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

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# 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)<br>2. Directorate of Medical Education (Medical Colleges)<br>3. Other systems of healing (AYUSH-Ayurveda, Yoga, Unani, Siddha, Homeopathy, Naturopathy) | 1. Central Government Health Scheme<br>2. Railways<br>3. Employees' State Insurance<br>4. Mining, Coal, Steel, Ports, Prisons, Armed Forces | 1. Private hospitals /practitioners (Modern medicine or AYUSH)<br>2. NGO facilities<br>3. Corporate Industries<br>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.

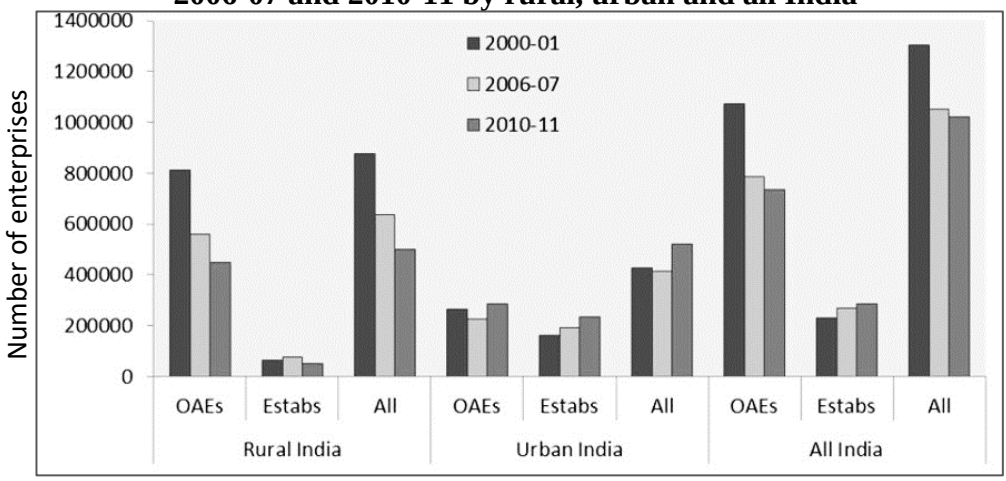
A census conducted in 62 major cities on organized health care sector in 2012 revealed that 95 percent of the total hospital facilities were private hospitals[60]. These private facilities were heterogeneous in nature and it ranged from small nursing homes to big corporate hospitals. Among the different 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.