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

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# **CHAPTER 1**

## **Research Problem and Research Questions**



## 1.1 Tuberculosis: 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

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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<sup>1</sup>. 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<sup>1</sup>. 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<sup>1</sup>.

### **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<sup>2</sup>. 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'<sup>3</sup>. 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<sup>1</sup>. The strategy also targets Zero TB-affected families facing catastrophic costs due to TB by 2020<sup>1</sup>. 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<sup>4</sup>. 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<sup>1</sup>. 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<sup>5</sup>. 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)<sup>1,5</sup>. 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.



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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<sup>6</sup>.

### **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<sup>1</sup>. Majority of poor countries in the world have a large and growing private medical sector<sup>7</sup>. Consequently, private health sector

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provides care to significant proportions of TB patients<sup>1,4,7-14</sup>. In many countries, people prefer to first approach private health sector when they are sick<sup>7</sup>. Patients often prefer private health sector even where public health sector facilities are available in their neighbourhood<sup>15</sup>. 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<sup>15</sup>. 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<sup>11,16,17</sup>. In addition, significant proportions of the TB cases seen by private sector are not notified to the NTPs<sup>1</sup>. Delays or failure in diagnosing TB cases will lead to longer periods of infectiousness and increased rates of deaths<sup>18</sup>. Similarly, inappropriate or inadequate treatment of the diagnosed TB cases will accelerate the emergence of multidrug-resistant TB (MDR-TB)<sup>19</sup>. 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<sup>1</sup>. There are estimated 4.1 million TB cases that missed notification in 2016<sup>1</sup>. There is also a higher likelihood of suboptimal care received by the TB patients that seek care especially from small scale private providers<sup>11,14,16,17,20-22</sup>. 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<sup>3</sup>.

### **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<sup>23</sup>. 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)<sup>23,5</sup>.

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

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other health sectors outside MoH<sup>23</sup>. 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<sup>1</sup>. 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** <sup>15, 24, 25</sup>

Health Sector	Strengths	Weaknesses
<b>Public Sector</b>	<ul style="list-style-type: none"> <li>• Qualified staff</li> <li>• Follows international/national guidelines</li> <li>• Services are usually free of cost</li> <li>• Infrastructure and staff available for home visit of patients, follow up during treatment and retrieval of patients who interrupt treatment</li> </ul>	<ul style="list-style-type: none"> <li>• Failure to satisfy patients' needs</li> <li>• Non-availability in the neighbourhood of patients, inconvenient location</li> <li>• Often overcrowded</li> <li>• Long waiting time</li> <li>• Lack of privacy leading to stigma</li> <li>• Lack of people's faith in the system</li> </ul>
<b>Private sector</b>	<ul style="list-style-type: none"> <li>• Better and more flexible access</li> <li>• Convenient timing</li> <li>• Friendly behaviour towards patients</li> <li>• Shorter waiting time</li> <li>• Greater confidentiality and greater sensitivity to user needs</li> <li>• People trust the providers</li> </ul>	<ul style="list-style-type: none"> <li>• Multiple types of providers</li> <li>• Unqualified/informal providers and traditional healers who follow different systems of healing</li> <li>• Need not necessarily follow standard guidelines</li> <li>• Likelihood of advising unnecessary investigations and prescribing</li> <li>• Higher cost</li> <li>• Inability to perform public health functions</li> </ul>

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<sup>6</sup>.

### **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)<sup>1</sup>. 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<sup>8-10,16</sup>. India has been in the forefront in experimenting PPM pilot projects since the inception of RNTCP. Encouraged by the success of the pilot projects, RNTCP in 2003 implemented a national intensified PPM project and subsequently in 2008 started to scale up PPM at national level<sup>26</sup>.

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<sup>25</sup>. 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<sup>26</sup>. RNTCP continued to engage the private sector also by developing special schemes that included monetary compensation for the engagement of private and NGO health sectors<sup>26</sup>. 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<sup>27,28</sup>. 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<sup>28</sup>.

### **1.4 The problem**

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

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recent TB prevalence surveys in high TB burden countries indicate that the actual incidence of TB could be even higher than the current estimates<sup>1</sup>. 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)<sup>29</sup>. 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<sup>30</sup>. 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<sup>4</sup>.

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

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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

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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.

