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

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## **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<sup>1</sup>. 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<sup>1</sup>. 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<sup>1</sup>.

### **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%<sup>1</sup>. 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<sup>174</sup>. 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<sup>175</sup>. 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

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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

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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% ( $61/100 \times 83/100$  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



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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<sup>1</sup>. Those patients who received inadequate or inappropriate treatment with anti-TB drugs are likely to develop MDR-TB<sup>176-180</sup>. 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

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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<sup>78,90</sup>. Thus, these pilots demonstrated that collaboration between RNTCP and private practitioners in India improved the TB case notification while

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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<sup>181</sup>. 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

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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%,

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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<sup>182</sup>. 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<sup>107</sup>. 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<sup>81</sup>.

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- 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<sup>103</sup>. 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

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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<sup>128</sup>. 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<sup>131</sup>. 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

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private sector providers dominate the health care system<sup>27</sup>. 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<sup>166,168</sup>. 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<sup>166</sup>. The study observed that the importance and the scope of



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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<sup>160</sup>. 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<sup>159,161,164,183</sup>. The shortages in the physical environment and infrastructure of healthcare management in prisons affect the quality

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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<sup>6,184,185</sup>. 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<sup>103</sup>. In addition, PPM ensures standard care for TB as determined by the

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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<sup>1</sup>.

### **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<sup>27,186-188</sup>.

### **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<sup>79</sup>. 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

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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<sup>79</sup>. 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<sup>79</sup>.

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<sup>80</sup>. 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)<sup>80</sup>. 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

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from US\$154 to US\$132 in the 4 years following the initiation of PPM<sup>81</sup>.

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<sup>80,81</sup>.

	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<sup>80</sup>.

	Before treatment for TB	During treatment for TB	
		RNTCP	Outside the RNTCP
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.

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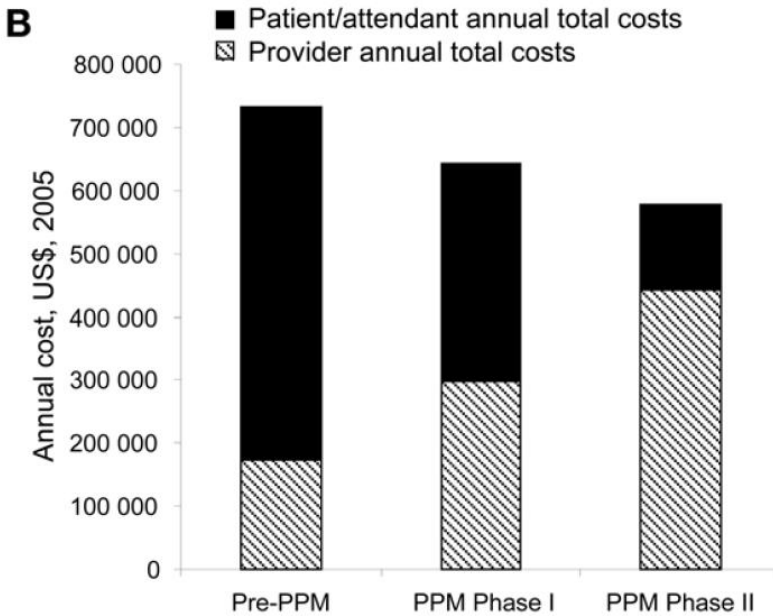
As described in the study of cost and cost-effectiveness by Pantoja et al, when both patients treated in the RNTCP and those treated outside the RNTCP were considered, implementation of PPM in two phases (Phase 1: introduction of PPM that began in mid-2001; Phase 2: intensified PPM that began in 2003)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

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)<sup>81</sup>



## **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<sup>1</sup>.

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<sup>1</sup>. 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<sup>189</sup>.

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

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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<sup>17</sup>. 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<sup>16</sup>. 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)<sup>190</sup>, traditional healers and informal providers (those without any academic qualification/license to practice) are widely spread across the country. In certain geographical locations,

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especially remote villages and urban slums, informal providers have a major presence<sup>60</sup>.

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<sup>191</sup>. 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’<sup>82</sup>. 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<sup>82</sup>. 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<sup>192</sup>. 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<sup>186</sup>.

### **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<sup>193</sup>.

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

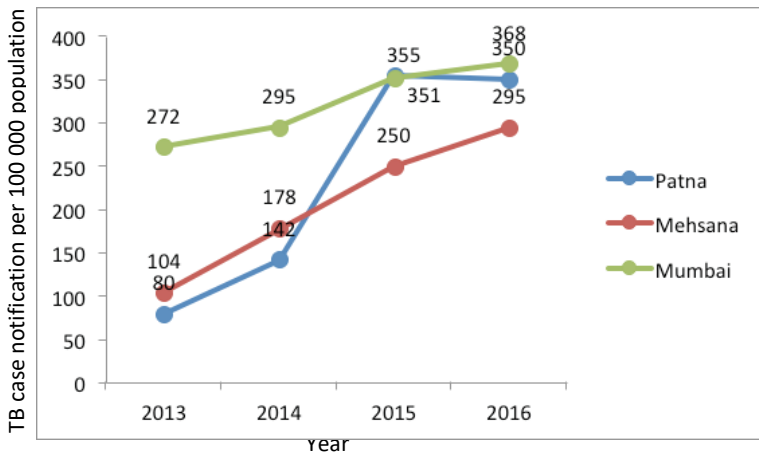
Steps were taken to control the over-the-counter sales of anti-TB antibiotics, though these actions have seen variable levels of success across the country<sup>186</sup>. Most recently, the program started providing drug regimens that can be taken daily replacing the existing thrice-weekly regimen with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

### **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<sup>186</sup>.

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



Directorate General of Health Services, Government of India)<sup>186</sup>. 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<sup>1</sup>. 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

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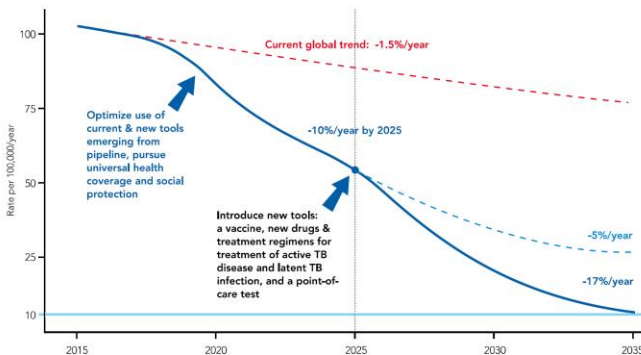
achievable in most of the high TB burden countries with the present levels of access to high-quality treatment. WHO also recognizes that ending the global TB epidemic will be feasible only if there is a dramatic decline in TB deaths and cases, elimination of economic and social burden of TB and reduction in the out-of-pocket expenditure for TB treatment<sup>1</sup>. 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<sup>1</sup>.

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.<sup>1</sup>**

**Desired decline in global TB incidence rates to reach the 2035 targets**



Source: **The End TB Strategy, World Health Organization<sup>3</sup>**

### **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. Patient 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 it 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 monetary 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

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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, it is 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<sup>1</sup>. 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?”



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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

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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

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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

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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 to 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.

