Global Fund Financing of Public–Private Mix Approaches for Delivery of Tuberculosis Care

*Lal, S. S., Uplekar, M., Katz, I., Lonnroth, K., Komatsu, R., Yesudian Dias, H. M. & Atun, R. Global Fund financing of public-private mix approaches for delivery of tuberculosis care. Trop Med Int Health 16, 685-692, (2011).

6.1 Introduction

According to the 2009 Global Tuberculosis Control Report of the World Health Organization (WHO), the acceleration in tuberculosis (TB) case detection rate achieved over the last decade now seems to be stagnating at a little over 60%. The global target of detecting 70% sputum smear-positive TB cases was not reached in 2005 and is unlikely to be achieved by the end of 2010[102].

Globally, efforts to strengthen TB control have been concentrated largely within the public sector health services directly under the scope of National Tuberculosis Programmes (NTPs)[7]. In many countries, diverse care providers outside NTPs, which manage significant proportions of TB patients, are yet to be integrated into national TB control efforts. These comprise public sector care providers such as prison health services under ministries of interior, military health services under ministries of defence or social security organizations under the ministries of labour as well as for-profit and not-for profit private sector care providers that include private practitioners, private hospitals, corporate health services and voluntary organizations. In some countries, the private sector has outgrown the public sector in health care provision. TB management practices of many non-NTP care providers have been shown to be uneven and cases detected by them are rarely notified[102]. However, studies show that engaging all relevant care providers through public–private mix (PPM) approaches helps to effectively harnesses

available capacity in the country by NTPs to expand coverage, improve access to quality care and programme outcomes and reduce cost of care to patients[81,103].

PPM for TB care and control implies public–private collaboration for delivery of TB services. It is a comprehensive approach to systematically involve all relevant health care providers in TB control and achieve national and global TB control targets. International Standards for TB Care (ISTC) offers an excellent tool to help standardize TB management practices of diverse care providers. In practice, countries have used the label PPM to denote 'public–public mix' when the NTP collaborates with other public sector care providers who have not traditionally been part of their network, including certain public hospitals or special health services under ministries other than the ministry of health, such as prison health services; and 'public–private mix' when the collaboration is between the NTP and private, voluntary or corporate sector care.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) – a major source of funding for NTPs – is a public–private partnership (http://www.theglobalfund.org). It provides around 63% of all international financing for tuberculosis control globally; which between 2002 and 2009 amounted to US$ 3.2 billion of approved funds[102]. The Global Fund requires applicant countries to set up national level partnerships in the form of country coordination mechanism representing diverse stakeholders including

civil society and people living with diseases. It finances grant implementation by public and private sectors in countries through a dual-track financing facility. However, to date, no studies have explored the extent to which PPM activities are financed by the Global Fund. While a number of country case studies show that global mechanisms have helped national and local TB programmes to establish and scale up PPM initiatives, the global scale of these activities is not known[102]. Enormous untapped potential still remains in translating global and national level partnerships into large scale collaborations among providers for delivery of TB care at the grassroots. Realizing this potential is essential to meet and maintain TB control targets[7,134].

The purpose of this paper is to map the extent and the scope of PPM interventions in TB grants financed by the Global Fund. It is hoped that this will provide useful lessons for NTPs, international technical agencies and financiers of TB programmes globally.

6.2 Methods

Two levels of analyses were applied: reviewing the evolution of support to PPM for TB care and control in Global Fund-supported TB grants as reflected in its official documents and mapping the distribution and characteristics of PPM initiatives within the Global Fund-supported programs. We supplemented this analysis with relevant data from 14 countries reported to WHO for the Global TB control report of 2010.

The official documents of the Global Fund include guidelines on submission of requests for funding as well as the monitoring and evaluation tool-kit, which provide grant recipients with an inventory of indicators to measure outputs of their activities[135]. Applicants are required to submit a performance framework with the indicators and targets against which grant's results are later measured[136]. We reviewed all performance frameworks of all TB grants, and considered a grant to include a PPM activity if an indicator was classified as such within the performance framework or if any of the indicators measured provision of any TB service with or through a non-NTP entity such as the private sector, prison, municipality, faith-based organization, and nongovernmental organizations (NGOs). The analysis of the distribution and characteristics of PPM initiatives within the Global Fund-supported programs, included measurement of (i) proportion of TB grants with PPM, in total, over time and their regional distribution; (ii) distribution of PPM implementers, categorized into prison health services, for-profit private sector, NGOs, others and unspecified, including changes in their composition over time and regional distribution; and (iii) the investment in PPM approaches as part of the overall funding in the TB grants studied and their regional distribution. Financing data were obtained from the Global Fund's Enhanced Financial Reporting System (EFR) which tracks utilization of Global Fund investments by grant recipients. The EFR includes a category 'PPM*/*ISTC'. Grants reporting financial data under this category were used to estimate the

investment in PPM. The EFR data used in this study represented 80% of Global Fund TB investments disbursed by the end of 2008.

WHO publishes an annual report on global TB control. The purpose of the report is to provide an annual assessment of the global TB epidemic and the progress made in implementing the Stop TB Strategy. For the global TB report of 2010, countries were asked to provide the data on the number of cases reported by non-NTP providers in the public and private sectors in 2009. Data obtained from 14 countries – Angola, Cambodia, China, Ghana, India, Indonesia, Islamic Republic of Iran, Kazakhstan, Myanmar, Nepal, Nigeria, Pakistan, Philippines, and Tanzania – are presented here. All 14 countries had received Global Fund grants for scaling up PPM and 11 reported to be implementing PPM countrywide. It was not possible, however, to determine whether the outcomes of PPM interventions in terms of contributions of non-NTP care providers to TB case notification were attributable solely to the Global Fund grants.

6.3 Results

6.3.1 Scope for PPM in Global Fund official documents

The Global Fund guidelines for submitting funding proposals promote collaborations among all relevant health care providers within countries to deliver health care services. The Global Fund supports existing and new innovative programmes both within and outside the health sector that promote public, private and non-

governmental efforts. The Global Fund's Technical Review Panel also considers PPM as an important attribute when assessing the technical quality of a proposal. The Monitoring and Evaluation toolkit developed by the Global Fund together with various partners includes indicators specific to PPM (Box 1).

6.3.2 Distribution and characteristics of PPM initiatives

The number of countries with PPM activities within the active TB grants supported by the Global Fund increased from 13 in 2003, the first year of Global Fund disbursement for TB, to 58 in 2008. Figure 1 shows the incremental numbers of proposals with PPM components. The proportion of Global Fund grants with PPM activities was highest in Southeast Asia (82%) and lowest in Sub-Saharan Africa (52%) (Figure 2).

Box 1.

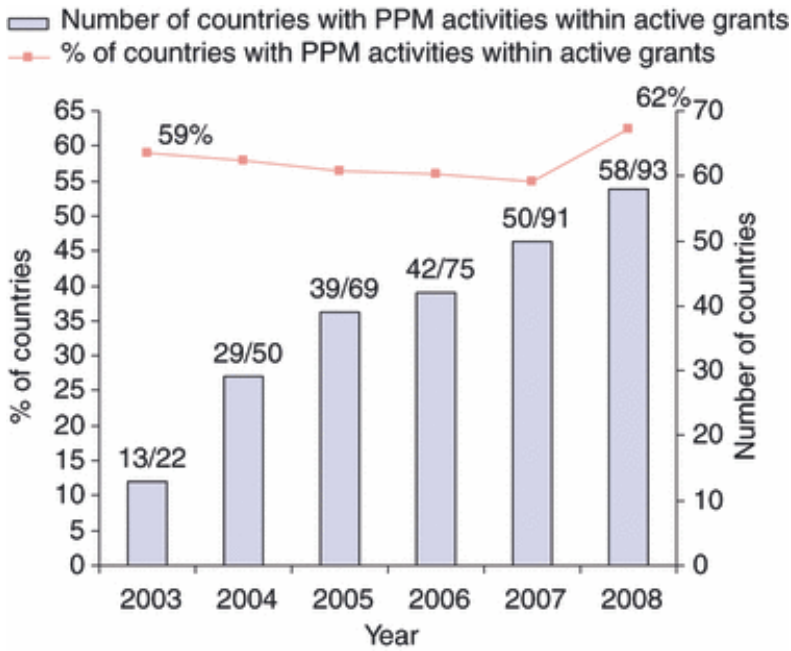
Examples of indicators for 'Engage all care providers' component of Stop-TB strategy included in the Global Fund monitoring and evaluation framework

1. Private and Public health providers (different types) collaborating with the NTP (number and percentage)
2. New smear positive TB patients referred by a specific type of health care provider among the new smear positive TB patients reported to the national health authority (started on treatment in NTP) (number and percentage)
3. New smear positive TB patients managed/supervised by a specific type of health care provider among all TB patients reported to the national health authority (number and percentage)
4. New smear positive TB patients successfully treated (cured plus completed treatment) among the new smear positive TB patients managed/ treated by a specific type of health care provider (number and percentage)
5. Private and Public health providers (different types) collaborating with the NTP (number and percentage)
6. New smear positive TB patients referred by a specific type of health care provider among the new smear positive TB patients reported to the national health authority (started on treatment in NTP) (number and percentage)
7. New smear positive TB patients managed/supervised by a specific type of health care provider among all TB patients reported to the national health authority (number and percentage)
8. New smear positive TB patients successfully treated (cured plus completed treatment) among the new smear positive TB patients managed/ treated by a specific type of health care provider (number and percentage)

Source: The Global Fund M&E Toolkit. Available at URL: http://www.theglobalfund.org/en/me/guidelines_tools/?lang=en#toolkit.

Figure 1.

Proportion and number of countries which received Global Fund support for PPM activities, by year



N, Number of countries with active TB grants that include PPM component and *D*, Number of countries with active TB grants.

Figure 2.

Number of countries with Global Fund support for PPM activities (proportion of the total number of active TB grants), by region and by year

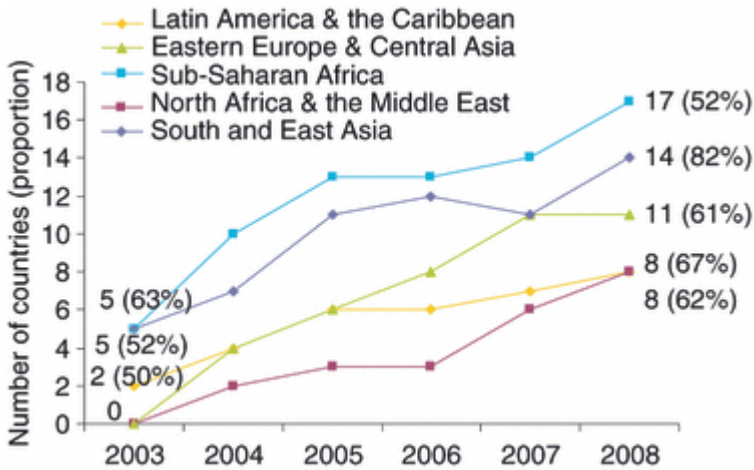


Figure 3.

Number of countries with Global Fund support for PPM activities (proportion of the total number of countries with Global Fund support for PPM activities), by implementer type and year

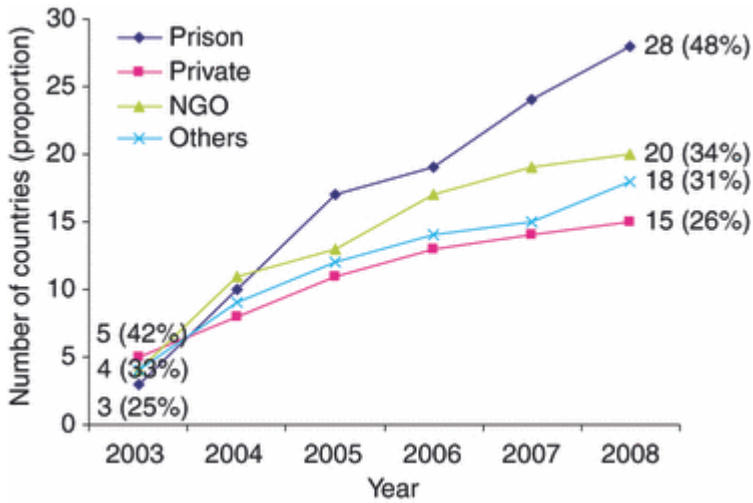


Figure 3 shows the types of care providers engaged in PPM. Between 2003 and 2008, while collaborations with NGOs and the for-profit private sector also increased, there was a sharp rise in NTPs engaging prison health services, predominantly in countries of Eastern Europe.

Care providers involved in PPM varied by region (Table 1). Collaboration with the for-profit private sector was greater in South Asia and East Africa while collaboration with NGOs was common in North Africa, the Middle East and South Asia. Links with prison health services were present in other regions including Eastern Europe and Central Asia, Latin America and the Caribbean as well as West and Central Africa.

6.3.3 Finances allocated to PPM activities in TB Grants supported by the Global Fund

Analysis of budget and expenditure data showed that by 2008, US$ 38.3 million (4.4%) of TB funding in the budgets of Global Fund-supported grants was allocated to PPM. The expenditure for PPM activities as a proportion of total expenditure in TB grants amounted to 5.4%, higher than that initially budgeted; 99% of the funding budgeted for PPM activities was utilized, compared to 80% for the TB budget for all activities.

Table 1.

Distribution of PPM implementers within countries with Global Fund support for PPM as of end 2008, by region

Region (*N*)	Percentage of countries with Global Fund-supported PPM				
	NGOs	Prisons	Private sector	Other	Not specified
East Asia and the Pacific (8)	38	38	25	38	0
Eastern Europe and Central Asia (11)	36	91	18	27	9
Latin America and the Caribbean (8)	25	63	0	50	0
North Africa and the Middle East (8)	63	25	38	25	13
South Asia (6)	50	17	67	17	50
East Africa (5)	0	40	40	0	20
Southern Africa (4)	25	0	0	50	50
West and Central Africa (8)	25	63	25	38	13
All regions (58)	34	48	26	31	16

N, Number of countries with Global Fund support for PPM activities, per region; Green cells – the regions with the highest proportion of countries with the specific PPM implementer.

The median amount budgeted in Global Fund grants for PPM activities was 5% of total. However, this amount ranged from 0.03%

to 69% of total, with Kyrgyzstan and Swaziland allocating over 50% of their funding to PPM. In most proposals this does not include cost of drugs and other consumables for the diagnosis and treatment of TB in the targeted health facilities, which falls under other budget headings.

Table 2.

Budgets and expenditures on PPM and ISTC by region

Region (*N*)	Budget (US$, 000s)	Percentage of Regional TB budget allocated to PPM activities	Expenditure (US$, 000s)	Percentage of Regional TB expenditure budget allocated to PPM activities
East Africa	388	0.4	366	0.4
East Africa and the Pacific	25 684	10.4	26 200	12.8
Eastern Europe and Central Asia	3 295	1.9	3 737	2.7
Latin America and the Caribbean	332	0.4	443	0.6
Northern Africa and the Middle East	336	0.4	165	0.3
South and West Asia	2 343	4.0	1 683	3.7
Southern Africa	1 338	2.0	1 194	2.8
West and Central Africa	4 598	6.9	3 988	6.8
Entire Portfolio	38 314	4.4	37 776	5.4

For PPM activities, the investments in China, Indonesia and Ghana were $US 18.8 million, $US6.1 million and $US3.5 million, respectively. The top two regions with highest share of their budget allocated to PPM were East Asia and the Pacific and, West & Central Africa (10.4% [US$ 25.7 million] and 6.9% [US$ 4.6 million] respectively). While the share of the TB budget allocated to PPM in Eastern Europe & Central Asia, and Latin America & the Caribbean is lower than in other regions, both regions have many grants for collaboration with prison health services, which are not always reported as a part of PPM. The expenditure data are based on a budget-line that relates to PPM and ISTC yet excludes some grants which did not report on their expenditure.

6.3.4 Country data

The mix of health care providers and health seeking behaviour of TB patients varies by setting. In China, hospitals are often the first point of care[137]. In rural areas of Bangladesh[138] and Cambodia[139], semi-formal 'village doctors' are the first level care providers. In India and Kenya, private practitioners are the first port of call for many patients with symptoms of TB[101].

Data compiled from 14 countries (including nine high burden countries) and published in the Global TB Report of 2010[140] demonstrated the important contribution of PPM to case notifications, between a quarter and a third of all cases in five countries (Table 3). Expectedly, there has been considerable variation in PPM approaches

and the provider groups targeted. This includes collaboration with pharmacies in Cambodia, private hospitals in Nigeria, public hospitals in China and Indonesia, and prison services in Kazakhstan.

6.4 Discussion

Evidence points to growth globally in the number and size of non-public sector health care providers in TB control, with a significant proportion of TB patients managed by them, albeit often with poor quality of care. But proactive engagement of them can yield substantial benefits for TB control. There is also a growing body of evidence, over the past decade, which indicates that in some countries PPM has helped improve programme performance by increasing case detection by 10% to 60% while maintaining the treatment success rates above 85%[141]. Importantly, in some settings, for-profit private providers engaged through PPM have been able to improve their treatment success rates from levels that are often below 50% to above the global target of 85[103].

Table 3 Contribution of PPM to TB case notification in selected countries (Reference WHO, 2010)

Country	Types of non-NTP care providers engaged	Coverage	Number of cases notified per year[1]	Contribution to total notifications (%)
Angola	Diverse public and private providers	Countrywide	4 591	12
Cambodia	Pharmacies, private clinics and hospitals	Countrywide	6 550	17
China	General public hospitals	Countrywide	337 286	37
Ghana	Diverse public and private providers	Countrywide	2 124	15%
India	Diverse public, private and NGO providers	14 large cities (50 million population)	12 450	36 of new smear-positive cases
Indonesia	Public and private hospitals	Countrywide	38 362	13
Islamic Republic of Iran	Diverse public and private providers	Countrywide	2 514	25
Kazakhstan	Prison health services	Countrywide	1 515	8
Myanmar	Private practitioners through the professional medical association	26 townships (6.4 million population)	8 526 (2008)	21
Nepal	Diverse public and private providers	Countrywide	2 519	8
Nigeria	Private clinics and hospitals	Countrywide	29 418	34
Pakistan	Private practitioners, NGOs and hospitals	Countrywide	43 162	14
Philippines	Private clinics and hospitals	30 million population	3 994	28% of new smear-positive cases
Tanzania	Private and NGO hospitals	Countrywide	11 492	19%

[1]Data for 2009 except where specified.

The importance and the scope of PPM are not often reflected at a level commensurate with the evidence, in the TB proposals and budgets submitted by countries. More than a third of the countries with active TB grants do not have PPM as a component. While the number of countries with active TB grants has increased from 22 in 2003, to 93 in 2008, the proportion of countries with PPM has not increased in this period despite additional Global Fund support for PPM. Of particular concern is the relatively low proportion of countries in sub-Saharan Africa with PPM supported by the Global Fund. We further observed a relatively low engagement of both NGO and private health sectors, which are key for PPM expansion.

There are also concerns regarding the nature of PPM and the way in which countries plan for PPM. Judging upon the PPM-related indicators used by countries on which Global Fund-supported programs report, many focus merely on training of providers, without a clear strategy on how to establish effective and sustainable collaboration. Proposals submitted to the Global Fund often lack explicit mention of what enablers and incentives (financial or non-financial) will be used for private sector engagement, such as supply of anti-TB drugs free of charge to private practitioners on the condition that they follow DOTS principles for diagnosis and case management[141]. Larger health care institutions taking on more complex roles in TB control will normally require financial compensation mechanisms, such as contracting on a capitation or fee-for-service basis. These aspects are rarely highlighted in proposals.

Similarly, the support structures for PPM, such as continuous supervision, monitoring and evaluation, are often inadequately described. Finally, in the reports submitted to the Global Fund there is often little information on the proportion of non-public health care providers involved and the percentage contribution by different providers[136,142]. All this will require more ambitious and better designed PPM plans to expand the engagement of non-public sector institutions in TB control to scale up services and improve outcomes.

There is useful guidance available to countries on PPM, including a tool to undertake a national situation assessment to decide on the need and scope of PPM in a country[143] (used successfully by at least a dozen countries), a PPM guidance document and a PPM toolkit that advises on different steps of implementing PPM in phases, and also steps to engage different types of providers[101]. These documents also include a planning framework for PPM in Global Fund applications; this framework is further elaborated in the Stop TB Planning Matrix and Framework for Global Fund TB proposal preparation[144]. The Global Fund currently does not have specific guidance on PPM, however, clearer guidance in the future would enable greater uptake of PPM.

The current median budget allocation for PPM activities of 5% is probably sufficient for limited engagement however the scaling up of PPM initiatives, especially those involving financial incentives requires more investment. In addition, a significant portion of the

budget has been allocated to training activities. The Global Fund recommends that countries follow the Stop TB Strategy and the larger tranches of funding for TB approved in R8 and R9 should further contribute to PPM activities.

The study could have underestimated the PPM within TB grants supported by the Global Fund, as there are limited data on sub-recipients of Global Fund grants including activities implemented by NGOs and the private or corporate sector, many of which are of PPM nature. Further limitation is the categorization of PPM types. Global Fund data highlights the recent expansion of PPM to prisons, and has ample examples for PPM in NGOs and the private sector, but none in public health facilities that are not part of the NTP, due to the difficulty in identifying such facilities within grant indicators. A further problem is the categorization of an activity under PPM. For example, in many grants, DOTS implementation in prisons was not classified as PPM. This partially explains the relatively low share of the TB budget allocated to PPM in Eastern Europe & Central Asia and Latin America & the Caribbean. Finally, the Global Fund is not the only financier of PPM activities and there is a lack of sufficient information to estimate the contribution from other funding agencies. All these limitations require further in-depth case studies.

Wide implementation of PPM requires good collaboration between the public and other health sectors. Innovative mechanisms appropriate to the nature of the settings such as certification of

provider and financial incentives should be put in place to ensure such cooperation. There are good examples from countries like India, where NTP tries to encourage and formalize PPM though initiatives that develop guidance documents to facilitate PPM partners to formally engage in PPM activities. We need robust case studies to illustrate further examples of good practice that has resulted in improved outcomes. Mechanisms aimed at providing appropriate incentives and providing online reporting tools to establish and sustain such collaborations are to be considered based on the relevance in specific settings.

PPM is cost-effective in diverse country settings[79,81,145,146]. A deeper analysis of PPM components of Global Fund country proposals and of the performance related to PPM could be of immense benefit not only to countries themselves but also to the technical and financial agencies supporting them. South-South learning opportunities should be encouraged, and lessons learned from country cases more carefully harnessed and disseminated. Clearly, significant untapped potential still exists in scaling up PPM across countries, particularly in light of the increase in TB funding in recent years.

CHAPTER 7*

Global Fund Financing of Tuberculosis Services Delivery in Prisons

*Lee, D., Lal, S. S., Komatsu, R., Zumla, A. & Atun, R. Global fund financing of tuberculosis services delivery in prisons. J Infect Dis 205 Suppl 2, S274-283, (2012).

7.1 Introduction

In the last 2 decades there have been concerted global efforts to scale up tuberculosis control. Efforts began with the introduction of the directly observed treatment, short-course (DOTS) strategy in the early 1990s, followed by the World Health Organization (WHO) Stop TB Strategy 2006, and in 2010 the Global Plan to Stop TB 2011–2015. These efforts have coincided with large amounts of new external financing, predominantly from the Global Fund to Fight AIDS, Tuberculosis and Malaria. However, despite these efforts and increased external financing, in 2009 there were >9 million new tuberculosis cases[140]. Although just over half of the 22 countries with a high burden of tuberculosis were on track to achieving the Millennium Development Goal 6 of halting and reversing tuberculosis incidence by 2015, less than half were on target to halving tuberculosis deaths by the same year[140]. Multidrug-resistant (MDR) tuberculosis poses a major threat for all countries, yet case notification was 30 000 globally in 2009, just over one-tenth of global estimates[140].

Although the Global Plan to Stop TB 2011–2015[134]calls for early detection and treatment of all tuberculosis cases and intensifying screening for the most-at-risk populations, including people in confinement, tuberculosis continues to be a social issue affecting the world's most marginalized and disadvantaged communities. Prisoners are an especially vulnerable population, with increased risk

of ill health, high levels of mental disorders, risk of self-harm, and high rates of infectious diseases such as tuberculosis and human immunodeficiency virus (HIV)[147]. Prisoners often come from the lowest socioeconomic groups in societies and, in many cases, from minority or migrant groups, all of which are marginalized groups that have a higher incidence of tuberculosis and MDR tuberculosis compared with the general population[148].

7.2 Tuberculosis in prisons

The latest available estimates suggest that as many as 10 million people worldwide are held in penal institutions. This prison population is expected to increase in the near future. Compared with estimates from 2007, by 2009 prison populations had increased in 71% of all countries, by 64% in African countries, by 76% in Asia, and by 68% in Europe[149]. Among this prison population, tuberculosis is a major cause of illness and death[150]. Globally, there is limited reliable information on the prevalence and incidence of tuberculosis within correctional facilities such as prisons and other types of detention centers. Furthermore, the contribution of tuberculosis rates in prisons to the transmission rates of new *Mycobacterium tuberculosis* infections in the general population is unclear[151,152]. However, available estimates suggest that tuberculosis prevalence rates within penitentiary settings are between 5 and 50 times higher than the rates observed in the general population[153].

In countries with a high prevalence of tuberculosis, the annual case notification rate of all forms of tuberculosis in prisons can be as high

as 7200 per 100 000 population[154]. In the countries of the former Soviet Union, prisons and other correction facilities, such as pre-detention centers, have some of the highest MDR tuberculosis rates reported globally. For example, the percentage of MDR tuberculosis in prison populations, as revealed by studies in Russia, has ranged from 12% to 55% in previously treated patients[155,156]. African countries such as Zambia and Botswana have drug-sensitive tuberculosis rates that are close to 4000 per 100 000 prison population[157], and in Tanzania up to 41% of prisoners had active tuberculosis[158]. In the context of Africa and the former Soviet Union, these very high rates of tuberculosis are particularly alarming given the potential for comorbidities of tuberculosis and HIV, the high HIV prevalence in sub-Saharan African countries[159-162], and high HIV levels in the injection drug user population in the countries of the former Soviet Union - a marginalized group that has disproportionately high levels of incarceration[150].

7.3 Prisons as breeding grounds for tuberculosis

The physical environment found in penitentiary settings provides an ideal breeding ground for tuberculosis. Overcrowding, inadequate ventilation, and lack of quarantine facilities all encourage efficient transmission of tuberculosis[150], and the lack of importance accorded to prisoners' health often results in inadequate financial and human resources to provide health services for treatment and prevention of infectious diseases. This is further exacerbated by factors that increase the risk of tuberculosis, including poor nutrition[163], personal

hygiene, drug addiction, and high-risk behaviors and practices, such as needle sharing and unsafe sex[154,164]. The structural environment under which prisons are managed and operated also creates challenges to tuberculosis prevention, control, treatment, and care, including the low priority placed on funding for healthcare services for prisoners, lack of control measures, lack of proper training in standard tuberculosis treatment and care practices, and lack of testing facilities and/or quarantine services for isolation[164]. There are often no linkages between the ministries of health that manage national tuberculosis programs (NTPs) and the ministries of interior or justice that manage prisons and the penal systems. As a result, prison settings often have both poor case and program management, as reflected by the high rates of drug-resistant tuberculosis and comorbidities such as HIV/AIDS/tuberculosis in prison settings[153].

The Stop TB Strategy envisions involvement of all public, voluntary, corporate, and private healthcare providers through public–private mix (PPM) DOTS approaches[165]. The strategy expands and enhances the basic components of DOTS and includes tuberculosis control strategies to effectively cater to marginalized populations such as prisoners. Expansion of DOTS services to prisons helps strengthen active case-finding activities among prisoners. The Global Plan to Stop TB 2011–2015 targets a case detection rate of 84% (for all cases and smear-positive cases specifically) and treatment of about 1 million confirmed MDR tuberculosis cases according to international guidelines by 2015. The Global Plan also pays special attention to the

protection of populations vulnerable to tuberculosis and drug-resistant tuberculosis to achieve its goals Drobniewski.

Despite the efforts spearheaded by WHO and supported by many international technical agencies and donors to expand PPM DOTS approaches, these novel approaches have had very limited uptake globally, with substantial variation across regions. Between 2003 and 2010, there was a sharp rise in NTPs engaging in prison health services, predominantly in Eastern European countries. Links with prison health services are increasingly evident in regions of Eastern Europe and Central Asia (EECA), Latin America and the Caribbean (LAC), and West and Central Africa (WCA)[166].

7.4 Neglect of tuberculosis prison health services

Prisons, considered to be a major stakeholder in the PPM DOTS concept, are not yet covered by the general public health services in many countries, especially when there is a separate healthcare system for the penal sector. Consequently, services under the NTPs, which are normally managed under the auspices of the public health services, do not cover prisons. This creates parallel systems for tuberculosis case management in prisons. Wherever the penitentiary sector is not covered by an NTP, there is a high likelihood of nonstandard diagnosis and care for tuberculosis patients. Even in settings where an NTP has established linkages with the penitentiary sector, tuberculosis patients may receive care, as defined by international guidelines, only during the period of confinement.

Those released from prisons when still under treatment for tuberculosis are more likely to discontinue treatment due to lack of follow-up once in the community. In many settings, mechanisms to follow up on such patients by placing them in another basic management unit of an NTP through ‘‘transfer out,’’ as envisaged in the DOTS strategy, may be difficult to organize owing to poor working relationships between prison authorities and community health providers[167].

7.5 Financing of tuberculosis services in prisons

Financing the diagnosis, treatment, and care for tuberculosis patients in penitentiary systems is an additional problem that needs to be addressed. Of the $47 billion needed for implementation of the Global Plan 2011–2015, the cost of DOTS implementation is $22.6 billion and the cost for interventions to manage drug-resistant tuberculosis is $7.1 billion. Although acknowledged as an important problem in global tuberculosis control, there are no estimates of the funding requirements for effective control of tuberculosis in prison settings. Similarly, to date, no studies have estimated the financing needed for tuberculosis control activities in prisons. Despite the evidence of higher rates of tuberculosis in prisons and the potential public health implications for the general population, available information indicates that the funding for tuberculosis control activities in prisons is disproportionately low[166].

The Global Fund, which has emerged as the largest international financier of tuberculosis control globally, is estimated to have

provided more than four-fifths of all external finances for tuberculosis in 2011. The financing went to support low- and middle-income countries with treatment; care and support; and advocacy, communication, and social mobilization interventions, including management of marginalized groups. By 2010, approximately $2 billion was invested for tuberculosis control in low- and middle-income countries[168]. The Global Fund's Framework document[169] underpins the principles that guide its operations. This document emphasizes country ownership in the allocation of Global Fund investments for programs to provide additional funding to support AIDS, tuberculosis, and malaria programs in order to reach the populations with the greatest need for treatment, care, and prevention services. Table 1 provides a brief summary of the Global Fund funding processes for country grant applications.

The Global Fund is also a major investor in tuberculosis control in prisons[166], although the extent and distribution of this investment has not been previously quantified. Therefore, we conducted a study to explore investments by the Global Fund for tuberculosis control in prisons and the services delivered for prisoners through Global Fund–financed grants between 2003 and 2010.

7.6 Search strategy, methods, and analysis

The Global Fund grants database, with an aggregate approved investment of $21.7 billion in 150 countries, was reviewed. We identified and analyzed 230 tuberculosis and HIV/tuberculosis grants

for which a grant agreement had been signed with the recipient country. We reviewed in the performance frameworks of 230 tuberculosis grants which had activities benefiting prisoners all grant output indicators (n 5 4031). We determined that a grant supported such an activity if the indicator referred to a target population as ‘‘prisoners’’ or ‘‘incarcerated population’’ or if the service was delivered in a prison setting. Our search included prison population–specific tuberculosis detection and treatment; care and support; screening and monitoring; and advocacy, communication, and social mobilization. It also included activities aimed at strengthening policy and the structural environment in order to facilitate better tuberculosis programs within prisons, for example, activities related to capacity strengthening of prison health staff to deliver and manage tuberculosis programs. Two multicountry grants in the Global Fund's East Asia and Pacific region were excluded because there was limited information based on the performance frameworks regarding the geographic locations of the services delivered through the programs supported by these grants. We also limited the scope of this exercise by excluding HIV grants, which would have delivered activities such as harm reduction for prisoners.

We mapped the extent of tuberculosis services provided by Global Fund–supported programs in prison settings by examining the trend and evolution of tuberculosis prison support by region from 2002 to 2010, the distribution of such activities by status of high tuberculosis and MDR tuberculosis burden[140], and the regional median prison

population rate per 100 000 national population by Global Fund region. In our mapping exercise, we used the country-level prison population rates for December 2008 obtained from the International Centre for Prison Studies[149] and excluded countries and territories not financed by the Global Fund–supported tuberculosis programs and those not eligible for funding due to high income status.

We also mapped services delivered by type of principal recipients, which include primary contract holders with the Global Fund that implement programs financed by the Global Fund. This was done to understand the extent of public–private partnership in tuberculosis program delivery in each setting and the nature of the various services provided to gain an overview of the comprehensiveness of an overall package of services delivered for tuberculosis care in prisons. Also, we analyzed the performance of tuberculosis grants that include tuberculosis services and those that do not include these services by comparing performance at grant and indicator levels. The Global Fund funds grants in 2 phases: phase 1, comprising 2 years of funding, and phase 2, comprising 3 years of funding. Grants are assessed for performance at the end of phase 1 to determine the amount of funding that will be provided in phase 2.

Grant performance is rated at 4 levels of performance: A1, B1, B2, and C, where A1 is the highest level and C is unacceptable. We compared the percentages of well-performing (A/B1) and poorly performing (B2/C) grants that included a tuberculosis service delivery component in prisons with those that did not.

Table 1. Summary of Global Fund Processes for Grants

Proposals are submitted by eligible countries, reviewed for soundness by the independent technical review panel, and recommended for approval by the Global Fund Board.
Potential principal recipients are nominated by the country coordinating mechanisms and assessed for implementation capacities, including financial and program management, monitoring, and evaluation, by the local fund agent, which is contracted by the Global Fund in each country. Weaknesses and gaps are identified and addressed before grants begin operation.
The local fund agent also provides grant oversight during the grant's life cycle.
For routine data reporting to the Global Fund, countries are encouraged to adopt a set of core output indicators that are agreed upon and defined in conjunction with international partners in the Monitoring and Evaluation Toolkit,[170] available at www.theglobalfund.org.
For each grant, countries select a set of indicators, with targets and reporting periods negotiated and agreed upon between the principal recipients and Global Fund in grant performance frameworks.
For disbursement requests, principal recipients are required to submit progress updates on results achieved for indicators in performance frameworks; this is usually done quarterly or semiannually.
Prior to submission to the Global Fund Secretariat, reports are verified by the local fund agent for content and accuracy.
Data verification processes include onsite data verifications on selected programmatic indicators and data quality audits on selected grant samples.

7.7 Results

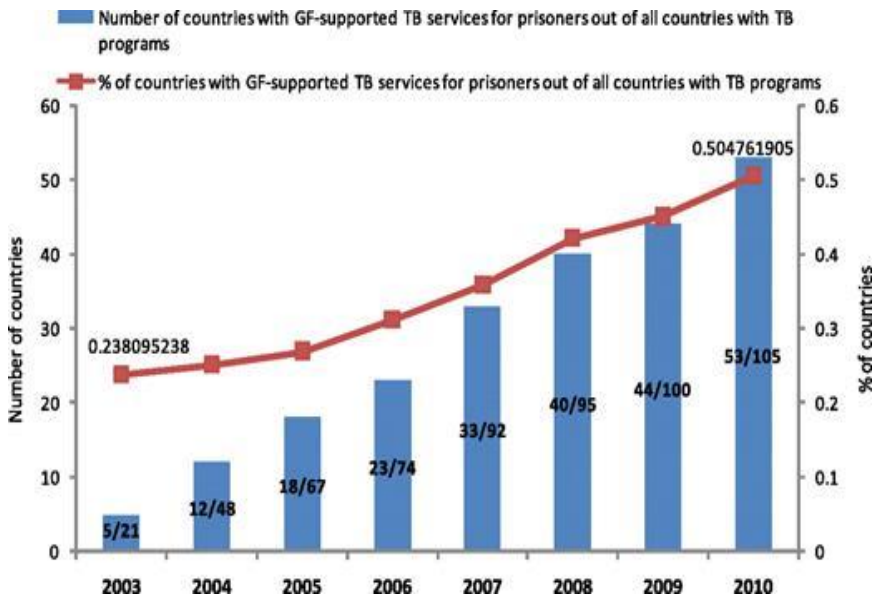
By December 2010, 53 of the 105 countries (50%) with Global Fund–supported tuberculosis programs delivered services within prison settings. The funding allocated to tuberculosis grants, which included tuberculosis service delivery in prison settings, consisted of $558 million, accounting for almost 28% of the $2 billion invested in all tuberculosis programs benefiting from Global Fund support. Of the $558 million disbursed for grants that included tuberculosis service delivery in prisons, $304 million (54%) went to nongovernmental principal recipients from civil society organizations, the private sector, and development partners. Based on reported expenditures from principal recipients by the end of 2010, an estimated $56 million was spent on PPM approaches (10% of $558 million), which would have included various services delivered in prison settings. However, no systematically captured data were available that would enable quantification of direct funding allocated in tuberculosis care and delivery within penitentiary settings.

Figure 1 shows the number and proportion of countries/territories that included tuberculosis service delivery in prison settings, by year. In terms of overall global support in these countries, there was a steady increase between 2003 and 2010, as the number of countries implementing tuberculosis service delivery in prison settings increased from 5 countries in 2003 to 53 by 2010. This increase was in tandem with the rise in overall number of countries receiving

Global Fund financing for all tuberculosis program support, which rose from 21 countries in 2003 to 105 countries by 2010.

Figure 1.

Number and proportion of countries/territories that included tuberculosis service delivery in prison settings, by year

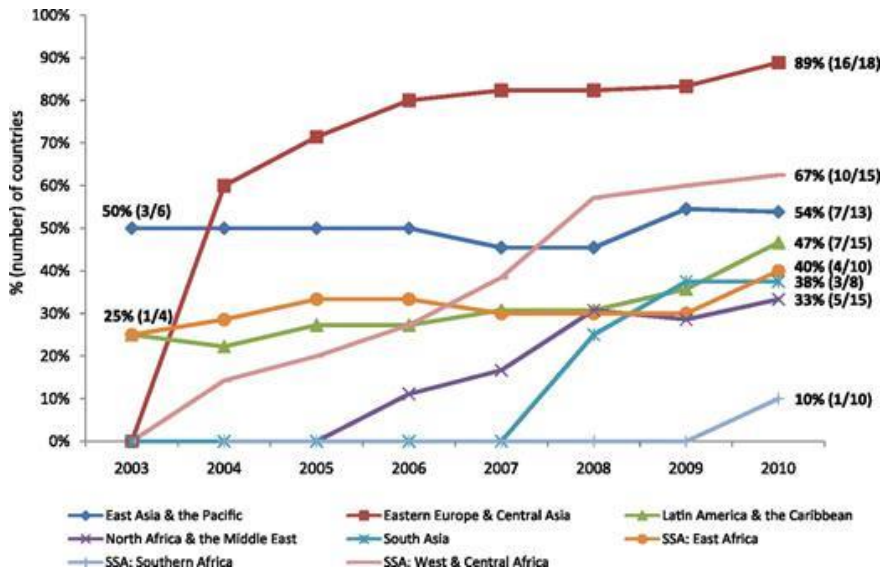


(Number of countries/territories with tuberculosis service delivery within prison settings number of all countries/territories with tuberculosis service delivery supported by the Global Fund).

Figure 2 shows that there is great regional variation in tuberculosis services delivered. Nearly 90% of all countries and territories (16 of 18) in the EECA region with tuberculosis grants included tuberculosis activities for prisoners. Approximately two-thirds (10 of 15) of countries in the WCA region with Global Fund–supported tuberculosis programs included tuberculosis services for prison populations. Between 2003 and 2010 in the WCA region and the Middle East and North Africa region, the number of tuberculosis grants providing tuberculosis services to prison populations substantially increased. This contrasts with the other 2 African regions of East Africa and Southern Africa, where many countries have high and rising HIV-tuberculosis coinfection rates and have few countries delivering Global Fund–financed tuberculosis services in prisons, with only 1 (Swaziland) of 10 countries in the Southern Africa region and 4 of 10 countries in the East Africa region providing such services.

Figure 2.

Number and proportion of countries that included tuberculosis service delivery in prison settings, by region and year

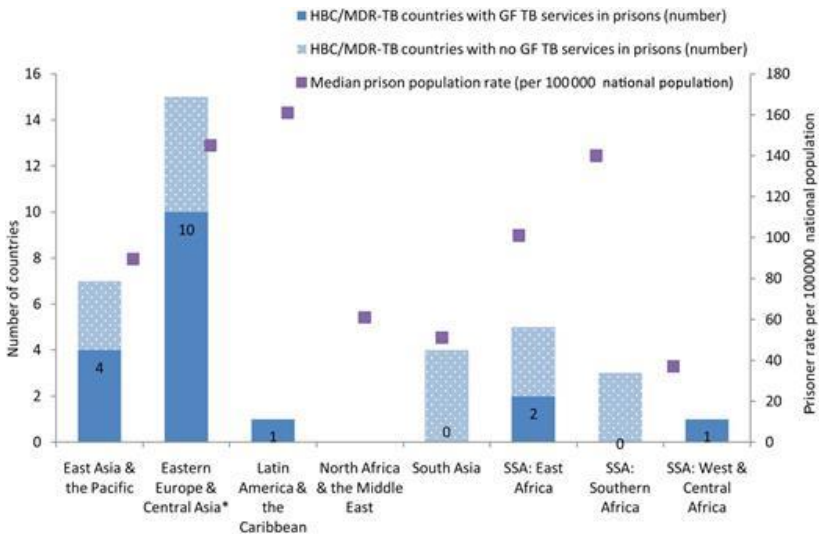


(Number of countries/territories with tuberculosis service delivery within prison settings/number of all countries or territories with tuberculosis service delivery supported by the Global Fund)

Figure 3 shows the distribution of tuberculosis service delivery in prisons in the WHO 22 high tuberculosis burden countries and the WHO 27 high MDR tuberculosis burden countries.

Figure 3.

Distribution of tuberculosis service delivery in prison settings by region and status of tuberculosis burden (High tuberculosis burden [HBC] or high multidrug-resistant [MDR] tuberculosis burden).



*The Eastern Europe and Central Asia region includes the high MDR tuberculosis burden countries Estonia, Latvia, and Lithuania, which are not eligible for Global Fund support.

Global Fund–supported tuberculosis programs were delivering services in prison settings in 18 of the 36 (50%) countries with either high tuberculosis or high MDR tuberculosis burden or both. The EECA region had the greatest number of tuberculosis/MDR tuberculosis burden countries receiving Global Fund–supported tuberculosis services in prison settings (n 5 10). Although the EECA region had the highest number of MDR tuberculosis countries worldwide and the second highest median prison population rate (145 per 100 000 national population), 5 countries in the region did not deliver tuberculosis services within prisons through Global Fund–supported programs. Of these 5 countries, 3 are ineligible to receive Global Fund financing due to their income status (Estonia, Latvia, and Lithuania).

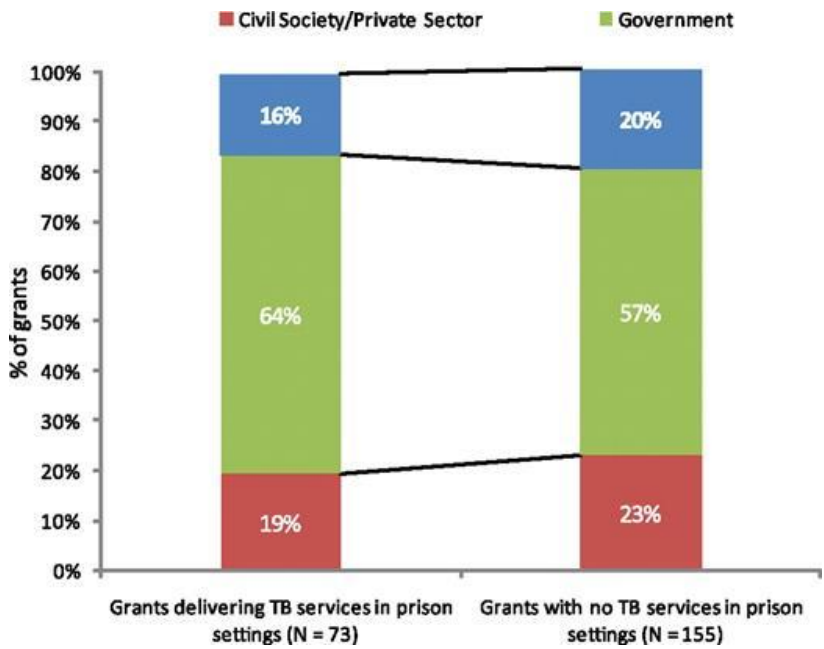
In the Southwest Asia region, 4 countries have both high tuberculosis and high MDR tuberculosis status, namely, India, Afghanistan, Bangladesh, and Pakistan. None of these high tuberculosis/MDR tuberculosis countries were implementing Global Fund–supported tuberculosis services in prisons. Similarly, in the Southern Africa region, not a single high-burden country (Mozambique, South Africa, and Zimbabwe) was providing any tuberculosis service in prisons, although this region has the third highest median rate for incarcerated population (140 per 100 000), as well as a high prevalence of HIV/AIDS and tuberculosis comorbidities. The East Africa region of Ethiopia, Kenya, and Tanzania had considerably higher prison populations both in terms of rates per 100 000 national population

and absolute total prison population compared with countries such as the Democratic Republic of Congo (DRC), Madagascar, and Uganda. These countries were providing tuberculosis care for prisoners using Global Fund finances. By contrast, DRC, Madagascar, and Uganda had programs providing tuberculosis services for prisoners through Global Fund–supported programs. Also of note is the WCA region, where 9 countries were delivering tuberculosis prison services through Global Fund–supported programs, although the region has 1 high-burden country (Nigeria) and the lowest median prison population rate (37 per 100 000) compared with the other 7 Global Fund regions.

Figure 4 depicts the comparison of service delivery by principal recipient types between tuberculosis grants delivering tuberculosis care in prison settings and grants without such delivery. Of the 228 grants examined, 73 (32%) delivered interventions in prison settings, while 155 did not specify similar services in their performance frameworks. A higher proportion of grants (146 of 228; 64%) delivering tuberculosis services in prisons were managed and implemented by governmental principal recipients (eg, ministries of health) compared with 130 of 228 (57%) grants with no mention of tuberculosis services provided for prisoners. However, this difference is not statistically significant (P>.05), with more than one-third of grants providing tuberculosis care in prison implemented by civil society, the private sector, and development partners.

Figure 4.

Comparison of service delivery by principal recipient type between tuberculosis grants delivering tuberculosis care in prison settings and grants without such delivery.



We examined the nature and types of services delivered to the incarcerated populations to ascertain the extent and scope of the package of services delivered as tuberculosis care in prisons in 6 areas: (1) tuberculosis detection and treatment, including diagnosis and treatment of smear-positive tuberculosis cases; (2) screening and monitoring, that is, screening of tuberculosis by chest radiograph, tuberculin skin test, etc, and monitoring, such as drug susceptibility testing, smear conversion, and treatment default; (3) advocacy and communication; (4) care and support, such as the provision of good nutrition, incentives, or enablers and psychosocial support to facilitate adherence; (5) treatment for MDR tuberculosis due to higher rates of MDR tuberculosis found within confined settings; and (6) strengthening of prison tuberculosis service delivery, such as monitoring policy and structural aspects of tuberculosis control to ensure an enabling environment conducive to effective service delivery in prisons (eg, prisons with tuberculosis control programs, prisons equipped with quarantine and isolation facilities, training of prison staff in tuberculosis referral and care, and doctors trained in infection control in prison settings).

Figure 5 shows the distribution of tuberculosis services delivered in prisons through Global Fund–supported grants. Nearly half (36 of 73; 49%) of the 73 grants delivering tuberculosis services in prisons focused on the provision of diagnosis and treatment of tuberculosis cases, while 27% (20 of 73) provided screening and monitoring services. More than half of the grants financed activities aimed at

strengthening tuberculosis service delivery capacity and providing an environment that could facilitate better program management and delivery within a penitentiary setting. By contrast, only 7% of grants (5 of 73) delivered MDR tuberculosis services in prisons, where drug-resistant tuberculosis is a major issue, especially among those who are confined. Similarly, in terms of the different types of services offered, the majority (50 of 73; 69%) of grants supported by the Global Fund offered only 1 type of service, with less than one-fifth delivering 2 types of services.

Figure 6 depicts the distribution of the different tuberculosis services delivered in prisons through Global Fund–supported grants, by region. There were regional differences in the extent of services delivered. Although countries outside the EECA region had predominantly 1 type of service delivered, countries within the EECA region had, by comparison, the highest number of services delivered, ranging from 2 to 3 areas of service.

Figure 5.

Comparison of services delivered in prisons through Global Fund–supported grants. ACSM, advocacy, communication, and social mobilization activities; MDR, multidrug-resistant.

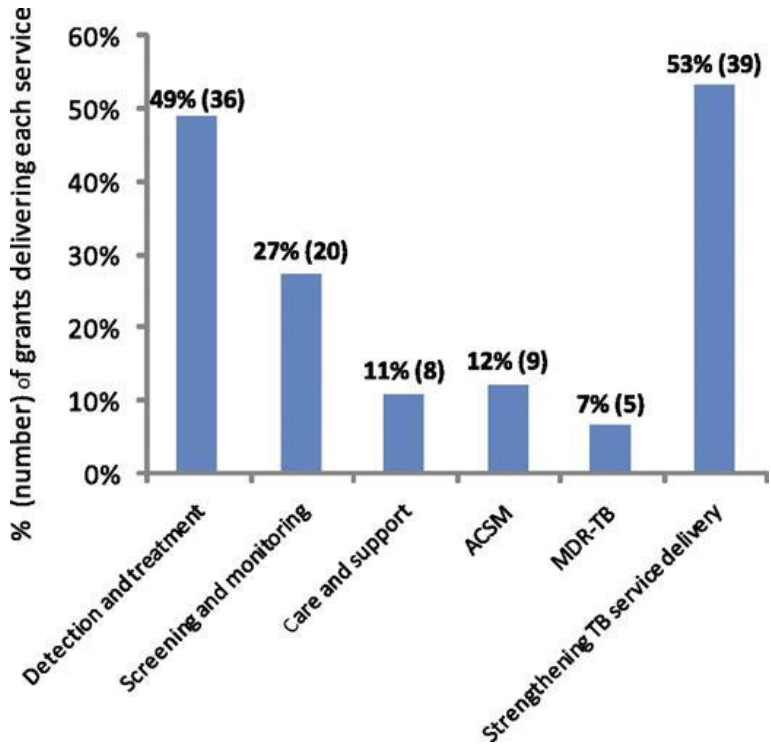


Figure 6.

Distribution of number of different tuberculosis services delivered in prisons through Global Fund–supported grants, by region.

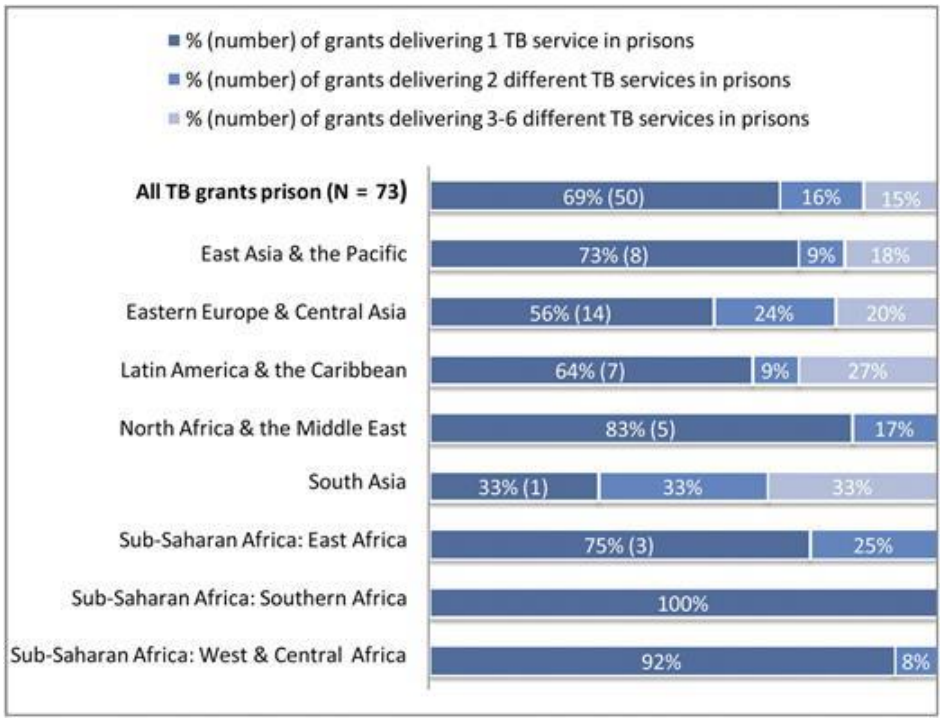
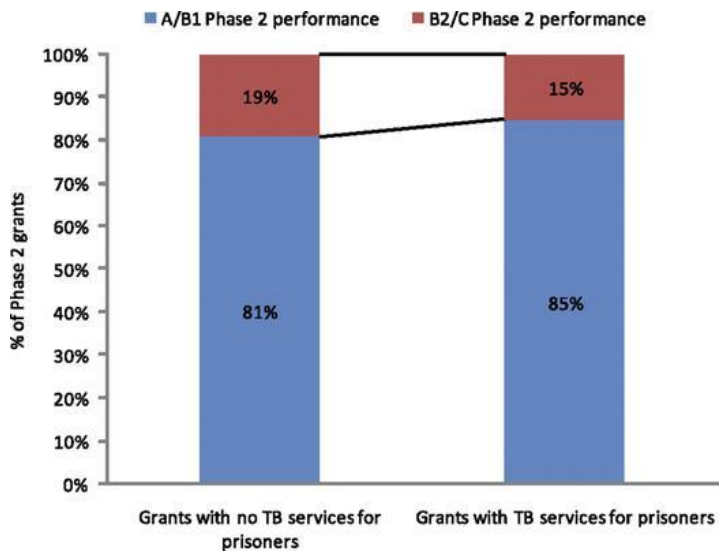


Figure 7 compares the performance of grants with tuberculosis service delivery in prisons. It shows that those with service delivery performed better compared with those without service delivery (P >.05). Comparison of performance of the tuberculosis grants shows that grants with tuberculosis service delivery in prisons had a slightly higher percentage of grants in the A/B1 category (85%) compared with grants without prison services (81%), although this difference is not statistically significant.

Figure7.

Grants with tuberculosis service delivery in prisons perform equally well as those without (*P* >.05).



7.8 Discussion

Tuberculosis morbidity and mortality among populations incarcerated in penal institutions are often many times higher than within the general population, posing an increased risk of tuberculosis for inmates of these institutions as well as the general society[159-161,164]. The physical environment of prisons concentrates and disseminates tuberculosis through overcrowding, poor ventilation, poor personal hygiene, and risky behaviors. In addition, the structural deficiencies of prison healthcare management, such as lack of funding for healthcare and inadequate infrastructure, staff resources, and expertise, adversely affect the quality of tuberculosis treatment and care. The all-too-frequent absence of linkages between the ministries of health and the ministries of justice and the limited interaction of the latter with NTPs, civil society, and the affected communities further exacerbate problems faced by inmates during their tenure and following discharge. Follow-up and referrals of tuberculosis patients in penal institutions during incarceration and upon discharge are not systematically tracked, and NTPs are not always notified of new cases, leading to an inadequate estimation of the size of the problem. Consequently, prison settings often have poor tuberculosis case and program management, resulting in high levels of drug-resistant tuberculosis and other comorbidities.

Incarcerated populations also have higher HIV prevalence compared with the general population[147], with prevalence levels.10%within prison settings in 20 countries[171]. This is, in part, exacerbated by high-

risk behaviors such as drug injection that lead to comorbidities beyond HIV such as high levels of hepatitis B and C. As the largest financier of international funding for tuberculosis, the Global Fund provides financing to tuberculosis programs to meet the needs of disadvantaged groups, especially the most vulnerable populations. Our study examined the scope and extent of Global Fund financing for tuberculosis service delivery in prison settings to gain an understanding of the current status of financing for this high-risk group by global region, the types of service delivered to prisoners, and the performance of these programs.

Our analysis shows that an increasing number of countries are benefiting from Global Fund support that funds the delivery of tuberculosis services in prisons. Although in many of these cases governments were the principal recipients of such grants, a significant proportion of these services were managed and implemented by civil society organizations, the private sector, and international agencies. This funding scenario demonstrates the potential scope for full, multisectoral collaboration and engagement of all providers, both private and public, which is an essential component of the Global Plan to Stop TB.

Tuberculosis grants to programs that included delivery of tuberculosis services in prison settings were performing equally well compared with tuberculosis grants without tuberculosis services in prisons. In relation to the scope and scale of tuberculosis services delivered in prisons, there was some variation across regions, with a

large number of countries in the EECA region delivering a range of services for prisoners, while the coverage of such services was almost nonexistent in Southern Africa. By contrast, a number of countries in the WCA region reported Global Fund support for tuberculosis service delivery for prisoners, despite the relatively lower tuberculosis burden and the lowest prison population rate in Africa. Of equal concern was the fact that no high tuberculosis burden countries in the Southwest Asia region had tuberculosis grants that were supporting activities aimed at delivering tuberculosis care within prison settings.

The particularly low coverage of tuberculosis services in Southern Africa, a region with a heavy HIV and tuberculosis burden, merits further investigation, especially given its relatively high median regional prison population rate and the large number of countries with rates twice as high as the global median and high absolute numbers of prisoners and populations infected with tuberculosis. The same holds for the Southwest Asia region, which has attracted no funding from the Global Fund for prison-based tuberculosis services. All regions need to scale-up further prison-based tuberculosis services because support is not always consistent with current needs, as measured by either high tuberculosis/MDR tuberculosis or HIV burden or high prison population rates.

There is a need to further examine the reasons for the good coverage achieved in the WCA region and to draw lessons learned for implementation in other regions. With the exception of the EECA

region, most prison-based tuberculosis programs supported through Global Fund grants offer limited services for prisoners. Therefore, there is a need to better define and promote a more comprehensive package of tuberculosis care tailored and adapted to delivery within congregate settings. In particular, the minimal provision of MDR tuberculosis services was highlighted in our analysis, perhaps not surprisingly, because drug-resistance management requires extensive expert resources and dedicated infrastructure and is even more of a challenge in prison settings, where medical and specialized skills and the available resources are severely constrained. This issue will need to be addressed with a sense of urgency given that MDR tuberculosis is particularly prone to propagation within prison walls[172].

Table 2.

Information Gaps and Challenges Identified in the Study

• Lack of systematically available financial data for tracking the funding allocated for tuberculosis service delivery in prisons from the Global Fund or other major international donors.
• Lack of financial information such as budgets and expenditures from correctional facilities to monitor domestic fund sharing.
• Different countries have different modalities for delivering tuberculosis treatment within penitentiary settings, e.g., as private–public mix or as part of regular public health service.
• Lack of a standard set of indicators for monitoring tuberculosis service delivery in prisons, with services delivered through Global Fund–supported programs not documented in grant performance frameworks.
• No information on how linkages between ministries of health and others function in the delivery of tuberculosis services for the incarcerated population.

We encountered several limitations during this analysis, primarily a shortage of relevant data globally and for the grants supported by the Global Fund (Table 2). First, there were no standardized financial data available from the Global Fund grants database that were codified to enable quantification of funding allocated and expended on prison-related tuberculosis service delivery at an aggregate level. Also, there was a paucity of systematically compiled information on the extent of international financing provided for tuberculosis service delivery in prisons by other major funding agencies, such as the World Bank and other bilateral and nongovernmental organizations[167]. This made it difficult to examine the Global Fund's contribution within an appropriate context of total funding for these services. Second, there was a lack of internationally agreed-upon and standardized tuberculosis service indicators specific to monitoring of program delivery in prison settings. This hampered our efforts to accurately capture the full extent of services delivered within Global Fund–supported programs because not all activities carried out in these programs were monitored by the performance frameworks for these grants, which track indicators deemed to be the most suitable for monitoring grant performance. In other instances, many countries did not include tuberculosis treatment and care activities as PPM in prisons because often there is no separate healthcare delivery system in prisons; tuberculosis care services are extended to prisons under regular public health functions. Thus, the true extent of service delivered to prisoners through Global Fund support might have been underestimated. Third, there are no systematically available estimates

of budget allocations for prison healthcare costs and expenditures by country. Typically, the budgets for NTPs do not include tuberculosis service delivery costs in penitentiary settings because these are the responsibility of ministries of justice or ministries of the interior, which oversee correctional facilities. Fourth, there is scant information on the linkages between ministries of health and other ministries involved in financing and delivering tuberculosis services in prisons. The absence of reliable financial information on prison-based tuberculosis services makes it difficult to explore factors that influence the uptake of Global Fund finances to deliver tuberculosis or other health services within penitentiary systems and to ascertain future resource needs and funding gaps.

7.9 Conclusions

Our study is an important first step in establishing an overall picture of financial support for prison-based tuberculosis services from international sources to protect and improve the health of prisoners, a disadvantaged and marginalized group. There are many areas in which tuberculosis control and overall healthcare provision in prisons can be improved. Prison settings have obvious advantages for direct observation of treatment and provision of high-quality care for a highly marginalized group with high levels of tuberculosis[154]. There is an urgent need to better understand the financing needs and cost-effective service delivery models for tuberculosis care in prisons, including models that provide meaningful linkages to affected communities and civil society, in order to mount a truly multisectoral

response to tuberculosis and overcome decades of unacceptable neglect[159-161,173].

Note

Potential conflicts of interest. D. L., and S. S. L. are employees of the Global Fund. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

CHAPTER 8

Discussion

8.1 Introduction

The overarching research question in this thesis is "In what manner and under which conditions can the private sector be engaged in health care as to increase the chances of an effective End TB Strategy that will achieve its targets for 2035" as given in the Chapter 1. This discussion chapter attempts to summarize the analysis of the manner and the various conditions of private health sector engagement in view of the targets of the End TB Strategy of the World Health Organization (WHO), by drawing relevant findings from the previous chapters of this thesis. To put the discussion into perspective, a quick recollection of the background including the global TB situation, End TB Strategy and the challenges in TB control especially in the backdrop of the private health sector is provided here.

8.1.1 Global TB situation

As discussed in the previous chapters, TB remains a major global public health problem and is one of the top 10 causes of death worldwide[1]. As per WHO's global TB report of 2017, there were 10.4 million incident TB cases in 2016 of which 10% were living with HIV. In 2015, 1.3 million people died of TB recording a mortality rate of 17 per 100 000 population[1]. There were 600 000 new cases with resistance to rifampicin (RR-TB) of which 490 000 had multidrug-resistant TB (MDR-TB). In addition, 123 Member States of WHO reported extensively drug-resistant TB (XDR-TB). Eighty

five percent of the 476 774 notified HIV-positive TB patients were started on antiretroviral therapy[1].

8.1.2 End TB strategy

WHO's End TB Strategy targets 95% reduction in TB deaths and 90% reduction in TB incidence by the year 2035 compared with levels in 2015. The current annual decline in deaths and incidence rate are respectively 4% and 1.9%[1]. The strategy has milestones set for 2020 and 2025 to achieve the 2035 targets. To achieve the End TB targets globally, the entire health system and all types of health care providers of especially the high TB burden countries will have to take part in TB control based on their levels of engagement and share in health care provision. WHO organized the first global health ministerial meeting in Moscow in November 2017[174]. The conference, attended by 79 Ministers and a total of 117 country delegations, came up with a declaration which reaffirmed the countries' commitment to end the TB epidemic by 2030 as envisaged in the Agenda 2030 for Sustainable Development of the United Nations and its Sustainable Development Goals (SDGs), End TB Strategy of the World Health Organization (WHO), and the Global Plan to End TB 2016-2020 of the Stop TB Partnership[175]. It is in this context that the findings of this thesis to be viewed.

8.1.3 Different types of health care providers in the context of TB control

As we have seen in the previous chapters, there are three types of health care sectors that are important in TB control namely the public

health sector under the ministry of health (MoH), health sectors in the public sector other than the MoH and the private health sector. In this thesis, for convenience, we included the health sectors outside the purview of MoH-led NTP under a group called non-NTP sectors. Within the private sector, the private-for-profit sector that practises modern system of medicine is the most dominant and relevant non-NTP health sector due to the large numbers of TB patients they cater to and the inability of the private sector to perform public health functions in TB control which ends up in suboptimal levels of care received by TB patients. Therefore, the thesis has additional focus on the private-for-profit sector that practises modern medicine. The remaining health care providers under private sector include providers that practise systems other than modern medicine (e.g. Homeopathy), indigenous or traditional systems of healing (eg. Ayurveda) and the informal care providers (eg. Unqualified/untrained practitioners, traditional healers, insufficiently trained paramedical staff). It has been important for NTPs to engage these practitioners to reduce the delays in diagnosis, prevent unauthorized and non-standard prescriptions of anti-TB drugs and to obtain their service as community stakeholders to increase the awareness about TB as well as to support patients to ensure treatment adherence.

8.1.4 Missing TB cases and the related TB control challenges

A simple calculation of how many TB patients are being notified and successfully treated in the current scenario will explain the vastness

and seriousness of the challenges in TB control. WHO reports that, of the estimated 10.4 million incident TB cases of 2016, only 6.3 million (61%) were notified. This means that 4.1 million TB cases are 'missing' from notification about whom the national TB programmes (NTP) have no information. When only 61% of the estimated 10.4 million incident TB cases are notified and 83% of these 61% (6.3 million) cases are successfully treated, as per available data, eventually we have the information about successful treatment of only 50% (61/100X83/100 which is 50% and equivalent to 5.2 million cases) of the incident 10.4 million TB cases. In addition, even among the notified TB cases, 1.1 (that is 6.3 - 5.2) million cases have met with unfavourable treatment outcomes other than treatment success such as failure, death, lost to follow up or not evaluated. There will also be a small proportion of patients who don't seek any care and will die due to TB in a short time. However, majority of the 4.1 million un-notified TB cases of 2016 would have sought care from non-NTP health care sectors, mostly private care providers. There is no guarantee that these patients received care as per international standards. Such TB patients broadly fall into four groups; 1) those who have not sought any care 2) those who sought care, but TB was not diagnosed 3) those who were diagnosed to have TB at a non-NTP health facility but received inappropriate or inadequate treatment with anti-TB drugs and were not reported 4) those who were correctly diagnosed and successfully treated, but were not reported to NTP. Most of those who have not sought care or those who are not diagnosed of TB even after seeking care would die

within a few years. Studies of the natural history of TB disease before the discovery and use of anti-TB antibiotics recorded 70% death rate among sputum smear-positive pulmonary TB within 10 years of being diagnosed[1]. Those patients who received inadequate or inappropriate treatment with anti-TB drugs are likely to develop MDR-TB[176-180]. It has been proved that there are plenty of issues in the diagnosis and treatment of TB cases in the private sector which lead to delayed or missed opportunity to diagnose TB as well as very low rates of treatment success. These in turn contribute to long durations of illness, increased rates of disease transmission in the community and larger percentage of people dying of TB.

8.2 Main findings of the thesis

The specific questions that the thesis discussed in detail in the preceding chapters are the following:

- How did the TB control program of India try to engage the private sector in TB control and what has been the effect of the early public-private mix (PPM) pilot endeavors?
- How did India scale up the pilot projects on private sector engagement in TB control to national level and what has been the learning?
- What has been the role of the Indian Medical Association in the engagement of the private sector in TB control and what is its relevance? What are the lessons for India and other

countries to learn from the unique endeavor of engagement of medical professional associations in TB control?

- What has been the landscape of funding from the Global Fund, the biggest international donor in TB control, for the engagement of the private sector in TB control?
- Do prisons that house around 10 million detainees, among whom TB is a leading cause of morbidity and mortality, get adequate funding for TB control?

- How did the TB control program of India try to engage the private sector in TB control and what has been the effect of the early public-private mix (PPM) pilot endeavors?

From the beginning of the implementation in 1997, Revised National TB Control Programme (RNTCP) of India has been making continuous efforts to partner with private health sector. Subnational units of RNTCP had implemented multiple pilot projects of PPM from 1999 onwards through collaborations developed locally. Chapter 3 of this thesis has given an overview of the analysis of the 14 documented PPM projects between 1999 and 2004. Six PPM projects that engaged private practitioners and another eight projects that engaged corporate sector or non-governmental organization (NGO) partners demonstrated significant increase in TB case notification; around 15% for the first group and between 12% and 98% for the latter. There were no significant differences between NTP and non-NTP health sectors in treatment success rates[78,90]. Thus, these pilots demonstrated that collaboration between RNTCP and private practitioners in India improved the TB case notification while

maintaining good treatment outcomes. It also demonstrated the ability of NGOs and private industry medical services to work with RNTCP. It was also noted that the presence of a strong public sector was critical for provision of necessary advocacy, training, and supervision. The findings highlighted the need and feasibility of building public-private collaborations and the significant potential they hold for improving TB control in India. These PPM projects informed RNTCP that the scene was set for a broad scale-up of PPM into routine practice for tuberculosis programmes.

- How did India scale up the pilot projects on private sector engagement in TB control to national level and what has been the learning?

Encouraged by the results of the various PPM pilot projects, RNTCP in 2003 implemented an intensified national scale-up of public-private mix (PPM) DOTS initially covering 50 million population in 14 major cities across the country[181]. It was done in a systematic manner based on national policy decisions of RNTCP and following uniform processes in all the cities while providing sufficient flexibility for necessary adaptations based on the local context. The project while working closely with the district level units of RNTCP and its functionaries recruited additional human resources to absorb the extra work due to intensified PPM implementation. To begin with, all the health care providers were mapped followed by basic sensitization on RNTCP and PPM. Newer tools targeting private care providers such as advocacy kits and a concise training module were also developed. Providers' recruitment was prioritized based on the

number of patients they managed which means those with higher number of clientele were enrolled first. A PPM-focused surveillance system was developed by the project to capture the implementation data disaggregated by various provider characteristics (eg. type, size) and patient characteristics (eg. age, gender). RNTCP's national schemes for engaging different types of providers were used for entering into formal agreements with private care providers. The national schemes offered support to private providers that included financial compensation and provision of logistics in addition to assistance in public health aspects such as registration of TB patients, treatment adherence support and recording of treatment outcome. There were also national advocacy campaigns undertaken by RNTCP to complement the local initiatives.

The project sensitized close to 16 000 health care providers whereas only a small proportion expressed interest in taking part in training. This was one of the lessons learnt about the challenges in getting private practitioners even for shorter sessions of training. In the 14 cities together, notification rates for new lung TB cases diagnosed by microscopy as well as all (diagnosed by microscopy and other tools) new cases increased respectively by 12% and 17% per 100 000 population. During the same period, in the comparison cities of the country, case notification rate of new smear positive and all new cases had registered a slight decline. All the non-NTP health care providers together had a share of 33% of the cases notified by RNTCP of which medical colleges had contributed 16%, private practitioners 6%,

NGOs 7%, other public providers 3% and corporate sector 1%. This helped RNTCP take decisions on prioritizing medical colleges for immediate engagement. Private sector including NGOs, contributed 18% of all notified new cases that were diagnosed by microscopy. Overall treatment success rate of the project was above the 85% target of RNTCP. However, in the case of medical colleges, cure rates were relatively low which was because the medical colleges due to their popularity had attracted patients from far off places who had to be transferred out to their own districts after a short period of hospitalization[182]. Treatment outcome information of many such patients were not available which led to relatively lower cure rates recorded. This helped RNTCP in framing policies for referral of such patients back to their neighborhood and mechanisms to follow up them until the treatment outcomes were reported, like in the case of patients managed by local RNTCP. Similarly, through this PPM project, RNTCP learnt that prioritization of large numbers of small scale health care facilities or individual private providers may not be as cost-effective as the engagement of large institutions such as medical colleges. Nevertheless, they constitute most private practitioners in the country who are approached by substantial proportions of patients[107]. Lessons from this project prompted major decisions by RNTCP to study the cost effectiveness of PPM and formulate mechanisms to engage small and individual health care providers in an effective manner[81].

- What has been the role of the Indian Medical Association (IMA) in the engagement of the private sector in TB control and what is its relevance?

As discussed in Chapter 5, RNTCP, from the time of initial days of its implementation, had made efforts to engage IMA though with very limited success. However, private medical practitioners were initially very doubtful about the claims RNTCP to be a superior programme compared to the previous NTP of India. While NTP transitioned to RNTCP, there has been repackaging of approaches in the diagnosis and treatment based on the guidelines of the DOTS strategy. However, the modern medicine practitioners in the private health sector had opposition to the principles of RNTCP. The opposition was around four major areas namely diagnosis, treatment, patient-related issues and physician-related issues as discussed in Chapter 5. IMA at national level was silent on this issue in the initial years. However, in the PPM pilot projects that evolved in New Delhi, Kannur and Kollam, IMA had acted as an interface between RNTCP and the private sector. All these pilot projects recorded very high percentages of participation of private health care providers and demonstrated significant increases in case notification[103]. These PPM projects also achieved high treatment success rates. In Kollam, a district in Kerala state of India, IMA's state secretary was directly engaged in PPM where his private hospital was designated as a RNTCP-endorsed facility. In Kannur, another district in Kerala, the secretary of IMA was the district TB officer who ensured IMA's close participation in the PPM pilot. Encouraged by the results of

these models, IMA and RNTCP together expanded the Kannur and Kollam models to the entire state of Kerala. When the state level expansion also resulted in increased participation of private practitioners and resultant increase in TB case notification, RNTCP requested IMA to expand this model to a few other states of India. All these models focused on training of private doctors and then linking their private care facilities to RNTCP. Better acceptance to the training and recruitment into RNTCP done by IMA among private doctors led to the decision of RNTCP to include IMA as its subrecipient for the Round 6 funding of the Global Fund's grant in 2007. In this project, IMA took the responsibility of expanding its private sector model to more states of India. As discussed in Chapter 5, IMA-Global Fund project covered 169 districts and 532 IMA branches serving 415 million population and over 55 000 IMA members. The project in a period of 8 years from 2007 to 2015 reached 103 254 private doctors through continuing medical education, trained 163 86 doctors and notified 112 409 TB cases. Over 4000 practitioners signed agreement with RNTCP and close to 5000 'DOT centres' were opened[128]. IMA-RNTCP partnership also helped in strengthening the relationship between RNTCP and the private sector and contributed to the development of strategic guidelines for formal engagement of private sector providers[131]. Lessons from this partnership also contributed to the evolution of the innovative concept of public-private interface agencies (PPIA) in India to facilitate the public-private collaborations. PPIAs are now being implemented in bigger urban areas where diverse kinds of

private sector providers dominate the health care system[27]. However, lapses like lack of clear mechanisms to measure the contribution of IMA and the absence of a formal agreement between RNTCP and IMA led to gradual weakening of this partnership. In addition, the IMA-Global Fund project, had no systematic mechanisms to follow up with the private practitioners after the training to establish RNTCP-approved services at their facilities. Evolution of the RNTCP-IMA partnership, the lessons learnt, and the challenges faced are valuable information that could feed into the policies of global TB control regarding the engagement of medical professional organizations.

- What has been the landscape of funding from the Global Fund, the biggest international donor in TB control, for the engagement of the private sector in TB control?

Multiple international and domestic donors had provided funding for PPM pilot projects in the initial years. As discussed in Chapter 6, The Global Fund, is the biggest international donor (currently contributing to 65%) of the total international funding for TB control[166,168]. Despite the global efforts to promote PPM, there was no information on the prioritization of PPM in the funding proposals as well as actual funding allotted and spent for PPM. Chapter 6 'Global Fund financing of public–private mix approaches for delivery of tuberculosis care' is the landscaping study of PPM interventions in TB control programmes supported by The Global Fund[166]. The study observed that the importance and the scope of

PPM were not often reflected in the TB proposals and the budgets submitted by countries. The proportion of countries with PPM had not increased despite additional Global Fund support for PPM. Relatively lower engagement of both NGO and private health sectors was also noted. The study commented that the median budget allocation for PPM activities of 5% was insufficient for scaling up of PPM initiatives. Initiatives in India such as mechanisms to formalize PPM through tools like guidance documents were highlighted by the study. The study recommended the need for innovative mechanisms such as certification of provider and financial incentives, depending on the local needs. Considering the 5 to 50 times higher TB prevalence rates within penitentiary settings compared with the general population, the study highlighted the need for expansion of PPM activities to prisons with adequate funding.

- Do prisons that house globally around 10 million detainees, among whom TB is a leading cause of morbidity and mortality, get adequate funding for TB control?

Among the prison population, tuberculosis is a major cause of illness[160]. Chapter 7, 'Global Fund Financing of Tuberculosis Services Delivery in Prisons', did a study as a follow up to previous study on Global Fund financing for PPM (Chapter 6). As discussed in Chapter 7, TB morbidity and mortality among prisoners are often many times higher compared with the general population and it poses an increased risk of TB for inmates as well as the general population[159,161,164,183]. The shortages in the physical environment and infrastructure of healthcare management in prisons affect the quality

of TB treatment and care. As of December 2010, 50% of Global Fund-supported TB programs delivered services within prison settings. Global Fund–supported TB programs were delivering services in prison settings in 50% of the countries with high TB burden. The funding allocated to tuberculosis grants, which included tuberculosis service delivery in prison settings, accounted for about 28% of the US$ 2 billion invested in all TB programs funded by The Global Fund. However, no systematically captured data were available that would enable quantification of direct funding allocated in tuberculosis care and delivery within penitentiary settings. The study was an important first step in establishing an overall picture of financial support for prison-based tuberculosis services from international donors. The study found that there were many areas where TB control and overall healthcare provision in prisons could be improved. The study also noted that there is an urgent need to better understand the financing needs and cost-effective service delivery models for TB care in prisons.

8.3 Chances of PPM

Having discussed the experience from different PPM projects and in the light of the discussion so far on the various related aspects of PPM, it's appropriate now to discuss the chances and challenges encountered by PPM.

8.3.1 Is there a need to engage the private sector?

There has always been a philosophical question: "Is it good or bad to engage the private sector in TB control and can't the public sector

alone run the NTP?" As has already been discussed in the previous chapters, if there is a strong, efficient and easily accessible public sector running the national TB control programme and if the people are generally accessing health care from the public-sector health facilities, there is no need to heavily engage the private sector. However, as discussed in the earlier chapters, public health sector in the developing world is generally weak, inefficient and failing due to which patients don't have trust in it[6,184,185]. The private sector in these countries will be competing with the public sector in broadening the clientele base and to maintain it. The private providers would also be deviating from the standard guidelines of diagnosis and treatment due to multiple reasons especially financial reasons. Especially in the high TB burden countries, there are public health sector-driven NTPs which run the programme, but large proportions of people access care from the private sector. Therefore, good performance of the NTPs alone is not sufficient to attract all TB patients to NTP services. Here comes the need for the NTPs to take initiatives to engage the private sector.

8.3.2 PPM improves case notification and ensures standard care to all patients

As discussed in the previous chapters, PPM interventions across the globe in general have proved that collaboration between the NTPs and non-NTP health care providers could significantly improve TB case notification while maintaining high rates of treatment success[103]. In addition, PPM ensures standard care for TB as determined by the

NTP is provided to patients irrespective of the sector from where they seek care. The contribution of PPM to total
TB notifications increased by more than 10% between 2012 and 2016 in Bangladesh, India and the Philippines, especially in areas where monitoring was in place[1].

8.3.3 Scope for innovations and adaptation

PPM strategy with flexibility for adaptation to local contexts and innovation allows NTPs to experiment newer approaches. Countries such as India are now moving towards a more inclusive approach with government's willingness to understand better the nature and challenges of the private sector and to implement practical and friendly approaches to engage the private sector instead of imposing the NTP policies on the private sector. PPIA model in India, communication campaign that advised people with symptoms of TB to report to NTP-endorsed private care facilities and use of Xpert MTB/RIF test in the private sector in Dhaka and Jakarta are examples for this transition from the conventional approaches of NTP[27,186-188].

8.3.4 PPM is cost effective

The first study on effectiveness, cost and cost-effectiveness of PPM in India was undertaken as early as in 2003. In this study, pilot projects in the cities of Hyderabad and Delhi, each serving around 500 000 population, were considered[79]. As far as effectiveness was concerned, the PPM projects in Hyderabad and Delhi detected respectively 26% and 47% additional TB cases than the comparison areas in the country. Both the projects registered high treatment

success rates close to or exceeding the then WHO target of 85%. For patients and their attendants, treatment in the public sector and in PPM projects allowed a substantial reduction in costs compared with those in the private sector that didn't offer RNTCP services[79]. The finding that there were no additional costs to the public sector for the extra cases successfully treated in Hyderabad proved the cost effectiveness of the project. PPM also resulted in an improvement in the number of cases successfully treated. The study proved that PPM in India was an effective, affordable and cost-effective approach to improving TB control in India. The study also had recommended that successful approaches to PPM should be scaled up alongside continued implementation and expansion of the public sector RNTCP programme[79].

A subsequent study done in Bangalore city of India in 2005 recorded the patient delay and health system delay in TB are shown in Table 1. While the mean patient delay was 21 days, the health system delay was 52 days. A health system delay of more than 7 weeks was positively related to large number of health contacts and a private practitioner as the first health care contact[80]. As shown in Table 2, patient had already spent US$ 145 before treatment for TB. The cost of treatment outside RNTCP was 6 times (US$ 127) than the cost in RNTCP (US$ 21)[80]. The study also proved that PPM implementation substantially reduced costs to patients, such that the average societal cost (the total cost to society which includes both private costs of patient plus any external costs) per patient successfully treated fell

from US$154 to US$132 in the 4 years following the initiation of PPM[81].

Table 1: Patient and health system delays (source: Economic evaluation of public-private mix for tuberculosis care and control, India. Part I. Socio-economic profile and costs among tuberculosis patients. International journal of Tuberculosis and Lung Diseases. 13(6):698–704. 2009); Pantoja et al[80,81].

	Mean days	Median days	p25–p75 interquartile range, days	Percentage of patients by delay interval: 0	1–7 days	8–21 days	22–42 days	43 days to maximum
Patient delay	21	7	3–20	7	45	24	11	13
Health system delay	52	34	16–68	3	8	24	22	43
Total delay	72	53	28–93	0.3	3	13	25	59

Table 2: Average cost per patient ($US) incurred by patients and attendants before and during treatment of TB within and outside the RNTCP. (source: Economic evaluation of public-private mix for tuberculosis care and control, India. Part I. Socio-economic profile and costs among tuberculosis patients. International journal of Tuberculosis and Lung Diseases. 13(6):698–704. 2009); Pantoja et al[80].

	Before treatment for TB	During treatment for TB: RNTCP	During treatment for TB: Outside the RNCTP
Medical fees	4.2	0.1	7.6
Drugs*	12	13	90
Diagnostic tests	26	0.4	NA
Hospitalisation	9.8	3.0	25
Transport	23	2.6	4.4
Time lost†	56	1.8	Not applicable
Interests on loans	4.6	0.4	NA
Costs for attendants	11	0.05	NA
Total	145	21	127

* Refers to associated drugs, including food packages, for patients treated under the RNTCP, and anti-tuberculosis drugs for patients treated outside the RNTCP. † Time lost due to directly observed treatment for costs during TB treatment, which implies the patient going to the health centre to take the medicines every day during the initiation phase and occasionally during the continuation phase. RNTCP = Revised National TB Control Programme; TB = tuberculosis; NA = not available.

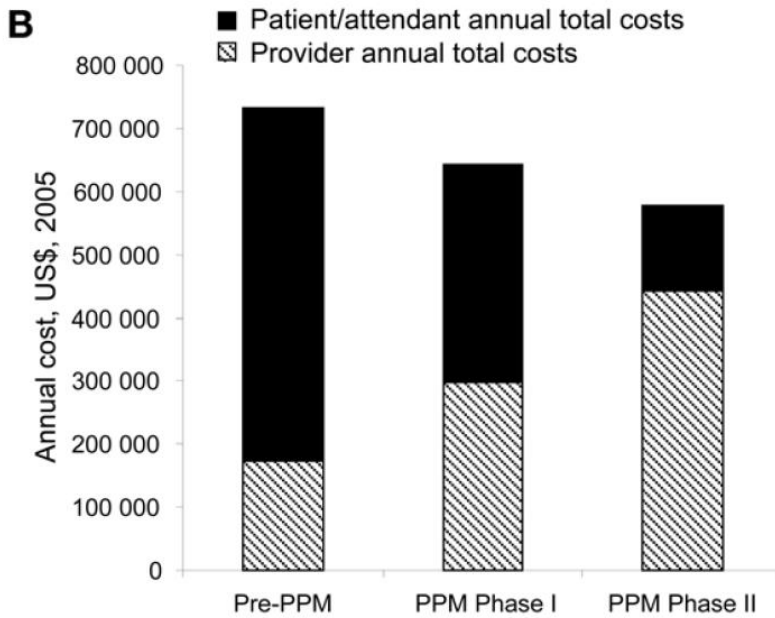
As described in the study of cost and cost-effectiveness by Pantoja et al, when both patients treated in the RNTCP and those treated outside the RNTCP were considered, implementation of PPM in two phases (Phase 1: introduction of PPM that began in mid-2001; Phase 2: intensified PPM that began in 2003) led to a fall in societal costs (Figure 1)[81].

The study explains that this was because while costs for providers increased over time, the total costs incurred by patients and their attendants decreased. This was the reflection of a shift of patients from non-RNTCP treatment to less costly RNTCP treatment. Costs incurred by patients and their attendants had come down from 75% of total societal costs pre-PPM to 23% of total societal costs in PPM Phase II.

Societal perspective ($US, 2005). Assumes that the total number of patients treated, within and outside the RNTCP, is the same in all three phases. However, there is a shift of patients treated outside the RNTCP to the RNTCP which results in a reduction in total costs during treatment for patients/attendants. Costs include costs for all providers within the RNTCP as well as for patients and attendants treated within and outside the RNTCP. These studies clearly showed that the implementation of PPM on a large scale can be cost-effective and that PPM implementation can increase treatment success rates across all types of non-NTP care providers.

Figure 1.

Annual costs of patient/attendant and provider



(source: Pantoja et al. Economic evaluation of public-private mix for tuberculosis care and control, India. Part II. Cost and cost-effectiveness. International journal of Tuberculosis and Lung Diseases. 13(6):705–712. 2009)[81]

8.4 Challenges encountered by PPM

While there have been consistent global efforts to engage non-NTP health sectors in TB control, led by NTPs applying PPM strategy, there are many existing and emerging challenges faced by PPM initiatives. Despite the implementation of TB control programmes globally in an organized manner since the early 90's, the TB epidemic has not changed much. The recent TB prevalence surveys in some high TB burden countries proved that TB incidence in many countries were grossly underestimated[1].

TB is concentrated mainly in lower income countries and populations and therefore a range of strategies are required to finance various public private mix (PPM) models in different settings. Currently, the predominant source of financing for PPM is input-based domestic and donor financing, Funding gap faced by TB control programmes affect investments in PPM also[1]. As reported by the USAID and The World Bank, sustainability of financing of PPM will rely in part on the incorporation of TB and PPM into domestic health financing streams[189].

Despite many innovative PPM interventions, PPM in India is faced with multiple challenges. The number of private health care providers, both formal and informal, is increasing exponentially. A repeat study 'Tuberculosis Management by Private Practitioners in Mumbai, India: Has Anything Changed in Two Decades?' conducted in 2010 as a 20-year follow up on the pioneering study in 1991 done

by Mukund Uplekar found that things have not changed much over the years. Clear majority of private practitioners are still unable to correctly prescribe medicines for a TB patient. Only 6 of the 106 respondents wrote a prescription with a correct drug regimen for TB; 106 doctors prescribed 63 different drug regimens[17]. This is in comparison with the study in 1991 by Mukund Uplekar 'Treatment of tuberculosis by private general practitioners in India' that had thrown light on the unexpectedly low levels of awareness among private medical practitioners about treatment for TB. This study was done in Mumbai city of India where the TB burden has been very high with estimated current annual incidence of 60 000 TB cases. Hundred private doctors in the study prescribed 80 different drug regimens, most of which were both inappropriate and expensive[16]. Similarly, despite the presence of regulatory frameworks including mandatory TB case notification in many countries, enforcement of such regulations remains a challenge.

The private sector, especially in India, is likely to continue to be diverse and largely disorganized due to the multitude of practitioners of different systems of medicine, running various types of health care facilities in contrasting settings. For example, in India, private practitioners practising systems other than modern medicine (AYUSH- Ayurveda, Yoga, Unani, Siddha, Homeopathy and naturopathy)[190], traditional healers and informal providers (those without any academic qualification/license to practice) are widely spread across the country. In certain geographical locations,

especially remote villages and urban slums, informal providers have a major presence[60].

A study done in Chennai, India, to understand the awareness, perception and barriers on TB notification among private practitioners showed that three-fourth of private practitioners were aware of the TB notification order by the government of whom only 33% had ever notified a TB case[191]. People especially the poor who are forced to access health care from the private sector due to the non-availability of services or suboptimal quality of care at the public health facilities are further disadvantaged due to this. Out-of-pocket and catastrophic expenditures make people poorer and more vulnerable to diseases including TB. People living in places such as remote villages, difficult to access tribal areas or urban slums heavily depend on the private providers available in their respective areas and they incur catastrophic expenses. Reaching the poor and marginalized, who have more likelihood of contracting TB and thereby by suffer from out-of-pocket and catastrophic expenditures, through PPM approaches remains a big challenge.

The above stated multiple challenges and the complex situation make it difficult for the TB programme managers also to organize systematic PPM activities. As has been pointed out earlier, adverse factors such as overburden in the public sector, diverse nature of private sector, difficulties in convincing the private sector to engage in partnerships due to lack of trust, inadequate resources, and often lack of capacity within the public sector or low priority for PPM act

as barriers for the programme managers. Inadequate funding and low priority pose challenges for researchers also.

8.5 Lessons from India for other countries

Despite the experimentation of the various fruitful pilot projects of PPM, RNTCP of India couldn't successfully scale up such models to bigger geographies at subnational or national levels. This is how RNTCP started considering newer strategies and innovative approaches. Some of the recent changes in the approaches and strategies of PPM in India are paradigm shifts from the conventional PPM thinking which are showing positive results in terms of enhanced funding for PPM and dramatic increases in terms notification of additional TB cases. Some of the newer approaches and innovations, as summarized below, would serve as examples for other countries that have situations similar to that of India.

8.5.1 Additional focus on PPM

In the recent years, the concept of PPM has been gaining a broader meaning in India. The National Strategic Plan (NSP) for TB elimination 2017–25 strategizes to replace mistrust between public and private sectors by constructive partnership. NTP would also work with the private care providers to deliver quality-assured Standards for Tuberculosis Care in India - compliant services to the entire population. For achieving this, RNTCP has established a scheme that offers incentives to the private providers for notifying TB cases and to TB patients for reporting to RNTCP. There is another scheme to

provide medicines free of cost to TB patients seeking care from private sector. NSP is developing a modern management information system (MIS) to monitor the delivery of drug kits to the patient as well as compliance to treatment. This will link to the sale of anti-TB drugs by the private pharmacies to link patients into the MIS. India plans to augment the availability of rapid molecular tests to make more diagnostic facilities available for patients referred by the private providers.

8.5.2 New Technical and Operational Guidelines (TOG)

RNTCP in its TOG published in 2016 describes a broader public-private partnership (PPP) based on the principles of 'Universal Health Care'[82]. The PPP is different from the PPM as it considers all health sectors as partners with equal responsibility in the implementation of TB control instead of using them as passive health care providers who will be approached by the public sector – driven RNTCP to share only certain roles based on their capabilities. RNTCP is working towards this goal with the basic philosophy that government is not the sole provider of services for TB and optimum efforts should be made to utilize the resources in the private sector. With this changed outlook, RNTCP is trying to move from the 'public health sector-centred' approach in TB control where the government is the controlling authority to the new 'patient-centred' approach where all stakeholders are considered equal partners who produce synergistic effects whereby TB patients are benefited[82]. To engage private sector providers, RNTCP has implemented a package of interventions in the project 'Universal Access to TB care'. The interventions are aimed at

improving TB notifications by offering information and communication technology support that is convenient to providers, free TB drugs for notified TB patients, and extending public health services including adherence support to treatment outcome for patients diagnosed and treated in the private sector.

8.5.3 Mandatory notification of TB

Declaring TB as a mandatorily notifiable disease by an executive order of the national government was a bold step taken by RNTCP[192]. RNTCP has also simultaneously developed a web-based case-based notification system 'Nikshay' which can also be accessed by the private health sector care providers to notify the cases they diagnose or treat. By 2016, as per Nikshay data, 70 952 private practitioners, 34 591 hospitals and 9835 laboratories were engaged in RNTCP. These providers notified 184 802 patients in 2016 which included 65 249 patients notified by private clinics and 46 263 patients by private laboratories[186].

8.5.4 Standards of TB Care in India

RNTCP developed Standards for TB Care in India (STCI) along the lines of International for TB Care. RNTCP took the help of organizations like IMA to propagate STIC.

8.5.5 Banning of commercial serological tests

India also lately banned the use of serodiagnostic test kits for diagnosis of TB due to its inconsistent and imprecise findings resulting in highly variable values for sensitivity and specificity[193].

8.5.6 Control on over-the-counter sale of anti-TB drugs

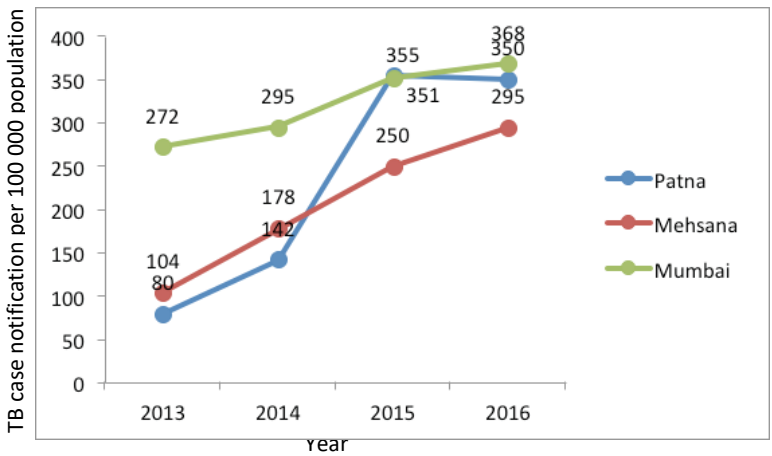
Steps were taken to control the over-the-counter sales of anti-TB antibiotics, though these actions have seen variable levels of success across the country[186]. Most recently, the program started providing drug regimens that can be taken daily replacing the existing thrice-weekly regimen with which the private sector has disagreement[186].

8.5.7 New and innovative approaches

RNTCP established PPIA to facilitate engagement of the private sector. Interface agencies were engaged in Patna and Mumbai cities to implement PPIA projects. PPIA mechanism helped in providing quality assured services efficiently to the patients who seek care from private health sector. Mumbai is a densely populated city of India with more than 12 million residents of whom at least 60% live in slums of very deplorable living conditions. Of the annual estimated 60 000 TB cases, the public sector was notifying only around 30 000 and the rest of the cases were assumed to have been seeking care from the private sector. The project is now notifying between 1500 and 2000 additional TB cases each month from the private health sector. In Patna city, the baseline case notification rate was very low and subsequent to the PPIA implementation, the case resulted in a steep increase achieving fourfold increase (Figure 2). PPIA models in Mumbai and Patna demonstrated the potential of PPIAs to dramatically increase TB case notification especially in urban areas. In the city of Mehsana, where the case notification showed a steady

increase, the public sector RNTCP enhanced its efforts to engage the private sector and encouraged the RNTCP staff to manage the service delivery intervention without an external agency as the interface[186].

Figure 2 Increase in TB case notification in PPIA sites (Source: RNTCP Annual Report 2017)



Directorate General of Health Services, Government of India)[186]. Picture shows the large increases in the TB case notification in Mumbai and Patna cities of India with the support of PPIA from the year 2014 when PPIA started implementation. 2013 shows the baseline figure. Blue, red and green lines represent the case notification trends respectively in Patna, Mehsana and Mumbai cities.

8.5.8 Digital health

Innovative approaches such as digital health and mobile phone applications are increasingly being used in PPM sites in the entire spectrum of TB care. This is contributing to the increase in the number of cases notified and ensuring treatment adherence by

patients on TB treatment. In what manner and under which conditions can the private sector be engaged in health care as to increase the chances of an effective End TB Strategy that will achieve its targets for 2035 (What does it take the End TB Strategy to meet its milestones and targets?) Before discussing the manner and conditions under which the private sector can be engaged in health care to increase the chances of End TB Strategy achieving its targets, it's important to review the WHO's general framework to achieving this.

8.5.9 WHO modeling for achieving End TB Strategy Targets

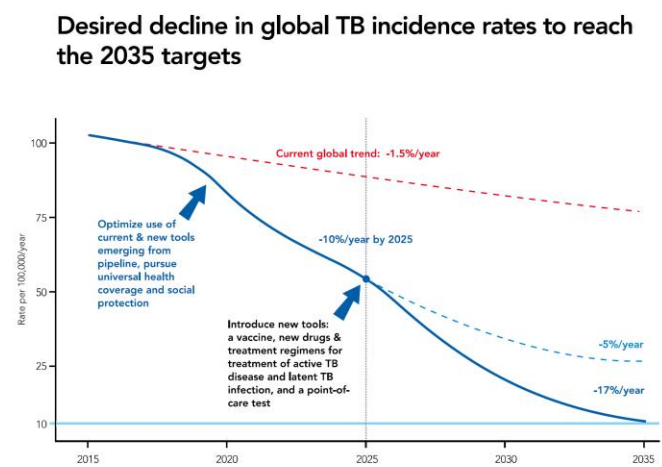
WHO has modeled certain scenarios to end TB by 2035 as shown in the figure 3[1]. The modeling predicts that if the global TB control progresses at the current pace, there will be only 25% reduction in TB incidence by 2035 against the End TB Strategy's targeted 90%. As can be seen in the figure 3 below, only by ensuring optimized use of current and new tools as well as ensuring universal health coverage and social protection by 2020 and introduction of tools such as new vaccines, drugs and regimens for treatment of active TB disease and latent TB infection, and a point-of-care test by 2025, 90% reduction in TB incidence can be achieved by 2035. To achieve the milestones of the End TB Strategy set for 2020 and 2025, the WHO model calls for an annual decline in incidence of 4-5% per year by 2020, and then to 10% per year by 2025. Similarly, the proportion of people with TB who die from the disease (the case fatality ratio) will have to be reduced to 10% by 2020 and then to 6.5% by 2025 (equal to the current level in many high-income countries) which is not easily

achievable in most of the high TB burden countries with the present levels of access to high-quality treatment. WHO also recognizes that ending the global TB epidemic will be feasible only if there is a dramatic decline in TB deaths and cases, elimination of economic and social burden of TB and reduction in the out-of-pocket expenditure for TB treatment[1]. The second of the three pillars of the End TB Strategy 'Bold policies and supportive systems' has included 'Engagement of public and private care providers' as one of its components[1].

Using the learning from the chapters of this thesis and based on the discussions so far, the manner and conditions under which the private sector can be engaged in health care to increase the chances of End TB Strategy achieving its targets is summarized as follows.

Figure 3.

Projected interventions required to achieve End TB targets for 2035.[1]



Source: **The End TB Strategy, World Health Organization[3]**

8.5.10 Understanding of the situation

Proper understanding of the nature of the epidemic, functioning of private health sector in the broader canvas of the health system and the behaviour of patients is an important condition for designing and planning private sector engagement. Nature of the epidemic is available from prevalence surveys and estimates. Mapping of private health care providers will give information about the nature and functioning of the private health care providers. There should also be complete understanding of the interactions between the public and the private sectors. Patent pathway studies will give information about the care seeking behaviour of the patients.

8.5.11 Adequate financing

As we have seen earlier, TB control is faced with inadequate funding and PPM doesn't receive the priority that is deserves in investment. International as well as domestic funding have to be ensured for PPM. In addition, investment directly in the private sector has to be encouraged in order to bypass bottlenecks in the public-sector mechanisms. Pooling of resources will reduce the cost while the participation will improve.

8.5.12 Commitment and the readiness of the NTP

NTP should be the political commitment, ownership and the required resources to contribute to PPM. NTP should be taking lead in providing stewardship as well as supporting in problem solving. Appropriate levels of sensitization will have to be provided to the

public-sector staff. There has to be a private sector focal point and adequate manpower to coordinate and work with the private sector.

8.5.13 Appropriate model

We assume that the WHO-projected interventions required to achieve End TB targets for 2035 fall in place as planned. However, the engagement of non-NTP health sectors, especially the private sector, is likely to remain as a barrier to reaching the 2035 targets. Depending on the context, appropriate models of private sector engagement have to be developed and implemented in high TB-burden countries with private health care sector as a major player. Pilot initiatives give the opportunity for innovations and learning and adapting while doing. The models should be able to be inclusive of all care providers. The roles and responsibilities of all partners should be clearly defined before the work is started. Engagement of private providers should be based on prioritization to avoid too much spreading and resultant thinning of the impact. For example, there is no need to directly engage all the formal and informal providers in service delivery. However, proper mechanisms should be there for referral and feedback between all bigger and smaller providers. Care should be taken to use the existing channels of communication and transactions between the providers and not to disturb the ecosystem. The private care should be aligned to adapt and practise the international or country-specific standards of care. The models should have enough flexibility for adaptations and midcourse corrections. In order to arrive at the best model, it will be ideal, to experiment pilots. Documentation of the experience and lessons learnt will be important

before the scale up. Scaling up at the appropriate time is important to create a dent on the epidemiology. The PPM should be innovative, have flexibility in approaches and have willingness to change, modify and adapt.

8.5.14 Sensitization/Training

Providing sensitization/training to the public sector about the need for PPM is important to make it convinced about the need for engaging private sector. Mentoring and creating a pool of trainers from the private sector is important. Appropriate and user-friendly tools should be used for training.

8.5.15 Provision of commodities

NTP should be responsible for ensuring commodities like laboratory reagents, drugs and other logistics. Newer and faster diagnostic tools and quality assured drugs have to be provided to all patients.

8.5.16 Information Communication Technology Platforms

Appropriately designed Information Communication Technology (ICT) platforms should be used to reduce human intervention and to make the processes faster and efficient. ICT has to be used in transmission of laboratory results, registration of TB patients, TB case notification and ensuring treatment adherence.

8.5.17 Engagement of professional organizations

Professional organizations of health staff especially doctors have to be engaged in the process from the beginning stages itself considering

their influence on the staff and their negotiation skills. In many settings, professional organizations would work as interface agencies.

8.5.18 Regulations

PPM will work only in an environment where there are regulations and they are implemented adequately. Regulations should cover areas such as proper adaptation of the laboratory guidelines, appropriate use of drugs, mandatory TB case notification, patient follow up and drug sales.

8.5.19 Incentives

Appropriate monitory or social incentives to public and private care providers, patients and treatment supporters from the community will contribute to the sustainability of PPM model. Mechanisms like accreditation of health care providers and facilities will work as social incentives. In addition, social business models will encourage more private care providers to participate.

8.5.20 Monitoring and Evaluation

Simpler tools for collecting, compiling, reporting and analyzing data has to be there for documenting, learning, adapting and replicating PPM models. Evaluation including cost effectiveness evaluation of the models will provide validation for replication/expansion.

8.5.21 PPM has to go beyond the government and NTP

It's a fact that the overall responsibility and liability of TB control in any country ultimately lies with the government due to its accountability to her people as well as global health. Nevertheless, in

the current scenario, vesting the entire responsibility of TB control on the NTPs is not practical or justifiable. This is mainly due to three factors in most of the high TB burden countries. These are 1) large proportions of TB cases continue to seek care from private health sector 2) slow but indisputable weakening of public health sector, the owner of NTPs and 3) steady and profound growth of the private health sector. This is the situation where there has to be consensus at all levels that nothing less than wider and comprehensive engagement of private health care sector can result in effective TB control. As already discussed earlier, there are non-NTP public health sector care providers that cater to large proportions of TB patients. These include health care settings of government organizations like prisons, industries like mines or public-sector undertakings like railways. Engagement of these health care providers is of extreme importance in order to achieve the global targets to end TB. Extensive coverage of prisons with standardized TB control is crucial as prisons house large numbers of people and provide conducive environment for the spread of TB.

8.5.22 Mere increase in case notification is not enough; successful treatment is equally important

It's a fact that the focus of PPM has been on increasing care notification by engaging private sector. However, the question whether detection of more cases is just enough comes up. Successfully treating all notified cases is equally important to achieve the goal and targets of End TB Strategy. To achieve this, there has to

be mechanisms to first notify the large numbers of TB patients receiving treatment from the private sector and to ensure treatment compliance by all such patients.

8.5.23 Quality of care under NTP has to be maintained

While there is increased emphasis on the engagement of the non-NTP health sectors in NTP, its crucial to ensure that the quality of care within the NTP is not compromised. It is important to ensure that all care providers adhere to international standards for TB care in the entire spectrum of services provided to TB patients. Adequate financial investment based on the needs especially for building and maintaining compact quality assurance mechanisms must be ensured.

8.6 Conclusion

There have been many successful PPM pilot projects across the world. As WHO reported, there have been more than 10% increase in case notifications between 2012 and 2016 in countries such as Bangladesh, India and the Philippines[1]. However, many countries face multiple challenges in implementing and scaling up PPM due to several factors already explained.

The overarching research question in this thesis is “In what manner and under which conditions can the private sector be engaged in health care as to increase the chances of an effective End TB Strategy that will achieve its targets for 2035?”

The End TB Strategy was formulated by WHO in a situation where the estimated TB incidence and deaths due to TB are very high while the targets in TB control must be achieved in a very short time. The vision of 'A world free of tuberculosis' and the goal of 'End the global TB epidemic' is not that easy to achieve especially with the current approaches and the level of efforts by the NTPs. Engaging and coordinating a multitude of diverse and unorganized health care providers, especially the private sector, is the biggest need and challenge to achieving higher rates of TB case notification and treatment success.

In order to materialize the concept of a TB-free world, WHO-projected interventions (as shown in Figure 3) such as optimal use of current and emerging tools as well as introduction of new vaccine, new drugs for treating TB disease and latent TB infection, a point of care test for diagnosing TB and pursuing Universal Health Coverage and social protection are non-negotiable. In addition, newer strategies and innovative approaches that have demonstrated success in PPM in countries like India have to be replicated and expanded in other relevant settings and countries. This would also require changes in the attitudes and approaches to the private sector especially by considering the private sector as a reality and therefore an opportunity rather than viewing it as a competitor or a barrier to effective TB control. NTPs will have to be more receptive and welcoming to partnerships and more flexible to accommodate the inherent distinctiveness and interests of the non-NTP sectors especially the

private sector. NTPs will have to demonstrate willingness to adapt to situations while the quality of care to TB patients is preserved. Appropriate and context-specific monitoring and evaluation tools will have to be developed and used to measure both quantity and quality of the contributions from the non-NTP sectors in TB control. Extensively use ICT platforms and digital tools will be required in facilitating the engagement of especially the private health sector. To achieve all these, there should be adequate resources especially funding which will be the primary responsibility of NTPs that will be supplemented by donor agencies. Introduction of new and enforcement of existing regulations to ensure standardized management of TB cases and to enable notification of all TB cases are two important areas to be given serious attention by countries. Engagement of all pertinent technical partners including medical professional associations will be key to the success of PPM interventions.

In a developing economy like India, in the background of the stark economic and social realities, achieving the End TB targets doesn't appear to be an easy task. This is mainly due to the disconnect between the public sector that controls the RNTCP and the private sector that cater to large proportions of TB patients without notifying clear majority of such cases to the RNTCP. While the public health sector is overall regulated by the government's guidelines, the private sector is often outside the dominion of these mechanisms leading to lapses in providing standardized care to TB patients. Private health

care facilities that generally exist as for-profit establishments wouldn't normally undertake public health functions of RNTCP for fear of impact on their income. Partnering with the RNTCP would necessitate the private health care facilities to either provide free services offered by the NTP or refer the patients to the public sector, either of which has direct impact on the income of private facilities. In addition, the public health activities to be undertaken as part of the national programme have costs that the private sector is naturally reluctant to bear by itself. Private sector in the usual practice considers TB as a health problem of an individual patient and therefore the private practitioners cannot be expected to spend time and resources to address the public health requirements. However, the independent operations of the private sector in TB case management leads to major public health problems impacting the whole world.

It's a global need that all TB cases are diagnosed and appropriately treated in India because a quarter of the global case load is in the country. India with a wide array of health care providers of which private sector being the biggest and most complex needs newer solutions as well as successful scale up of the proved mechanisms. Similarly, there is no 'one size fits all' solution available to engage the private sector care providers. New measures such as regulatory actions to implement mandatory TB case notification, restricting the use of non-standard diagnostic tools and drugs, subsidizing services, incentivizing patients and community, compensating non-public care

providers for their services, ensuring local ownership, using interface agencies to engage private sector and mobilizing domestic funding have to be widely employed. For achieving a dramatic progress in TB control, it is crucial to look for new solutions outside the routine national programme and boldly implement innovative approaches.

A survivor of MDR-TB in India in a meeting of the civil society consortium of India on 21 February 2017 said "When I became very sick, I didn't know what it was. I consulted many doctors in my neighborhood who repeatedly prescribed cough mixtures and general antibiotics for many weeks. When I was finally diagnosed to have TB, I couldn't believe it. I thought a person like me of higher socio-economic status can never get TB. The treatment I received didn't work and later my condition was diagnosed as MDR-TB which was a lifetime shock for me. Due to confidentiality issues, I didn't want to visit government hospitals which are often not friendly towards patients. But I had to struggle a lot a get treatment for MDR-TB as the drugs were not available in the private sector from where I sought care. They said there are restrictions by the government. I heard a lot of discussions about partnership between the government and the private sector while I was running from pillar to post for second-line TB drugs for my treatment. I, as a patient, wanted to get cured of my MDR-TB. My parents and relatives wanted to save my life. I wanted medicines from some source or other to come back to my previous life. I was not concerned about who gives me medicines. I was not

interested in the conflicts between the public and private sectors. I needed the right medicines to kill the bacteria in my lungs”

This is a loud and forceful message which tens of thousands of desperate TB patients echo around the world and especially in India. Governments, private health care providers, NGOs, technical agencies and donors anywhere in the world can no more turn a deaf ear to such messages. We need to act urgently and responsibly. We are already late by decades.

8.7 Suggestions for future research

In the past few years, several developments have happened in the area of TB control. For example, use of new and faster diagnostics, new drugs, modified drug regimens, incentives, use of digital technology and innovative approaches in implementation such as engaging informal health care providers have been introduced in TB control. Most of these changes have implications on the engagement of private sector. Future research should focus on the usefulness of these newer approaches and their contribution to improved TB control.

SUMMARY OF CHAPTERS

Chapter 1. Research problem and Research Question

This chapter presents the research problem as well as research questions in the background of a brief overview of a few aspects such as TB as a global public health problem, global and country-level efforts to control TB, TB control issues in the public and private health sectors and public-private mix in TB control as a strategy.

The overarching research question in this thesis is "In what manner and under which conditions can the private sector be engaged in health care as to increase the chances of an effective End TB Strategy that will achieve its targets for 2035?" The specific sub questions that are discussed in detail in the following chapters are the following:

- How did the TB control program of India try to engage the private sector in TB control and what has been the effect of the early PPM pilot endeavors?
- How did India scale up the pilot projects on private sector engagement in TB control to national level and what has been the learning?
- What has been the role of the Indian Medical Association in the engagement of the private sector in TB control and what is its relevance? What are the lessons for India and other countries to learn from the unique endeavor of engagement of medical professional associations in TB control?
- What has been the landscape of funding from the Global Fund, the biggest international donor in TB control, for the engagement of the private sector in TB control?

- Do prisons that house around 10 million detainees, among whom TB is a leading cause of morbidity and mortality, get adequate funding for TB control?

Chapter 2. Introduction

This chapter provides a comprehensive picture of TB disease epidemiology, multidrug-resistant TB and other comorbidities of TB, especially HIV/TB. The chapter also discusses the social determinants of TB. The various modes of diagnosis, treatment and prevention of TB are discussed in this chapter. The chapter also touches upon the ongoing global TB control efforts and explains the problems faced due to the suboptimal engagement of the private health sector in TB control. The development and evolution of Public-Private Mix (PPM) approaches in TB and the challenges faced are also discussed in adequate detail. TB control situation of India which has the highest TB burden and managed by a health system with heavy presence of private health sector is discussed. Indian TB program's long history in the engagement of private sector and the development of innovative PPM models are presented as a case study.

Chapter 3. Improving tuberculosis control through public-private collaboration in India: literature review (article published in British Medical Journal).

This chapter reviews the characteristics of public-private mix projects in India and their effect on case notification and treatment outcomes for tuberculosis. The study analyzed data from 14 projects and found

that PPM activities were associated with increased case notification, while maintaining acceptable treatment outcomes. The study recognizes that collaborations between public and private providers of health care hold considerable potential to improve tuberculosis control in India.

Chapter 4. Intensified scale-up of public-private mix: a systems approach to tuberculosis care and control in India (article published in International Journal of tuberculosis and Lung Disease). This chapter describes the processes and outcomes of the systems approach adopted in the intensified scale-up of PPM implemented by the India's National Tuberculosis Control Programme (NTP) covering 50 million population in 14 major cities. Intensified PPM resulted in a 12% increase in notification of new smear-positive pulmonary TB cases. Treatment success was above the 85% target for all sectors combined. The study concluded that the systems approach to the intensified PPM scale-up was productive, however, many challenges and barriers to scale-up of PPM in India remains.

Chapter 5: Role of professional bodies in TB control: An untold story of the Indian Medical Association (IMA) in fighting TB

The study tries to summarize the history of Indian Medical Association's approaches to the Revised National TB Control Programme (RNTCP) of India and the role IMA played in PPM in TB control of India. The study also analyzes the barriers in the IMA's journey in PPM including, reluctance and lack of experience on both

public and private sides, the ways and means through which these barriers have been addressed through the engagement of IMA, the level of success and the remaining challenges.

Chapter 6. Global Fund financing of public–private mix approaches for delivery of tuberculosis care (article published in Tropical Medicine and International Health).

This chapter maps the extent and scope of PPM interventions in TB control programmes supported by the Global Fund. The study found that fifty-eight of 93 countries and multi-country recipients of Global Fund-supported TB grants had PPM activities in 2008. Engagement with 'for-profit' private sector was more prevalent in South Asia while involvement of prison health services has been common in Eastern Europe and central Asia. In China, India, Nigeria and the Philippines, PPM contributed to detecting more than 25% TB cases while maintaining high treatment success rates. The study concluded that in spite of evidence of cost-effectiveness, PPM constitutes only a modest part of overall TB control activities. Scaling up PPM across countries could contribute to expanding access to TB care, increasing case detection, improving treatment outcomes and help achieve the global TB control targets. This study threw more light on the TB control situation in prisons. The study found that while the share of the TB budget allocated to PPM in Eastern Europe & Central Asia, and Latin America & the Caribbean is lower than in other regions, both the regions had many grants for collaboration with prison health services, which were not always reported as PPM. The study

recommended deeper analysis of PPM components of Global Fund proposals and of the performance of grants.

Chapter 7. Global Fund financing of tuberculosis services delivery in prisons (article published in Journal of Infectious Diseases):

This chapter gives the review of The Global Fund grants database to identify TB and HIV/TB grants and activities that monitored the delivery of tuberculosis treatment and support activities in penitentiary settings. The study mapped the distribution and trend of number of countries with tuberculosis prison support by year, geographic region, tuberculosis or multidrug-resistant tuberculosis burden, and prison population rate. The study found that fifty-three of the 105 countries (50%) with Global Fund–supported tuberculosis programs delivered services within prison settings. Nearly two-thirds (64%) of these grants were implemented by governments, with the remaining by civil society and other partners. In terms of services, half (36 of 73) of grants provided diagnosis and treatment and an additional 27% provided screening and monitoring of tuberculosis for prisoners. The range of services tracked was limited in scope and scale, with 69% offering only 1 type of service and less than one-fifth offering 2 types of service.

Chapter 8. Discussion

This chapter summarizes the analysis of the manner and the various conditions of private health sector engagement in view of the targets of the End TB Strategy of the World Health Organization (WHO), by drawing

relevant findings from the previous chapters of this thesis. The chapter also discusses the chances of PPM, the need for PPM, scope for innovations and adaptations in PPM, cost effectiveness of PPM, the challenges faced by PPM, lessons learnt from India and other countries and finally what does it take the End TB Strategy to meet its milestones and targets. Multiple challenges and the complex situations make it difficult for the TB programme managers to organize systematic PPM activities. In order to achieve the concept of a TB-free world, WHO-projected interventions such as optimal use of current and emerging tools as well as introduction of new vaccine, new drugs for treating TB disease and latent TB infection, a point of care test for diagnosing TB and pursuing Universal Health Coverage and social protection are non-negotiable. In addition, newer strategies and innovative approaches that have demonstrated success in PPM interventions in India and elsewhere have to be replicated and expanded in relevant settings and countries. The chapter pronounces the need for NTPs to proactively engage the private sector in order to make standardized services to all TB patients.

Nederlandse samenvatting

Hoofdstuk 1. Onderzoeksprobleem en onderzoeksvraag

De overkoepelende onderzoeksvraag in dit proefschrift luidt: "Op welke manier en onder welke voorwaarden kan de particuliere sector betrokken worden bij de gezondheidszorg om de kansen te vergroten op een effectieve “Beëindig Tuberculose-Strategie” (Engels: End TB Strategy) die zijn doelstellingen voor 2035 zal bereiken?"

Specifieke deelvragen worden in detail in de hoofdstukken behandeld:

- Hoe probeerde het Tuberculose-bestrijdingsprogramma van India de particuliere sector te betrekken bij de bestrijding van Tuberculose (TB) en wat was het effect van de eerste pogingen tot Publiek-Private-samenwerking?
- Hoe heeft India de proefprojecten over de betrokkenheid van de particuliere sector bij de bestrijding van tuberculose opgeschaald naar het nationale niveau en wat is het leerproces geweest?
- Wat was de rol van de Indian Medical Association bij de betrokkenheid van de particuliere sector bij het beheersen van TB en wat is de relevantie van deze rol? Wat zijn de lessen voor India en andere landen om te leren van deze unieke inspanning van een medische beroepsorganisatie bij TB-bestrijding?

- Wat was het financieringslandschap van het Global Fund, de grootste internationale donor in TB-bestrijding voor de betrokkenheid van de particuliere sector bij TB-bestrijding?
- Ontvangen gevangenissen met ongeveer 10 miljoen gedetineerden, waaronder tuberculose een belangrijke oorzaak is van morbiditeit en mortaliteit, adequate financiering voor TB-bestrijding?

Het inleidende hoofdstuk presenteert het onderzoeksprobleem en de onderzoeksvragen en beschrijft daarbij TB als een wereldwijd probleem voor de volksgezondheid. Verder wordt aandacht besteed aan wereldwijde en landelijke pogingen om TB te beheersen, TB-bestrijdingskwesties in de publieke en private gezondheidssectoren, en "Publiek-Private Mix" (PPM) als strategie voor TB-bestrijding.

Hoofdstuk 2. Introductie

Dit hoofdstuk biedt een uitgebreid overzicht van TB-epidemiologie, multiresistente TB en andere co-morbiditeiten van TB, met name HIV/TB. Het hoofdstuk bespreekt ook de sociale determinanten van TB. De verschillende manieren van diagnose, behandeling en preventie van tuberculose worden besproken. Voorts wordt ingegaan op de lopende wereldwijde pogingen tot TB-bestrijding en worden de problemen besproken rond de suboptimale inzet van de private gezondheidssector bij TB-bestrijding. De ontwikkeling van Public-Private Mix (PPM)-benaderingen bij TB en de uitdagingen waarvoor deze staan worden in detail besproken. De situatie met

betrekking tot TB-bestrijding in India, dat de hoogste TB-ziektelast heeft en wordt beheerd door een gezondheidszorgsysteem met een sterke aanwezigheid van de particuliere gezondheidssector, wordt in detail besproken. De lange geschiedenis van het Indiase TB-programma en de betrokkenheid van de particuliere sector en de ontwikkeling van innovatieve PPM-modellen daarbij, wordt gepresenteerd als een case studie.

Hoofdstuk 3. Verbetering van tuberculosebestrijding door publiek-private samenwerking in India: literatuuronderzoek (artikel gepubliceerd in British Medical Journal).

Dit hoofdstuk gaat in op de kenmerken van publiek-private mixprojecten in India en hun effect op de melding van gevallen en de behandelresultaten voor tuberculose. De studie analyseerde gegevens van 14 projecten en vond dat PPM-activiteiten geassocieerd waren met een verhoogde melding van gevallen, met instandhouding van acceptabele behandelresultaten. De studie benadrukt dat de samenwerking tussen publieke en private zorgverleners aanzienlijke mogelijkheden biedt om de tuberculosebestrijding in India te verbeteren.

Hoofdstuk 4. Geïntensiveerde opschaling van publiek-private mix: een systeembenadering van tuberculosezorg en -controle in India (artikel gepubliceerd in International Journal of Tuberculosis and Lung Disease)**.**

Dit hoofdstuk beschrijft de processen en resultaten van de systeembenadering van de geïntensiveerde opschaling van PPM geïmplementeerd door het Nationale Tuberculosebestrijdingsprogramma(NTP) van India, dat 50 miljoen inwoners in 14 grote steden omvat. Intensievere PPM resulteerde in een toename van 12% in de melding van nieuwe uitstrijk-positieve gevallen van pulmonaire TB. Het behandelingssucces voor alle sectoren samen lag boven het streefcijfer van 85%. De studie concludeerde dat de systeembenadering van de geïntensiveerde PPM-opschaling productief was, maar er zijn nog veel uitdagingen en belemmeringen voor opschaling van PPM in India.

Hoofdstuk 5: De rol van professionele instanties in TB-bestrijding: een onverteld verhaal van de Indian Medical Association bij de bestrijding van tuberculose.

De studie verschaft een overzicht van de geschiedenis van de benadering van Indian Medical Association (IMA) van het herziene nationale TB-controleprogramma (RNTCP) van India, en de rol van IMA in de PPM bij de bestrijding van TB in India. De studie analyseert ook de belemmeringen in de inspanningen van de IMA in de PPM. Aan de orde komen de terughoudendheid en gebrek aan ervaring aan zowel publieke als private zijde, de methoden en middelen waarmee barrières zijn aangepakt door IMA, de mate van succes en de resterende uitdagingen.

Hoofdstuk 6. Financiering door het Global Fund van publiek-private mixbenaderingen voor levering van tuberculosezorg (artikel gepubliceerd in Tropical Medicine and International Health)**.**

Dit hoofdstuk geeft een overzicht van de omvang en reikwijdte van PPM-interventies in TB-bestrijdingsprogramma's die worden ondersteund door het Global Fund. Uit de studie bleek dat 58 van de 93 landen en transnationale partnerschappen die door het Global Fund werden ondersteund in 2008 PPM-activiteiten hadden. In Zuid-Azië was de commerciële private sector meer betrokken, terwijl in Oost-Europa en Centraal-Azië de activiteiten zich richtten op gezondheidszorg in gevangenissen. In China, India, Nigeria en de Filippijnen droeg PPM bij aan het opsporen van meer dan 25% gevallen van TB, terwijl de behandelingssuccessen hoog bleven. De studie concludeerde dat PPM, ondanks het bewijs van kosteneffectiviteit, slechts een bescheiden onderdeel vormt van de totale TB-controleactiviteiten. Het opschalen van PPM in verschillende landen kan bijdragen aan de uitbreiding van de toegang tot TB-zorg, het verhogen van de detectie van gevallen, het verbeteren van de behandelresultaten en het behalen van de wereldwijde TB-bestrijdingsdoelstellingen. Deze studie werpt meer licht op de situatie van TB-bestrijding in gevangenissen. Uit de studie bleek dat hoewel het aandeel van het TB-budget voor PPM in Oost-Europa en Centraal-Azië en Latijns-Amerika en het Caribisch

gebied lager is dan in andere regio's, beide regio's veel subsidies hadden voor samenwerking met de gezondheidsdiensten in gevangenissen, die niet altijd gerapporteerd worden als PPM. In de conclusie wordt het belang benadrukt van een diepere analyse van PPM-componenten van Global Fund-voorstellen en van de prestaties van gesubsidieerde initiatieven.

Hoofdstuk 7. Financiering door het Global Fund van tuberculosebehandeling in gevangenissen (artikel gepubliceerd in Journal of Infectious Diseases)**.**

Dit hoofdstuk geeft een overzicht van de gegevensbank van het *Global Fund*-fonds om TB- en HIV/ TB-subsidies en -activiteiten te identificeren. Het gaat hierbij om subsidies en activiteiten om de tuberculosebehandeling en ondersteunende activiteiten in penitentiaire instellingen te monitoren. Het onderzoek bracht de verspreiding en trends in kaart van het aantal landen met tuberculosebestrijding in gevangenissen per jaar, geografische regio, tuberculose of multiresistente tuberculose ziektelast, en de bevolkingsdichtheid van de gevangenissen. De studie wees uit dat drieënvijftig van de 105 landen die door het Global Fund ondersteund werden diensten leverden in gevangenissen. Bijna 64% van deze subsidies werd uitgevoerd door regeringen, de rest door het maatschappelijk middenveld en andere partners. Bij 36 van de 73 verstrekte beurzen ging het om diagnose en behandeling. In 27% van de gevallen werd voorzien in screening en monitoring van

tuberculose voor gevangenen. Het bereik van de gevolgde diensten was beperkt qua reikwijdte en schaal, 69% bood slechts 1 soort dienst aan, en minder dan een vijfde bood 2 soorten diensten aan.

Hoofdstuk 8. Discussie

Dit hoofdstuk verschaft een samenvatting van de analyse van de manier en de verschillende condities van betrokkenheid van de private gezondheidssector in het licht van de doelstellingen van de End TB Strategie van de Wereldgezondheidsorganisatie (WHO). Het hoofdstuk bespreekt ook de kansen van PPM, de noodzaak van PPM, ruimte voor innovaties en aanpassingen in PPM, kosteneffectiviteit van PPM, de uitdagingen waarmee PPM te maken heeft, lessen die zijn getrokken uit India en andere landen, en ten slotte de gevolgen van de End TB Strategie om de TB mijlpalen en doelen te halen. Meerdere uitdagingen en de complexe situaties maken het voor TB-programmamanagers moeilijk om systematische PPM-activiteiten te organiseren. Om het ideaal van een TB-vrije wereld te bereiken zijn de interventies uit de WHO plannen en strategieën niet onderhandelbaar. Bij deze interventies gaat het om: optimaal gebruik van huidige en nieuwe instrumenten, evenals de introductie van een nieuw vaccin, nieuwe geneesmiddelen voor de behandeling van TB-ziekte en latente TB-infecties, een point of care-test voor het diagnosticeren van tuberculose en het nastreven van universele ziektekostenverzekering en sociale bescherming. Bovendien moeten nieuwere strategieën en innovatieve

benaderingen die succesvol zijn gebleken in PPM-interventies in India en elders worden gerepliceerd en uitgebreid in relevante omgevingen en landen. Nationale TB preventie-porgramma's dienen proactief de particuliere sector te betrekken bij het maken van gestandaardiseerde diensten voor alle TB-patiënten.

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ABBREVIATIONS

ABBREVIATIONS

AYUSH	Ayurveda, Yoga, Unani, Siddha, Homeopathy, Naturopathy
BCG	Bacille Calmette-Guerin
CBNAAT	Cartridge-based Nucleic Acid Amplification Test
CGHS	Central Government Health Scheme
CHC	Community Health Centre
CTD	Central TB Division
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment, Short-course
DRC	Democratic Republic of Congo
EECA	Eastern Europe and Central Asia
EFR	Enhanced Financial Reporting System
ESI	Employees State Insurance
HIV	Human Immunodeficiency Virus
IMA	Indian Medical Association
IMPACT	Indian Medical Professional Associations' Coalition against TB
ISTC	International Standards for TB Care
LAC	Latin America and the Caribbean
LTBI	Latent TB Infection
MDG	Millennium Development Goals
MDR-TB	Multidrug-resistant Tb
MoH	Ministry of Health
NAAT	Nucleic Acid Amplification Test

NCD	Non-Communicable Disease
NGO	Non-Governmental Organization
NSP	new smear-positive
NTP	National TB control Programme
OAEs	Own-Account-Enterprises
PHC	Primary Health Centers
PMDT	Programmatic Management of Drug-resistant TB
PPIA	Public-Private Interface Agency
PPM	Public-Private Mix
PTB	Pulmonary TB
RNTCP	Revised National Tuberculosis Control programme
SC	Sub Centre
SDG	Sustainable Development Goal
STCI	Standards for TB Care in India
TB	Tuberculosis
TOG	Technical and Operational Guidelines
UHC	Universal Health Care
UNOPS	United Nations Office for Project Services
US$	United States Dollars
WCA	West and Central Africa
WHO	World Health organization
XDR-TB	Extensively Drug-Resistant TB

A private practitioner of Unani (Perso-Arabic traditional medicine as practiced in Mughal India and in Muslim culture in South Asia and modern day Central Asia) in Jaipur city of Rajasthan, India who became a treatment supervisor for patients in his neighborhood. While he practised Unani in his clinic, he referred presumptive TB patients to the health care facilities that provided services under the Revised National TB programme of India. He was trained by the Revised National TB Control Programme of India in identifying and referring presumptive TB patients, supervising drug consumption by TB patients until their last dose and ensuring their follow up test done in time until their treatment outcome is reported.

But I have promises to keep,

And miles to go before I sleep,

And miles to go before I sleep….

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Curriculum vitae

Lal Sadasivan Sreemathy was born on 30th July 1962 in Thiruvananthapuram district in Kerala State of India. He currently works as Director, Infectious Diseases – TB Portfolio of FHI 360, a nonprofit human development organization based in North Carolina, USA. In his current position, Lal leads the global TB portfolio of FHI 360 by providing senior technical guidance and oversight to global as well as country-based programs implemented in various countries.

Lal is basically trained as a physician and he took his medical degree (MBBS) from The Government Medical College, Thiruvananthapuram, India in 1990. Lal has also done Master of Public Health (MPH) from the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, India in 1998 and Master of Business Administration (MBA) from the Indira Gandhi National Open University, New Delhi, India in 2010.

After completing his medical degree, Lal started his career as a practicing physician in 1990 and he continued it until 1997 when he secured admission to the MPH course. In the beginning of this period of seven years, he attended additional training in surgery and psychiatry after which he worked as Project Officer of a non-governmental organization. From 1994, Lal worked as a family doctor in his own private clinic. From 1996 to '97, Lal worked as an assistant surgeon in government hospitals where he had the opportunity to treat TB patients under the pilots or early phases of the Revised National TB Control Programme (RNTCP) of India based on the WHO-recommended DOTS strategy. In 1997, Lal joined MPH course which he completed in 1998.

In 1999, Lal was recruited as a TB Medical Consultant of the World Health Organization (WHO), based in South India, to provide technical assistance and supervision to the implementation of RNTCP. In this job, Lal developed some of the very early and successful models of TB - public-private mix (PPM) projects in India. After four years in this job, in 2003, Lal was selected as the National Professional Officer of the WHO, based in New Delhi, to lead the national scale up of TB - PPM in India. In this job, Lal led the engagement of private and other public sector health providers that were not collaborating with the RNTCP. He also led major economic evaluations of PPM in India. Using the data and the lessons

learnt from these initiatives, Lal has authored/coauthored various scientific articles on PPM in India. In 2007, Lal was recruited by WHO as an international officer (Technical Officer -TB and HIV) in East Timor. In this job, he led the development of the national guidelines on TB and TB/HIV and the program for management of multidrug-resistant TB patients. In 2008, Lal was recruited by The Global Fund, Geneva, where he worked in different capacities at senior manager level until 2013. While in this job, Lal published scientific papers on The global Fund assistance for PPM activities as well as TB care in prisons. In 2013, Lal moved to the USA after accepting the role as TB Technical Director of PATH.

From 2004 onwards, Lal has been a member of the WHO-led Working Group on TB-PPM and currently he is co -Vice Chair of the group. Lal also serves as a member of the Pediatric TB Working Group. From 2017, Lal is a member of the Technical Review Panel of The Global Fund and he also serves as a member of the WHO-led Digital Health Task Force. Lal has authored/coauthored several scientific articles in international peer-reviewed journals.

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