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# OPPORTUNITIES AND CHALLENGES TO DEVELOP EFFECTIVE STRATEGIES FOR PRIVATE SECTOR ENGAGEMENT TO END TUBERCULOSIS IN INDIA



August 2017

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# ACRONYMS

<b>AYUSH</b>	Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
<b>CBNAAT</b>	Cartridge-Based Nucleic Acid Amplification Test
<b>DNA</b>	Deoxyribonucleic Acid
<b>DOTS</b>	Directly Observed Treatment-Short Course
<b>DR-TB</b>	Drug-Resistant Tuberculosis
<b>DST</b>	Drug Susceptibility Testing
<b>FDC</b>	Fixed Dose Combination
<b>GP</b>	General Physician
<b>HIV</b>	Human Immuno-deficiency Virus
<b>KII</b>	Key Informant Interview
<b>LPA</b>	Line Probe Assay
<b>MDR-TB</b>	Multidrug-Resistant Tuberculosis
<b>NQPP</b>	Non-qualified Private Practitioner
<b>PCR</b>	Polymerase Chain Reaction
<b>PEA</b>	Political Economy Analysis
<b>PPIA</b>	Public-Private Interface Agency
<b>QPP</b>	Qualified Private Practitioner
<b>RNTCP</b>	Revised National TB Control Program
<b>TB</b>	Tuberculosis
<b>WHO</b>	World Health Organization
<b>XDR-TB</b>	Extensively Drug-Resistant Tuberculosis



# EXECUTIVE SUMMARY

## Background

*Mycobacterium tuberculosis* is one of history's most successful pathogens. It causes tuberculosis (TB), a communicable disease that can affect the lungs, kidney, spine, or brain and may lead to death. Because of its communicability and devastating effect on populations, it has been the focus of attention of governments around the world. Despite significant gains in treatment and prevention, TB remains one of the top ten causes of death worldwide.

Emergence of forms of the bacterium that are resistant to modern drugs (drug-resistant TB, or DR-TB) is a cause for concern. Resistance to two of the most powerful drugs used for TB treatment is termed multiple drug-resistant TB, and to four of the core anti-TB drugs is termed extensively drug-resistant TB. Drug options for DR-TB are limited and expensive, and the treatment is prolonged.

India has the highest burden of TB in the world, accounting for a fourth of the 10.4 million cases worldwide, and an estimated 480,000 people died from TB in India in 2016. In that year, 1.75 million TB cases were notified by the country, which is much less than the expected 3.6 million TB cases per year.

The Government of India is determined to end TB and has committed to eliminate TB by 2025. India has actively been fighting TB since 1962. It began its efforts with the *National TB Program*, which was revised in 1993 – and called the *Revised National TB Control Program* (RNTCP) – to incorporate the World Health Organization (WHO)-recommended *Directly Observed Treatment-Short Course* (DOTS). *DOTS-Plus* was launched in 2007 to manage DR-TB and was expanded to the entire country by 2012-13. In 2012, the Government of India developed a *National Strategic Plan* (for 2012-2017) that identified universal access to quality TB care as a central goal. The newly drafted *National Strategic Plan* in 2017 (for 2017-2025) recognizes the need to deploy comprehensive interventions for TB elimination under four strategic pillars: Detect-Treat-Prevent-Build.

The National Strategic Plans see the private health sector as key to achieving their goal of universal access to quality TB care. The first points of contact for over half of all TB patients are private health care providers. Heterogeneous and unregulated, private health care providers have varied knowledge of the *Standards for TB Care in India*, leading to delay in initiating treatment, further spread of the disease, and drug resistance when improper dosages are prescribed. Adherence to treatment by patients is a complex, dynamic phenomenon with many factors determining their treatment-taking behavior.

## Objectives and Methodology

This study undertakes a Political Economy Analysis (PEA) of the participation of private health care providers in TB care in four states (Bihar, Gujarat, Maharashtra, and West Bengal) in India to improve understanding of how their involvement in the national program could be enhanced. In doing so, the study will provide Ministry of Health and Family Welfare and USAID with strategy options to improve cross-sector partnerships.



The broad question that the study addresses is how the private health care providers could be leveraged to meet the goals of India's TB program. PEA has been used to map the local context, actors, and key relationships. By examining the socio-political, economic, and ecological factors that affect participation of private sector providers in TB prevention and care, the study has enabled the piecing together of an analysis of the TB sector in parts of India.

At the national level, researchers gathered qualitative data through in-depth interviews using snowball sampling, a sampling methodology that relies on recommendations from initial interviewees to identify subsequent ones from whom to capture relevant views. In the capital city of the four states of interest, in-depth interviews and group discussions were conducted with identified stakeholders. Stakeholders were also asked to rank various stakeholders on the basis of their power and interest in a government reform to increase participation of private health care providers.

Researchers visited functioning public-private mix projects in the four states to interview patients, providers, and project staff to understand the drivers of health seeking behavior and how policy has a bearing on them. Throughout the interview process, special attention was directed toward understanding the dynamics and complexity of private health care providers' engagement in response to public policies and public provision of services, as well as the landscape of opportunities for enhanced public and private sector involvement in TB.

The study has limitations: Researchers visited only four locations in the country, mostly state capitals and one nearby rural area; for a country the size of India, this is only a dipstick. The findings are thus strictly true of only these locations and cannot be taken to be the norm. Because providers were approached through the public-private mix agency, only those engaged with the project were met and hence the perspective of private providers who are not engaged with the government TB program could not be explored. Similarly, the hard-to-reach and often invisible patients of TB could not be reached.

## Desk Review

A detailed desk review was carried out using the three distinct phases of the TB treatment seeking pathway as the basis. Within each phase, demand-side, supply-side, and policy-related activities were uncovered to identify key issues and actors of the ecosystem. In this way, issues that must be at the forefront of the reform agenda were delineated.

## Pre-Diagnosis Phase

Key issues among patients and the community are lack of awareness regarding TB, social exclusion faced by those with TB, and environmental factors related to distance, cost, and perception of access result in patient-led delay in seeking care.

A low index of suspicion with respect to TB, moral hazard resulting from information asymmetry, lack of awareness about diagnostic protocols among providers of first contact, and underutilization of newer and more sophisticated diagnostic techniques often lead to a delay in patients receiving care. It is crucial for the first contact provider to remain cognizant of the possibility of TB in all cases of cough as well as symptoms suggestive of extra-pulmonary TB.

Government policy is relatively silent on this phase of TB care. Implementation issues that are gradually improving but still sub-optimal include notification of TB, ineffective application of the *Standards for TB Care in India*, and the lack of recognition of informal providers in government policy. There also needs to be more support for research in this area.

## Diagnosis Phase

Social stigma associated with the diagnosis of TB, cost of diagnostic tests and related opportunity costs, and accuracy of TB tests are some of the main determinants of whether early diagnosis and resulting (timely) treatment are received by the patient. These are the key issues identified in the diagnosis phase.

Disjuncture between the focus of treatment of cough in the public and private sectors, diagnostic delay, and unavailability of inexpensive, rapid tests for TB all contribute to late diagnosis, a major cause of death in TB patients. The private sector experiences much more diagnostic delay than the public sector.

Poor adherence to diagnostic protocols, ineffectual dissemination of *Standards for TB Care in India*, ineffective administrative machinery to regulate the TB market, and lack of sufficient research and innovation for care diagnosis remain problems that must be addressed. While the policies and guidelines are clear, gaps in their implementation remain. Dissemination of important regulations such as Standards for TB care in India continue to be a challenge as practitioners in the private sector remain wary of government regulations.

## Treatment Phase

Lack of awareness about TB and its treatment protocols is a major barrier to treatment. Other demand-side hindrances include the inability of the patient to adhere to the treatment, notification requirements driving patients underground, patient discomfort with the direct observation strategy, and patients shopping for treatment among various provider options.

Supply-side hindrances include unavailability of drugs including Fixed Dose Combinations (FDCs) and drugs for treating DR-TB in the private sector, arbitrary treatment protocols in the private sector, and the qualification of the treating providers. Patients who seek care in the private sector experience a greater delay in treatment than those who first seek care in the public sector, and they often have more difficulty accessing proper drugs.

Certain issues must be kept in mind when deciding how to improve the treatment of TB patients. They include: a lack of mutual trust between public and private sector, drug unavailability, low case notification from the private sector, the authoritative attitude of the public sector, and a dearth of research and innovation in regard to the development of new drugs.

## Stakeholder Analysis

A Likert Tool was used to gather interviewees' responses on the interest and power of stakeholders. A pre-identified set of stakeholders, with an apparent or possible stake in the issue being investigated, were proposed as interviewees. Interviewees were also offered the chance to identify other stakeholders. Using the World Bank's methodology for Stakeholder Analysis, stakeholders were classified into four categories: promoters, defenders, latents, and apathetics. A stakeholder map was constructed that contains 26 categories of stakeholders, capturing the views of 27 experts at national and state level.

**Promoters:** The government and its affiliates as well as large private players and their organized bodies are heavyweights in the Stakeholder Analysis. Expectedly, those with the greatest power and influence over the reform process are the government (Central TB Division) followed by funding, technical, and implementing partners. This is matched with strong interest, indicating this group is strongly involved in the reform process as well capable of advancing or blocking it.

**Defenders:** Small chemists and small labs rank low on their ability to implement change. While patients, symptomatics, and communities attach high priority to the reform, they also rank low, as their ability to influence reform is quite limited. When the government does look to enhance partnerships, it should look into tapping the larger players first – not only will this enable them to exploit scale economies but may also prove to be the most effective way to bring about change.

**Apathetics and Latents:** Only corporate hospitals, non-health-related government ministries such as finance, and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH) practitioners attach a 'low' priority or interest to the reform.

## Patient Pathways

The track that a patient chooses from the point of first contact to the completion of treatment is known as the Patient Pathway. Patient Pathways were observed in four settings: Kolkata, West Bengal; Mehsana, Gujarat; Mumbai, Maharashtra; and Patna, Bihar.

In Kolkata and Patna, symptomatics visit Qualified Private Practitioners (QPP) in urban areas and Non-Qualified Private Practitioners (NQPP) or AYUSH doctors in rural areas as their first point of contact. In Mehsana, symptomatics visit QPPs in urban areas and AYUSH doctors in rural areas. NQPPs have not been involved in the program. In Mumbai, first contact care is provided by AYUSH doctors who then refer patients to qualified practitioners, chest specialists, and TB specialists for further treatment.

Findings of the study spanning the four states reinforced the Patient Pathway of TB care of three broad phases: the pre-diagnosis phase in which the patient attempts to locate the right treatment provider, the diagnosis phase in which a definitive diagnosis of TB is made, and the treatment phase in which the patient receives the treatment for TB. However, the study found that each of these phases is influenced by the environmental conditions in which the patient makes these personal choices.

## Political Economy Analysis

PEA maps out local context, actors, and key relationships to allow for the identification of recommendations. It enables an understanding of the socio-political, economic, and ecologic factors that affect private sector participation in TB care and prevention and helps to create a landscape analysis of the TB sector that can inform strategies to leverage relationships and actors.

**Patients:** Patients are the core individual units that represent overall demand, forming one end of the political economy dyad of patients and providers. Their behavior and decision making is influenced by the attitude and norms of their communities. Patients are also steered by their personal situation and ability to actualize the opportunities that they have, which may be modulated by factors such as financial condition and expectation of cure.

**Providers:** Providers constitute the supply aspect of the political economy of TB, and are motivated by market forces. India has a great variety of providers, ranging from NQPPs to highly qualified chest and TB specialists. Private provider incentives and disincentives are importance. The factors that steer provider choices include the need to build a reputation, retention of patients, and profits.

**Patient and provider cross linkages:** The most important cross linkage is the one between patient and provider, as it establishes the relationship between the primary actors who have the power to decide the course of the Patient Pathway. The importance of the cross linkages between the provider and the community and between the patients and the market should also be considered because these can have a significant impact on the attitudes of the provider and the behavior of patients.

**Policy:** The main function of policy is to explicitly or implicitly influence the considerations that direct decision making. Policy intervenes in the relationship between patients and providers by the incentives

and disincentives it creates. It works primarily by altering information symmetry, availability, prices, and regulations to change the decision-making considerations of patients and providers.

## Demand-side Issues

Changing community attitudes are supporting the formation of networks and helping in adherence to treatment. Although crowded urban settings make isolation of patients more difficult, they conversely engender acceptance within families and communities. As more and more people become aware that TB is curable, rural patients are increasingly willing to seek a diagnosis of TB.

Stigma and discrimination related to TB are associated with the communicability of the disease. Interviewees told researchers that the stigma surrounding TB has declined in Mehsana, Mumbai, and Patna due to increased awareness about better treatment outcomes, leading symptomatics to more readily accept a diagnosis of TB. People have fewer inhibitions about getting treated than in the past. Symptomatics have also become more open to testing of family members. Exceptions remain, such as in the case of arranging a girl's marriage or other socially sensitive situations. In contrast, interviewees reported that stigma surrounding TB remains high in Kolkata due to lack of awareness. People there are hesitant to even talk about TB in general, let alone their symptoms. Acceptance of a TB diagnosis remains low because of the fear of social exclusion. This prevents symptomatics from seeking care, especially in the public sector where information is seen as less secure.

Awareness is having a huge impact on the health seeking behavior of patients. Increased awareness has led people suspected of having TB to seek early medical care and has increased demand for diagnostic tests. In Kolkata, people do not necessarily correlate cough with TB. Their health seeking behavior is influenced by this lack of awareness and poor literacy. People often self-medicate at first. This delays diagnosis and treatment. Increased awareness often leads people to avail services of private diagnostic facilities. In Mehsana, Gujarat, quality of care in the private sector has positively affected the demand for private services, despite the availability of free services in the public sector.

Access to free, high-quality diagnostic tests in the private sector has enabled increased diagnosis by reducing delays caused by the costs associated with the tests. Provision of quality-assured free drugs in the private sector also has led to increase in demand by reducing the financial burden on patients, and in particular has given poor patients access to quality treatment. Nevertheless, the cost of seeking treatment remains high in all states, deterring routine check-ups and follow-up visits. High consultation fees charged by the private providers prevent poor patients from approaching them.

Environmental factors such as timing, distance to diagnostic centers, and distance to the private provider play an important role in determining the demand for TB services, because they may present both direct and opportunity costs for the patient, for example, those who must take time off from work and travel long distances for care. These costs are influenced by background factors such as support networks, overall financial condition, and the experience of side effects.

Support networks in the household, in social circles, and at the workplace greatly help in adhering to drug regimens and completing treatment. Adherence to treatment is critical to better cure rates. The prolonged duration of TB treatment, side effects such as nausea and acidity in many patients, and the need for patients to take time off work to rest makes it difficult for patients to complete treatment. Poor patients might have to make a trade-off between TB treatment and working to sustain themselves. Keeping the patient motivated to complete treatment was reported as a challenge in all states. Many patients discontinue treatment as soon as they begin to feel better, not understanding the need to complete a full regimen.

Better cure rates have improved willingness of people to complete treatment. Treatment completion rate in the private sector has increased to about 70 percent in Kolkata, 90 percent in Mehsana, 70 percent in Mumbai, and 74 percent in Patna.

## Supply-side Issues

Awareness of providers of first contact goes a long way to improve timely detection of TB. A lack of awareness about diagnostic protocols as well as non-adherence to Standards of TB Care in India act as barriers to timely TB detection.

The availability and accessibility of TB services determines their use. The schedules of and distance to government testing centers discourage people from using them. The private sector is seen as more accessible and convenient in Mumbai and Patna because public centers are open only during working hours and are very crowded. In Kolkata, old and defunct machines in the government hospitals have restricted public sector use. However, Cartridge-Based Nucleic Acid Amplification Test (CBNAAT) machines have been made available in the government sector in most districts in all states. Availability of alternative diagnostic procedures in private practice has resulted in a positive change. Private practitioners have begun to conduct definitive tests for TB at first contact with the patient.

Government support for TB diagnosis and treatment in the private sector has led to increased clientele for private sector practitioners. TB projects have helped boost business for first contact providers, private labs, and chemists. Associating with a national program boosts the reputation, and client load, of providers. Patients may refer their doctor to their family and friends, which leads to further increase in clientele and benefits to the provider.

Existing relationships with labs and pharmaceutical companies create a moral hazard for providers in regard to patient diagnosis and treatment. Pecuniary considerations play a role in the choice of tests and drugs prescribed. This results in an extra financial burden on the (mostly poor) patients.

The medical profession has added responsibility since there is a high level of information asymmetry between the patient and the provider. The doctor may decide not to (completely) disclose the diagnosis of TB to the patient in order to continue seeing, and charging him/her. Doctor concerns about patient stigma may also delay disclosure and thus lead to delay in treatment.

Incentivization of private providers motivates them to coordinate with the TB program. Financial incentives are critical to engaging providers and chemists because as business owners, they are concerned with profits. An increased customer base and mark-up on the cost of drugs is an enabler for them to participate in the program and align to government norms despite their busy schedules.

Rapport building by providers is crucial for early detection of the disease and treatment completion. The private health care providers interviewed in all four states also see it as a good business practice for building future clientele, though this is difficult in Kolkata, where patients are hesitant to talk about their problems and reveal symptoms of TB. Building personal relationships is difficult to do in the crowded, competitive market in which the patient buys treatment.

Some private providers work on TB treatment because they believe that it is a social good. The physicians in Mumbai and Patna view treating TB as important as doing 'social work.' They see effective treatment of TB as a way to maintain the reputation of the physician, who, as a 'good' doctor in the community, will expand his practice. For this reason, many first contact providers are self-motivated to identify and treat TB patients.



## Policy Sphere

Major gaps exist in the availability of facilities for diagnosis and treatment of TB in the private sector. The RNTCP is trying to fill those gaps by making standard diagnostic tests and drugs freely available in the private sector. Availability of and access to GeneXpert testing has helped to improve diagnostic outcomes. Although CBNAAT machines are available in all states, availability of cartridges is limited in Mehsana and Kolkata. Availability of sputum collection centers and transportation facility has also improved, which is helping close the major gaps that exist.

Timely procurement and availability of drugs is a concern in both private and public sectors. Even though free drugs are available in the public sector, some patients buy them from the private sector because of ease of access. Stock-outs in the public sector have reduced confidence in public sector systems. Treatment of DR-TB is the preserve of the public sector; DR-TB cases diagnosed in the private sector are referred to the public sector for treatment.

Most patients seeking TB care lack the financial capacity to get complete treatment in the more expensive private sector. Thus, making diagnostic tests and drugs in the private sector free helps patients to seek care as well as to adhere to treatment.

While increasing the number of free services for TB in the private sector is good, the private sector was found to be largely unsupervised in its practices in all areas. Although regulation of the private sector is weak, often leading to misdiagnosis, incorrect treatment, and lack of follow-up in the heterogeneous private sector, efforts are being made to regulate the sector and align it to government norms to achieve the goals of the End TB strategy.

Considerable efforts are being made by the government in three of the four states to engage with informal providers. Private sector participation in TB diagnosis has been strengthened. Advocacy, Communication, and Social Mobilization projects are being run by the government, and funds are allocated to states to conduct these campaigns and initiatives. The government is working closely with an interface agency to manage TB and address trust issues between public and private sector highlighted specifically in Bihar and West Bengal.

## Recommendations

The study provides an analysis of information and wisdom gathered from stakeholders in four settings of public-private partnership initiatives. These can be used to inform strategy and policy formulation.

Policy tools can be used to alter the incentive-disincentive equilibrium between patients and providers by explicitly and/or implicitly altering the considerations that direct decision making by both. Policy has recourse to four primary tools to do this: information, availability, pricing, and regulation. These are discussed in the section that follows.

### Addressing Information Asymmetries

- **Awareness generation:** Important messages for greater awareness are that successful TB treatment leads to better survival rates; that strong medicines are used in treatment that knock out strong bacteria; and that TB patients must be cared for so that they can go back to work. Spreading awareness about TB will increase the number of patients who seek treatment and encourage community support for people on TB treatment, enabling more people to complete the full course of treatment.

- **Patient counseling:** Information that would be useful includes awareness about the dos and don'ts of TB; the need for getting tested; the availability of supplementary drugs and nutrition supplements at low cost; and need for follow-up and adherence. Proper patient counseling could support early diagnosis and prevent further transmission of the disease.
- **Reminder messaging for patients:** These have been put in using phone/ web technologies in each of the models studied and have been successful. Reminder messaging is presently being carried out in all four project sites with good results. The use of technology needs to be continued and expanded to cover future private sector initiatives.
- **Provider education:** All providers should be educated in the Standards of TB Care in India. Platforms to showcase private provider efforts to adopt diagnostic and treatment protocols are needed to encourage more providers to work on TB. Success of TB treatment leading to better survival rates due to private doctors' initiatives should be showcased as further encouragement for providers. Expansion of the market of private providers who have built their reputations from successfully treating TB should be emphasized, as should their participation in a social and national good. This could lead to gains both in the pre-diagnosis and the treatment phases of the disease.

### Availability of Diagnostic and Treatment Services

- **Capacity expansion:** Recognizing the important role that first contact providers play in screening patients with TB from a larger set of respiratory and other conditions is required for the successful implementation of TB care and prevention. Conditional payments to first contact providers who make a definitive diagnosis of TB may be a worthwhile investment against disease spread.
- **Listing of private health care providers:** Private health care providers value their connections with the government sector. By listing providers who have completed a short course on Standards of TB Care in India, practical benefits in terms of better compliance with diagnostic and treatment protocols could be realized.
- **Diagnostic sample transportation:** Patients living far away from the district headquarters are unlikely to be able to make use of free diagnostic services such as CBNAAT. The feasibility of using a hub-and-spoke model to collect diagnostic material and transport it to a hub for testing should be considered. Another solution might be to increase the total number of CBNAAT machines in order to meet an exploding demand for the test.

### Pricing of Services

- **Subsidized diagnostics:** Greater compliance and early diagnosis was reported in projects where subsidy was provided. Making diagnostics available for free to patients in the private sector would greatly aid in early diagnosis and notification of the disease.
- **Free or subsidized treatment:** By the same count, greater numbers of patients are likely to begin and complete their treatment if its financial burden were reduced.
- **Patient adherence incentive:** Programs such as the Beti Bachao campaign provide for incentives to families, which are held in escrow until the desired result (girl attaining majority) achieved. A similar conditional cash transfer program could be considered for TB to overcome the opportunity costs that patients incur during treatment. We recommend that rewards should be linked to adherence beyond the intensive phase.

- **Nutritional supplements:** Nutritional supplementation has been shown to significantly improve patient outcome especially as many patients are poor and undernourished. There have been calls from the Prime Minister's Office to begin such supplementation, which is a feature of programs against HIV and AIDS and Severe Acute Malnutrition among under-five children. Supplements may be worthwhile investments, possibly through tie-ups with corporations under Corporate Social Responsibility initiatives.
- **Physician's treatment completion incentive:** Incentives to physicians for ensuring that their patient completes treatment would compensate for the additional demands put on them by the program, as well as for the reporting costs incurred. This would make private practitioners much more inclined to take a more active role in TB care and prevention.

### **Strengthening Government Regulation and Systems**

- **Uniform definitions of diagnosis and treatment closure:** Appropriate indicators for definitive diagnosis of TB and closure of treatment should be established because it is important to have data that depict consistent information. Consistent definitions for diagnosis and treatment closure in both public and private sectors would add confidence to comparisons made between these datasets.
- **NIKSHAY initiative:** This initiative will help to eliminate duplication in listing of TB patients especially if linked to a unique ID number such as Aadhar, which is widely available. This is critical so that reliable numbers of those on treatment can be gathered and dropping out of treatment can be tracked.
- **Reserve the use of bedaquiline:** Ensuring rational use of bedaquiline is critical to the success of India's TB care and prevention efforts. There should be a framework regulating its use for treatment of DR-TB in both the public and private sector.
- **Management of private sector initiatives:** Extending and expanding private sector initiatives through third-party administrators are recommended. It is clear that the management burden of including the private health care providers is considerable. By taking the support of third-party administrators, the government system would be responsible primarily with managing them, rather than the tens and thousands of individual providers. Operational learning from present-day pilots could be an important resource.

For India to successfully end TB, effective policies to involve private health care providers will play a decisive role.



# I. TUBERCULOSIS IN INDIA

A communicable disease, tuberculosis (TB) is caused by the bacterium *Mycobacterium tuberculosis* that attacks the lungs or other parts of the body such as the kidney, spine, or brain. If not treated properly, TB can be fatal. With recorded evidence of TB of over 6,000 years and sobriquets such as “the captain of death,” TB is counted among the most successful pathogens in history (Divangahi et al. 2010). TB is a long-haul disease; its treatment and care requires both pragmatism and astuteness. Airborne transmission makes TB highly communicable. When a person has been exposed to someone with TB disease and has breathed in the TB bacteria, that person may become infected with TB. If a person with latent TB infection does not take preventive medicine, the bacteria may grow and cause active TB disease. TB symptoms may include a constant cough that lasts two or more weeks, chest pain, weakness, and loss of appetite. When a person has active TB disease in the lungs or larynx, the individual may be contagious and cause infection in other people, particularly those with whom they spend the most time.

TB in colonial India was a result of social conditions and practices that made people susceptible to the disease: poor housing, spitting in public places, multiple people eating from a common utensil or sleeping in the same room, shutting off openings meant for light for the sake of purdah, and low per-capita consumption of dairy and meat (Neelkantan 2017). These social determinants have not changed much.

In addition, the bacteria that cause TB sometimes become resistant to the drugs used to cure it. Multiple drug-resistant tuberculosis (MDR-TB) is a form of TB in which there is a resistance to two of the most powerful drugs that are used for TB treatment, and extensively drug-resistant tuberculosis (XDR-TB) is a form in which there is resistance to four of the core anti-TB drugs. A person with active TB disease needs to take several TB medicines for months in order to become well and not infect others. Treatment options for drug-resistant tuberculosis (DR-TB) are limited, and the duration of treatment is even longer, and more costly than that for drug-susceptible forms (Winston and Mitruka 2012).

Estimates of epidemic extent have expanded despite gains made in a global reduction in deaths and incidence of the disease. In 2015, there were an estimated 10.4 million new cases of TB worldwide of which 1.0 million (10 percent) were among children. People with HIV accounted for 1.2 million (11 percent) of all new TB cases (WHO 2016). Six countries, India among them, accounted for 60 percent of the new cases in 2015. There were an estimated 580,000 cases of MDR-TB in the same year with India and the Russian Federation, accounting for 45 percent of them. Although the number of deaths fell by 22 percent between 2000 and 2015, TB is one of the top ten causes of death worldwide. An estimated 1.4 million patients died of TB during 2015 and an additional 0.4 million deaths resulted from TB among persons living with HIV (WHO 2016).



## I.1 Landscaping TB in India

India has the highest burden of TB in the world, accounting for a quarter of the 10.4 million cases worldwide and the death of an estimated 480,000 of the country's people (WHO 2016).

By 2015, India had achieved the *TB Millennium Development Goals* and *STOP TB* target of 50 percent reduction in TB prevalence and mortality due to TB. India is a signatory to the *Sustainable Development Goals*, which have the backing of the World Health Assembly. It has further endorsed the *End TB Strategy* that calls for a world free of TB, with measurable aims of 50 and 75 percent reduction in incidence and related deaths, respectively, by 2025; corresponding reductions of 90 and 95 percent by 2035; as well as zero catastrophic expenditure due to TB (WHO 2013a). The *National Strategic Plan 2017* outlines a new vision for 2020 that places emphasis on bold and innovative strategies to significantly reduce TB burden in India by ensuring universal access to quality-assured TB care as per *Standards for TB Care in India*.

India's response to TB began with the *National TB Program* in 1962 with universalization of the BCG vaccine at a time when there was little in the way of treatment of TB in the country. The program brought little appreciable change to the situation of TB. Commentators have ascribed this to inadequate funding for program activities, over-reliance on X-ray for diagnosis, interrupted drug supply, and low rates of treatment compliance (Ministry of Health with Family Welfare 2017a). Soon thereafter, the country began what is termed 'conventional chemotherapy,' but this ended when advanced drugs such as Rifampicin and Pyrazinamide became available in 1986.

In 1993, TB was declared a global health emergency and India designed a *Revised National TB Control Program* (RNTCP). The RNTCP was expanded in its second phase to include the entire nation in March 2006. In RNTCP phase II, the country sought to consolidate gains already achieved, initiate services to address TB-HIV co-infection and MDR-TB, and extend the RNTCP to the private sector. The RNTCP II adopted the World Health Organization (WHO)-recommended Directly Observed Treatment-Short course (DOTS).

*DOTS-Plus* was launched in 2007 for the management of DR-TB in India. It refers to a DOTS service with additional elements for DR-TB. Limited progress between 2007 and 2009 led to the introduction of *DOTS-Plus* guidelines in 2010. The RNTCP planned to make DR-TB services available across India by the end of 2011; *DOTS-Plus* (now referred to as the "Programmatic Management of Drug Resistant TB") met that target in 2012-13. The services were integrated into the main RNTCP services at the local level (Ministry of Health and Family Welfare 2011).

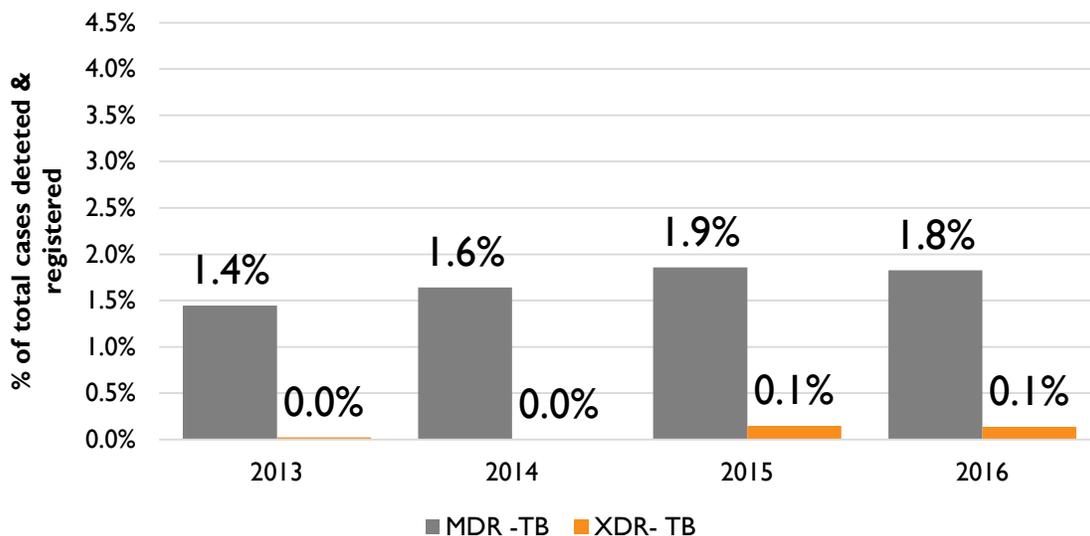
DOTS has five components:

1. Sustained political and financial commitment in terms of adequate resources and administrative support.
2. Diagnosis by sputum smear microscopy.
3. Short course anti-TB drugs given under direct observation to ensure adherence through the entire course of treatment.
4. Uninterrupted supply of drugs supported by a robust national TB program.
5. Monitoring of individual patients to ensure complete treatment for every patient.

In addition to the five main components of DOTS, DOTS-plus emphasizes the importance of expanding laboratory capacity including microscopy and culture/drug sensitivity testing, treatment design, adherence to difficult regimens for long periods of time, side-effect management, drug procurement, enhanced reporting, and identifying human and financial resource constraints. DOTS-Plus has been shown to strengthen the basic DOTS strategy to fight the more complex cases of MDR-TB (Ministry of Health and Family Welfare 2011).

The RNTCP has resulted in impressive improvements in terms of people diagnosed and treated for TB. In 2016, the RNTCP notified 1.75 million TB patients from the public and private health sectors combined and an additional 33,820 DR-TB patients (Ministry of Health and Family Welfare 2012). As Figure 1 shows, there has been a creeping increase in the number of DR-TB cases in the past four years, after an initial flat base rate over the years 2000-2012.

**Figure 1: DR-TB Cases Detected and Registered**



During the pendency of the RNTCP, the government has undertaken several initiatives that are set out in the National Strategic Plan 2012-2017. The aim of the plan is to achieve universal access to quality TB diagnosis and treatment. It was under the RNTCP that ‘Patient Wise Boxes’ were developed; they contained the full course of treatment in an attempt to ensure that the patient did not interrupt treatment for lack of drugs. A robust electronic surveillance system ‘NIKSHAY’ has been put in place to record and report patient-level information from both public and private sectors (Ministry of Health with Family Welfare 2015). Guidelines, i.e., the Standards for TB Care in India, have been developed and adopted to unify diagnosis and treatment procedures for public and private sector alike. TB was declared as a notifiable disease through Gazette notification dated 7 May 2012, and since then private providers nationwide have notified nearly 230,000 TB patients. Innovative approaches, including interface agencies and e-voucher systems for free drugs, have been put in place as successfully pilots to engage more private providers and improve quality of care (Ministry of Health with Family Welfare 2012).

The RNTCP sees the private health care providers as an important ally in the fight against TB, ensuring that its policies recognize the role that those providers could play in supporting government efforts. Budgetary provisions for working with private providers are 5 percent of the total RNTCP outlay in accordance with National Rural Health Mission norms. To this end, the government has put in place specific strategies to engage with the sector since 2002. The *National Guidelines for Partnership* established in 2014 lists a variety of ways in which private providers' capacities could be used for better TB outcomes. Among these are efforts to undertake advocacy and community mobilization, diagnosis and treatment, dealing with TB co-morbidities, and supporting program management. All these schemes have substantial incentives for activities such as conducting advocacy activities, case finding, case notification, and supporting and reporting treatment completion. A Public-Private Mix Coordinator is to be appointed to every state and district and is responsible for the full expansion of the scheme (Ministry of Health with Family Welfare 2014).

In 2015, an RNTCP Joint Monitoring Mission was undertaken by government officials and national and international experts. Its report (Ministry of Health with Family Welfare 2015) noted that the RNTCP is underfunded, and the gap between the allocation of funds and the investment needed to reach the goals of the National Strategic Plan is growing. The RNTCP will require Rs. 15,000 million per year to achieve the targets of the National Strategic Plan and achieve the goals of the End TB Strategy. Instead, yearly allocations have, in fact, been much below the RNTCP's budget requests. In addition, the length of the chain of disbursements leads to delays in funds reaching the district level.

More specifically, during the first three years of National Strategic Plan implementation, i.e., 2012-2015, budget allocations to the RNTCP remained unchanged at the Rs. 7,100 million level and then dropped in FY 2015-2016 to Rs. 6,400 million. This is because, in 2014, the Ministry of Health and Family Welfare slashed the health budget citing a fiscal deficit and underutilization of funds as the prime reasons. Thus, while the RNTCP demonstrates a high financial absorption capacity in terms of the actual amount received, expenditure remains much lower than the original budgetary demands at the start of the year.

Despite the many achievements of the RNTCP, the Joint Monitoring Mission 2015 observed that the National Strategic Plan (2012-2017) was not on track, and that several challenges in addition to financing remain. Firstly, despite putting NIKSHAY<sup>1</sup> in place, the problem of delayed data entry and incomplete records persists, in particular because the system captures patients mostly in the public sector. Even though the number of cases notified from the private sector has shown an increasing trend, only a small proportion of private providers actually participate in notification (see Figure 2 in the next section). Secondly, procurement and supply chain management continues to be problematic with delays in the procurement of GeneXpert systems for diagnosis, bad storage conditions for drugs, and limited capacity of states on procurement in case of emergencies. The report specifically mentions the ten-month stock-out of GeneXpert cartridges in Andhra Pradesh. Lastly, the report highlights that the lack of engagement of the program with the private providers is still a huge gap.

The Joint Monitoring Mission 2015 noted that many challenges remain in the engagement of the public sector with the private one as it seeks to build and draw upon private sector capacities to improve TB outcomes for patients receiving care in the private sector. The mission found that 70 percent of TB patients first approach private sector services and that the majority of diagnoses are made within it – however, most of these go unreported in the existing TB notifications. Further, a cross-sectional community-based survey in 30 districts found that nearly half of self-reported TB patients are missed by TB notification systems in these districts (Satyanarayana et al. 2011). Although government declarations and programs have expressed commitment to working with the private sector since 2002, this has not worked as well as was hoped. Challenges recognized include limited resource allocation, lack of

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<sup>1</sup> NIKSHAY is a web-based solution for monitoring TB patients and ensuring effective functioning of the RNTCP.

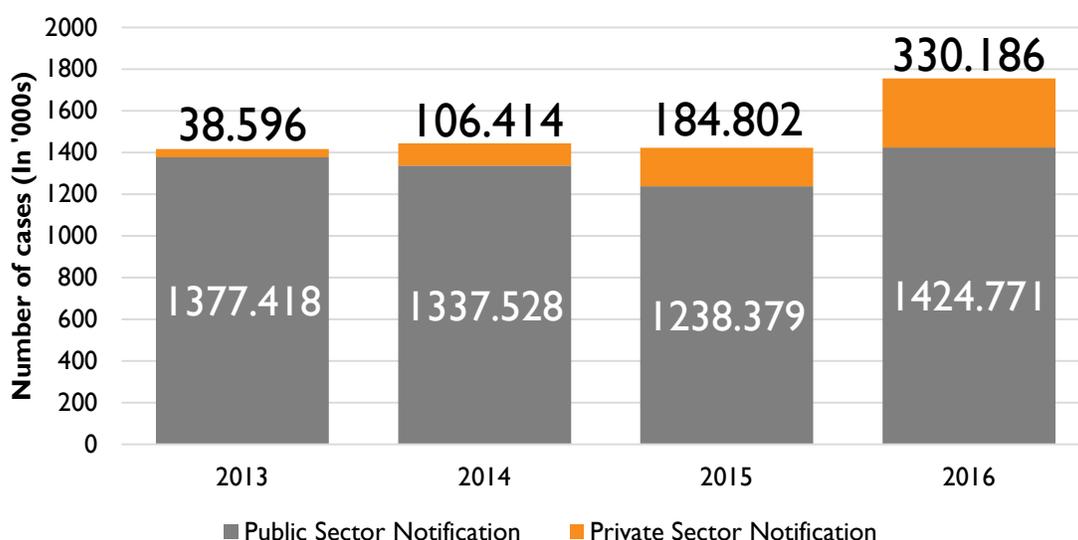
competencies in managing the public-private interface, and lack of an institution that could act as a medium between the government and private sector providers.

The National Strategic Plan proposed for 2017-2025 has been built on the success of and learning gained from the last National Strategic Plan and states that even though considerable efforts have been made to scale up basic TB services in the public health system by treating more than 10 million TB patients under RNTCP, the rate of decline is too slow to meet the 2030 Sustainable Development Goals and 2035 End TB targets. It is suggested that new comprehensively deployed interventions are required to accelerate the rate of decline in TB incidence. Therefore, four strategic pillars of “Detect-Treat-Prevent-Build” have been integrated for moving toward TB elimination (Ministry of Health with Family Welfare 2017b).

## 1.2 The Private Sector

Through the RNTCP, the Indian government is making efforts to ensure the maximum case finding and state-of-the-art TB treatment; however, the public sector alone cannot detect and treat enough TB to ensure its prevention and care. In order to meet the Sustainable Development Goals and the End TB goals, a deepened engagement of the private sector in TB care and treatment is essential. Figure 2 depicts the number of TB notifications from the public and private sectors since 2013.

**Figure 2: TB Notifications from Public and Private Sector**



The private sector in India is extraordinarily heterogeneous, with fully qualified specialist providers at one end of the spectrum to providers from other systems of medicine, and non-qualified private practitioners (NQPPs) at the other; not only this, the market is further fragmented by the range of institutions varying widely in size and sophistication. Nonetheless, this sector remains the mainstay of outpatient care in India (Hazarika 2011).

The Government of India's National Strategic Plan (2012-2017) identifies 'Universal Access to Quality TB Care' as its central goal. A key approach to achieve this is the involvement of and engagement with the private health sector. The National Strategic Plan aims to strengthen the public-private mix with the explicit targets to achieve (i) prompt reporting of TB cases diagnosed in the private sector to the RNTCP, (ii) increased number of TB cases referred to the program, and (iii) improved quality of care in the private sector. It notes that the RNTCP will engage with and involve the private sector "at a scale commensurate with their dominant presence in the healthcare in India." The National Strategic Plan recognizes that "as patients seeking care usually first visit private providers," effective engagement with these providers will reduce delays and limit transmission, capturing TB cases at their initial points of care (Ministry of Health and Family Welfare 2017a). With this background, the document acknowledges the need for private sector engagement for TB prevention and care, noting that "In order to reach the universal access for TB it will be necessary to make the participation of the private sector effective in order to be able to obtain information on notification and treatment success rates from this sector." It makes it clear that it recognizes the importance of engaging with the private health care ecosystem in order to achieve its goals, and puts this partnership at the forefront of the government's policy agenda.

Adherence to the long course of TB treatment is a complex, dynamic phenomenon with a wide range of factors impacting patient's treatment-taking behavior. Therefore, allowing flexibility for doctors to prescribe the drugs that they think best suit the individual patient needs would ensure high-quality care and improved adherence in the private sector. Recognizing the importance of NQPPs, often referred to as 'quacks,' and Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH)<sup>2</sup> doctors as the first point of contact is inescapable. It is crucial to recognize them as key stakeholders in any public-private mix strategy toward TB care and prevention. Other key stakeholders are the private laboratories and X-ray facilities. Transactional relationships ensure that the private sector is well knit and add complexity to interventions in this space.<sup>3</sup>

Regulation of the private sector providers is weak, although there have been many efforts to regulate and consolidate the marketplace. Numerous studies have documented persistent evidence of misdiagnosis, incorrect treatment, and lack of follow-up among the heterogeneous (and largely unregulated) private providers (Udwadia et al. 2010). Studies suggest that the diagnostic and care pathways before the patients reach a DOTS center are too costly, long, and complex to follow, which leads to pre-diagnosis loss to follow-up in TB patients. These issues are further compounded by the absence of drug availability controls, leading to drug resistance. Some patients were previously required to take as many as seven or eight pills per day, negatively impacting adherence (Gautam and Saha 2008). The use of Fixed Dose Combinations (FDCs) is prevalent in the private sector. The use of FDCs in drug regimens has reduced the pill burden and also reduced the chances of irrational drug prescriptions.

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<sup>2</sup> AYUSH doctors have received government-accredited training in India's traditional systems: Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy.

<sup>3</sup> KII-9

In sum, the private sector is the first point of care for more than half of the patients with TB.<sup>4</sup> It has been argued that strategies to prevent TB through public sector health services will have little impact if inappropriate management of TB patients in private clinics continues unabated, and ignoring the private sector could particularly worsen the epidemic of MDR and XDR forms of TB in particular (Udwadia and Moharil 2014). Although a proportion of patients might eventually get treated in a public facility, patients have been shown to almost always approach a private practitioner first. Many of these private practitioners have little, if any, knowledge of the Standards for TB Care in India. By the time patients receive appropriate treatment for the disease, they may:

- Have transmitted TB to several others
- Be financially exhausted
- Have developed DR strains of TB

There are several instances where private-public partnerships have been effective. A recent experience from Practical Approach to Lung Health pilot project implementation, funded by the Government of Kerala, has shown that a clear treatment protocol, good-quality training, and continuous supervision and monitoring among the private providers has rationalized the prescribing practices and improved the quality of care for chronic respiratory disease patients (Rakesh et al. 2016).

Another example of a successful public-private mix model is the Private Provider Interface Agency (PPIA) model launched in 2013. In Mehsana, Mumbai, and Patna, the PPIA is working to strengthen the capacity of private practitioners in slum areas to ensure early and accurate diagnosis of TB. PATH is acting as the PPIA in Mumbai to increase the private sector's role in achieving universal access to TB services in partnership with local community-based organizations. These organizations have set up registration desks at hospitals for patients diagnosed with TB and provide benefits such as generating electronic vouchers for patients to receive free testing, medicines, and reminders via text messages and phone calls to take their medicines. Their staff also provides counseling to TB patients and their families (Nair et al. 2015). This model of engagement has led to increasing treatment success rates by improving adherence to treatment regimens and providing psychological support to patients.

Efforts of USAID's Health Finance and Governance project to improve the effectiveness and efficiency of TB service provision are pertinent. In Kyrgyzstan, where over-hospitalization was the norm for TB care, the project has helped the government transition to a more efficient output-based payment system for TB hospitals. By paying TB hospitals more to treat contagious or difficult-to-treat DR cases, and less for simpler cases, the new payment system has helped shift patients to WHO-recommended full outpatient treatment, wherever possible.<sup>5</sup>

In sum, it is well accepted that the private sector is massive and heterogeneous. It is also known that the services provided by it are of highly variable quality. Yet it continues to dominate the market and continues to be the preferred choice for patients with a cough who may have TB.

The most recent National Strategic Plan (2017-2025) acknowledges the important role played by the private sector and proposes to address patients seeking care in the sector in order to achieve its goals. The new scheme will have suitable incentives for private doctors and patients to report TB cases coupled with another scheme to provide free of cost medicines to TB patients going to a private provider (Ministry of Health and Welfare 2017a).

Political Economy Analysis (PEA) has been identified as the preferred tool to examine how the participation of the private sector in India's TB program can be enhanced.

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<sup>4</sup> KII – 4,8,11,13

<sup>5</sup> Health Finance: <https://www.hfgproject.org/focusing-health-financing-end-tuberculosis/>. Accessed April 1, 2017.

## 1.3 The Study Process

PEA examines the forces that create a particular developmental or governance challenge and identifies opportunities and actors that drive change locally. It must be appreciated that the terms ‘political’ and ‘economy’ are not independent of each other. Simply put, PEA examines political actions and strategies through the lens of economic institutionalism, with the main focus on key actors, their interests, and what enables or hinders their cooperation (Acosta and Pettit 2013).

PEA is a tool that is well suited for the task at hand; it differs from other context-specific methodologies with its focus on understanding why the context exists in its current form and how power is manifest and transferred by actors within it. PEA maps out the local context, actors, and key relationships and allows for identification of recommendations to better engage the private sector to improve the quality of TB diagnosis, treatment, and care. By examining the socio-political, economic, and ecological factors that affect private sector participation in TB prevention and care, PEA enables the piecing together of a landscape analysis of the TB sector and informs strategies that can leverage relationships and actors.

The broad question that the study addresses is how the private sector can be leveraged to meet the goals of India’s TB program. In keeping with the PEA approach, several issues that require enquiry with each set of actors are as follows:

- Explore the social, economic, and political barriers and enablers to achieve the End TB Strategy in India.
- Identify influencing factors that have the potential to improve private sector engagement to prevent TB in India.
- Provide recommendations to the program on how to overcome barriers to End TB in India through private sector involvement by reducing the burden on India’s most poor and vulnerable populations, reducing existing inequalities posed by the TB burden, and reducing TB-affected people treatment costs, income loss, and overall financial household burden.
- Provide recommendations for advocacy efforts, policy actions, economic strategies, stakeholder engagement and strategic partnerships to advance TB political commitments through private sector engagement.

To understand the workings of the private health care ecosystem, researchers visited functioning public-private mix projects in four cities of four states to meet with patients, providers, and project staff to understand the drivers of care seeking behavior and how policy has a bearing on them. A detailed interview guide, which includes all of the questions that were asked in stakeholder interviews, enabled us to explore the areas outlined in the PEA approach; this is attached at Annex A.

Researchers visited only four locations in the country; for a country the size of India, this is a limiting factor. Each of the locations visited was an urban area (mostly state capitals), although a rural area close by was visited in one location. The findings are thus strictly true of only these locations and cannot be generalized to the entire state. Because providers were being approached through the agency of the project, only those engaged with the project could be met and hence the perspective of private providers who are not engaged with the government TB program could not be explored. Similarly, the hard-to-reach and often invisible patients of TB could not be reached.

Despite the limitations listed above, the visits proved very valuable and form the basis of the findings that follow in Chapter 3.

## 2. DESK REVIEW

Engagement with the private sector is crucial to strengthen outcomes of the TB program in India. As the government strengthens its resolve to engage, it must identify opportunities and limitations to do so, allowing it to fine-tune its policies and strengthen the mechanisms of private sector delivery. The purpose of this desk review is therefore to understand the political economy of the TB scenario and policies that facilitate or impede relationships between the public and private sectors.

PEA has been used to attain a deeper understanding of the actions and motivations of key stakeholders involved in TB diagnosis and treatment and to determine how these various actors influence outcomes.

Researchers developed a simple analytical framework by which to organize the PEA desk review. It uses a matrix of two typologies. The first consists of three distinct phases in the TB patient pathway: the pre-diagnosis phase, diagnosis phase, and treatment phase. Second, each of these phases has a set of activities: demand-side, supply-side, and policy sphere. This framework of phases and activities is used to delineate and present the issues that must be at the forefront of the reform agenda, and the actors who may support or resist it.

### 2.1 Pre-Diagnosis Phase

The onset of symptoms suggestive of TB and the pathways that determine when, where, and how patients seek medical care have implications for the planning of TB care and treatment. An early diagnosis of TB is the first, and perhaps the most critical step to TB prevention and care is widely recognized as the most important way of preventing transmission and lowering incidence. The National Strategic Plan recognizes that while the program has “consistently achieved” WHO-recommended targets of case finding, TB incidence is not decreasing rapidly enough – and that the early and timely identification of all TB cases is a pre-requisite for effective disease prevention and care.

#### 2.1.1 Demand-side Issues

**Key actors:** Communities, patients, symptomatics, treatment providers such as general physicians and informal providers, DOTS providers

**Key issues:**

- Lack of awareness among the community regarding TB
- Social exclusion related to TB
- Environmental factors related to distance, cost, and perception of access

Examining TB patients, as well as those showing symptoms and the larger community to which they belong, is pertinent to understanding the demand for TB care in the pre-diagnosis phase. The pathways of care that symptomatics (persons with symptoms suggestive of TB, i.e., cough for two weeks or more; fever especially at night; weight loss and loss of appetite) are likely to follow in the event of ill health shed light on the types of interventions and initiatives that could be deployed on the ground in order to generate demand and increase awareness about TB care. The role of the community as a whole in determining these pathways, through institutional mechanisms such as community norms and group behavior, is an important determinant of health seeking behavior.

A feature of the RNTCP is that it allows persons with symptoms of TB, such as persistent cough, to choose not only their pathway and preferred destination to seek care, but also their own time. But studies have documented that the patient often either misses or disregards symptoms (Mistry et al. 2016). Delay in detecting TB and initiating treatment not only lowers the chances of effective treatment, but also increases the chances of spreading the infection through the community (Frieden 2004). Raising the ‘index of suspicion’ of TB among symptomatics is thus a significant challenge to tackling TB.

A study collected information on the health seeking behavior of 234 new sputum positive patients in Tumkur (Karnataka) and identified ‘patient delay’ as an important hindrance to early TB detection (Kumar et al. 2016). The study found that at the onset of TB symptoms (predominantly persistent cough), only 54 percent of patients went to a health care facility (government or private), with a median delay of 15 days. Similarly, a study conducted in Mumbai found a median delay of eight weeks among 64 percent of TB patients; another study among 656 persons with symptoms of persistent cough at Ranchi observed significant patient delay (more than 30 days) among 76 percent of respondents (Samal 2016; Shamim et al. 2015).

The literature identifies many factors behind this patient delay, chiefly that patients often don’t take their symptoms seriously (Mistry et al. 2016). Other reasons include reliance on self-treatment using over-the-counter medication, financial constraints, going to alternative non-specialized treatment providers first (quacks, alternate medicine, etc.), low awareness about the disease, and the perception that TB is a poor man’s disease. A study in Delhi about treatment seeking behavior of patients found that some of the patients who sought services from informal providers (as the first source of medical care) also sought a second opinion from either chemists or other informal providers repeatedly before going to a qualified practitioner (Mistry et al. 2016, Muhammed et al. 2015, and Uplekar et al. 1998). Even after seeking medical care from a qualified practitioner, some went back to informal providers (Kapoor et al. 2012).

Another important cause for patient delay is stigma. Since TB carries a strong negative image in the eyes of society, patients with symptoms might resist seeking care for fear of social exclusion if diagnosed with TB. The way people treat those with TB, especially close contacts, is also a source of worry to patients (Saad, Tirkey, and Khan 2016). Societal stigma arises mostly out of fear of contracting the infection from TB-infected individuals, and has been documented to have serious socio-economic consequences, particularly for women’s health seeking behavior (Courtwright and Turner 2010). In some communities, female TB patients and women who are suspected of having active TB are likely to be divorced, sent back to their parents’ homes, and have fewer chances of getting remarried (Wasibord 2005).

Provider-led delay in the pre-diagnosis phase may also occur, especially if the provider of care at first contact is unable to distinguish prospective TB cases from other cases with TB-like symptoms. Since the association of persistent cough with ‘nothing serious’ prompts most people to get themselves checked by a general physician (GP) and not a specialist, GP lack of awareness about TB slows the cycle of TB diagnosis and treatment (Pai 2016).

The RNTCP National Guidelines for Partnership 2014 recognize that there is an unmet need for advocacy, communication, and social mobilization to support ongoing TB prevention and care efforts in several districts. Through appropriate interventions, the government aims to mobilize local political commitment and resources for TB, empower people and communities affected by TB, and reduce stigma and discrimination against people suffering from TB and their families. It further notes that Panchayati Raj institutions, self-help groups, faith-based organizations, community-based organizations, and other NGOs can play a facilitating role (Ministry of Health and Family Welfare 2014).

Generation of ‘demand’ therefore is an important element of TB prevention and care. Patna is good example of how different stakeholders like the NGOs, drug shops, and individual doctors can be engaged on a continuous basis to support the government in conducting awareness campaigns and interventions at the level of the community. Organizations such as Ajeevika have worked in areas with a large migrant population on awareness building and communication.<sup>6</sup> In Rajasthan, under Project Axshya, volunteers go from house to house creating awareness about TB and identify and refer those with two or more weeks of cough for sputum examination. Albeit difficult, volunteers under this project have been able to collect sputum samples from symptomatics residing in remote areas or from those who are otherwise unable to travel (Ministry of Health and Family Welfare 2016).

## 2.1.2 Supply-side Issues

**Key actors:** Doctors of first contact in small and corporate hospitals, NQPP, small and corporate chemists

**Key issues:**

- Low index of suspicion with respect to TB
- Moral hazard
- Lack of awareness about diagnostic protocols among providers of first contact
- Underutilization of newer and more sophisticated diagnostic techniques

In the pre-diagnosis phase, when patients are experiencing symptoms but do not recognize, or are denying, the seriousness of their condition, they do not differentiate between different treatment providers and are most likely to go to the one who is most easily accessible.<sup>7</sup> Segmentation does not take place in this phase; GPs, family physicians, AYUSH doctors, pharmacists, and informal providers all might be the first point of contact for many persons with symptoms of TB (Slama et al. 2013). From the point of view of the provider of first contact, what they are dealing with is persistent cough, for which there is a variety of possible causes that range from simple postnasal drip to sarcoidosis. It is not uncommon for pulmonary TB to be misdiagnosed as pneumonia.

Pharmacists then come into the picture, either as the next step to the doctor’s prescription, as a second point of reference, or for self-medication. If either of the two – doctor or pharmacist – fails to recognize TB and/or refer TB patients to appropriate facilities, the Patient Pathway gets disrupted. The systematic development of a differential diagnosis for cough would help not only the doctor in correctly detecting prospective TB cases, but also the patient who can then take the necessary steps in a timely manner.

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<sup>6</sup> KII-12

<sup>7</sup> KII-8



In this phase, then, it is crucial for the first contact provider to be aware about treating cough in a particular manner. A study of diagnosis behavior in Chennai found that among private practitioners who saw patients with cough lasting more than two weeks in the week prior to being interviewed, only 52 percent sent more than 5 percent of these patients for TB laboratory testing (Murrison et al. 2016).

With doctors attempting to detect TB early and an increasing reliance on newer diagnostic techniques in the market, the nexus between doctors and private labs that provide these tests sometimes results in a moral hazard. TB diagnosis is one area in which physicians actively advocate expensive testing methods to their patients in place of other, less expensive tests that may be equally conclusive (Pai 2013). The private labs doing these tests may, upon successfully meeting referral quotas, share a certain proportion of profits with the prescribing doctor. Another problem is that private practitioners often doubt that sputum-based diagnosis and a few drug treatment options, supposedly meant for resource-starved state facilities, are in the best interests of their patients; they therefore prefer other testing methods (Uplekar, Pathania, and Raviglione 2001). Depending upon the context and the socio-economic background of patients, some GPs even pitch themselves as specialists to the wider community, acknowledging that their ability to do so is the result of the setting in which they practice, as spotlighted by our discussions.

Limited awareness about diagnostic protocols and a low index of suspicion among the providers of first contact are some other issues on the supply side.

Incorrect diagnostic protocols manifest themselves in two main ways: (i) continued use of serological tests despite explicit policy directive against them, and (ii) underutilization of sputum smear microscopy and overuse of chest X-rays. This could be the result of low awareness among providers about the RNTCP guidelines regarding TB diagnosis. Even when they suspect TB, most private health care providers send patients for X-rays and blood tests, and do not recommend sputum testing. This absence of uniformity in diagnostic practices prevents prompt TB diagnosis. A study notes that underutilization of sputum microscopy and over-reliance on chest radiography is an important factor behind poor case diagnosis of TB (Bhargava et al. 2011). It also estimates that despite the WHO issuing a policy against the use of serological tests and efforts of the Indian government to ban the manufacture, import, distribution, and use of serological test kits for the diagnosis of TB in 2012, “an estimated 1.5 million TB serological tests are done in India alone every year at an expenditure conservatively estimated at US \$15 million per year” (Bhargava et al. 2011). This is despite the fact that the positive predictive value of sputum smear result is more than 90 percent, while that of chest X-ray is around 66 percent (Balasangameshwara and Chakraborty 1993).

The National Strategic Plan notes: “In a community survey in Uttar Pradesh, patients with prolonged cough visited the private sector, where a ‘blood test’ was commonly requested compared to the sputum test that ought to have been done.” It further notes that chest X-rays are “non-specific,” and can result in “over-treatment” and “ineffective serologic blood tests.” In fact, these ineffective TB serological tests are not even licensed in most countries and their widespread use in India has caused “patient harm” (Ministry of Health and Family Welfare 2012). Serological tests are meant to diagnose TB by looking for antibodies in the blood sample. However, detecting antibodies in the blood is extremely difficult and has low sensitivity and specificity. Commercial serological tests for TB such as the Anda-TB IgG have been banned due to variable results, saving countless persons from inaccurate test results and unnecessary expense.

Similar findings were made by a survey of 228 private health practitioners in Chennai between 2014 and 2016 (Murrison et al. 2016). The study evaluated the practices of these providers for ten Standards for TB Care in India standards and found that the median rate of adherence was four, concluding that their TB management practices, including the diagnostic protocols were “heterogeneous” and “suboptimal.”

Moreover, only 25 percent of all private practitioners used culture or molecular testing for patients with clinical suspicion of TB.

Discussions with experts on TB care in India reveal contrasting beliefs on the need for these actions. While some experts felt that the private sector did not lack knowledge regarding RNTCP guidelines and that training them would at best be a supplementary and secondary activity, some also shared the lack of willingness on the part of the private sector to attend capacity-building sessions. For an international training to which over 100 doctors were invited, only 17 turned up.<sup>8</sup> Non-attendance could be attributed to doctors' reservations about suspending his/her practice for days to attend training and thus losing daily earnings.

Further, there is little awareness about the availability of different tests in the market (Purohit et al. 2015). For instance, discussions for this study revealed that GeneXpert is not a test that the average physician would be aware of. Also, while the test itself may be easy to administer, technicians to administer it are not commonly available.

A low index of suspicion for TB among health care providers is another important issue that impedes TB prevention and care. A study of 175 practitioners in Mumbai found that though all the physicians reported seeing at least one patient with typical TB symptoms for more than two weeks in the preceding year, the patient had to visit a doctor several times before s/he was 'suspected' of having TB. The patients were treated with broad-spectrum antibiotics and drugs for other symptoms during the first few visits, usually a period of 10-14 days (Pai 2013). Symptoms sometimes recede with antibiotics, creating a false sense of complacency.<sup>9</sup> Efforts to raise providers' index of suspicion take place sporadically, and the response from the private sector has not been enthusiastic. Further, clinicians express hesitation in diagnosing their patients and suggesting TB tests as there is a fear that they will lose the patients and their credibility will be affected.<sup>10</sup>

### 2.1.3 Policy Issues

**Key actors:** Central TB Division, Drug Controller of India, funding and implementing partners

**Key issues:**

- Government policy relatively silent on this phase in TB care
- Poor track record on notification of TB
- Ineffective application of Standards for TB Care in India
- No recognition of the role of informal providers in government policy
- Insufficient research in this area

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<sup>8</sup> KII-9

<sup>9</sup> KII-7

<sup>10</sup> KII-8

The RNTCP's strategy and program design is committed to finding cases early in the course of disease. The main tools that government can employ in the policy space are availability, price, and regulation. The National Strategic Plan (2012-2017) identifies better case finding as a "priority of this plan" with the objective of early detection of 90 percent of all TB cases. It states that "the core of the current RNTCP approach to case finding is the identification of people with continuing cough of two weeks in public health facilities, and referral of chest symptomatics for sputum smear microscopy at a decentralized, quality assured microscopy centers" (Ministry of Health and Family Welfare 2012). This policy focus ties in with the Standards for TB Care in India that categorically state that "any person with symptoms and signs suggestive of TB including cough for longer than two weeks, fever for longer than two weeks, significant weight loss, hemoptysis, and any abnormality in chest radiograph must be evaluated for TB" (Ministry of Health and Family Welfare 2012). The RNTCP Guidelines also recommend active screening and intensified case finding among high-risk groups. In May 2012, India declared TB to be a notifiable disease. This was done with the aim of improving the collection of patient care information by requiring all private doctors, caregivers, and clinics treating a TB patient to report every case of TB to the government.

Since in this phase we are dealing with 'TB-like' symptoms and not actual TB – not until diagnosed – government policy is fairly silent as compared with its active role in the pricing, availability, provisioning, and regulation of different aspects of TB diagnosis and treatment in the succeeding two phases. While effective engagement of private providers is recognized as a key measure to enhance early case detection, the RNTCP has been abysmally poor at doing that. This poor engagement shows in two specific ways: (i) private health care providers are often not aware of the Standards for TB Care in India; and (ii) private providers and the public system have weak linkages that result in failures of implementation (Satyanarayana et al. 2015).

Lack of proper case notification in the public sector is another challenge that offsets the benefits of early detection to some extent. In 2011 in RNTCP, although 953,032 patients were diagnosed as sputum smear-positive, only 844,920 patients were registered, a gap of over 100,000 patients. Evaluation of these defaulting patients found that many were untraceable, had died, or had taken treatment from the private sector. Many patients had not even collected their test reports and there was no system to trace them (Ministry of Health and Family Welfare 2012).

Much of the care at first contact is provided by NQPPs or by GPs belonging to allopathic or other systems of medicine. A study in Maharashtra of treatment behavior of practitioners found that patients' first point of contact constituted more non-allopath practitioners with a recognized qualification in one of the indigenous system of medicine than allopaths (Uplekar et al. 1998).

Mention of informal providers and chemists is not found in government policy as it leans more toward a dichotomous understanding of health care, dominated by the public and the private sector. It has yet to incorporate these key providers into the fold of policy making, and devise strategies to effectively use them (Kapoor et al. 2012). Their importance as points of first contact means that they could be involved (keeping in view legal constraints) so as to widen the coverage of RNTCP services and ensure early diagnosis of TB.

Research is crucial to improve case detection through informal and formal private providers. Critical questions include the incentives in this sector for identification of cases, methods to ensure a high index of suspicion, and prescription practices in the pre-diagnosis phase among others.

## 2.2 Diagnosis Phase

The second phase of the patient pathway is diagnosis. The accuracy of the TB test serves as one of the main determinants that facilitate early diagnosis and timely treatment. The accuracy of the test is based on its sensitivity (its ability to detect people with TB) and specificity (its ability to detect people who do not have TB). Tests that are used for TB diagnosis fall into the following categories:

1. **Sputum Smear Microscopy:** This is the mainstay of diagnosis in the RNTCP. Sputum is a thick fluid that is produced in the lungs. A sample of sputum is collected by asking the person to cough deeply to produce the fluid. This is the recommended TB test in countries with a high rate of TB infection. Sputum smear microscopy is relatively inexpensive and easy to carry out. The test results are available within a few hours. The specificity index of this test is high; however, the sensitivity is only about 50-60 percent.
2. **Chest X-ray:** X-ray was the test of choice in the early days of the TB program. Unfortunately, other diseases resemble TB on X-rays and are also liable to be misinterpreted. Therefore this test is neither very specific nor very sensitive and needs to be supplemented by other tests.
3. **Line Probe Assay (LPA):** Rather than directly visualizing the bacteria that cause TB, or the effects of TB on lung architecture, LPAs indirectly detect the presence of *M. tuberculosis* by amplifying the DNA (deoxyribonucleic acid) present in the sputum by PCR (polymerase chain reaction). These tests have been shown to have high specificity and sensitivity including the facility of detecting both Isoniazid and Rifampicin resistance, the marker of MDR-TB. However, they are difficult to use and require highly sophisticated equipment and training levels to be effective. Hence, they require national- or state-level laboratories for use.
4. **CBNAAT/GeneXpert:** CBNAAT is a cartridge-based fully automated NAAT (nucleic acid amplification test) that allows rapid and accurate detection of TB and MDR-TB. It also has better sensitivity in detecting TB co-infection in HIV patients. The accuracy of CBNAAT is significantly higher than sputum smear microscopy. CBNAAT uses a sputum sample and can give a result in less than two hours. It provides a much faster way for diagnosis in comparison with culture, which is a slow and cumbersome process. The usage of CBNAAT increases accuracy and reduces time lag in detection, allowing initiation of early and appropriate treatment. Its downside is that the test is expensive and requires sophisticated equipment that is difficult to maintain. While the cost of the test is as high as US\$17, the Bill and Melinda Gates Foundation, PEPFAR, and USAID have jointly subsidized it to bring down the cost of the test to US\$9.98.
5. **Culture:** This continues to be the gold standard of diagnosis. Both the specificity and sensitivity index of culture is high. However, a major disadvantage with the culture test is the time it takes to deliver the results, which ranges from four to 12 weeks. Also, a culture is expensive, as it requires special sophisticated infrastructure.

Thus, some tests are accurate but expensive, others require a long time to provide results, and yet others require significant laboratory investments. The detection of TB, MDR-TB, and XDR-TB require continued attention. What is urgently required is a simple, and inexpensive, point-of-care testing solution for TB detection.

## 2.2.1 Demand-side Issues

**Key actors:** Patients, symptomatics, DOTS providers

**Key issues:**

- Social stigma associated with a diagnosis of TB
- Cost of diagnostic tests and related opportunity costs

Demand in the diagnostic phase is largely determined by the providers whom patients access; patients are doctor-led with regard to TB diagnosis. Thus diagnostic protocols that are followed are a function of provider advice rather than by patient choice.

An important determinant of the provider-patient interaction is the stigma that a diagnosis of TB carries (Courtwright and Turner Norris 2010). Diagnostic protocols prescribed by NQPPs and GPs of first contact are often determined by the perception of self-stigmatization by patients. Hence, diagnosis with a specific test for TB is often postponed as other differentials of cough are worked through.

De-stigmatization of TB could boost the demand for TB diagnostics; this may be the basis of the use of celebrities such as Sh. Amitabh Bacchan, a TB survivor, as brand ambassador for the RNTCP. In addition to the involvement of celebrities as brand ambassadors, panchayats could be sensitized and involved in awareness generation and stigma reduction related to TB (Ministry of Health and Family Welfare 2012).

Several environmental factors may affect the level of demand for TB diagnostic facilities. Cost, for instance is a significant factor. Cost includes the cost of the tests themselves, cost of transportation and miscellaneous costs incurred during the day, and so forth. Patients also have to bear the loss of their daily earnings because of their inability to work that day. Inputs from various experts indicate that the timing and distance of government testing centers may preclude their use.<sup>11</sup>

## 2.2.2 Supply-side Issues

**Key actors:** Individual doctors, doctors in small and corporate hospitals, pulmonary physicians, small and corporate labs, small and corporate chemists

**Key issues:**

- Disjuncture between focus of treatment of cough in public and private sectors
- Diagnostic delay
- Unavailability of inexpensive, rapid tests for TB

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<sup>11</sup> KII-8

One of the major reasons identified for death of TB patients is late diagnosis. It is well documented that a delay in diagnosing TB patients results in high level of infection in the community. Delay may also lead to a more advanced disease state, and in turn further spread of the disease and overall mortality. Diagnostic methods used in the public and private sectors seem disjointed. With its focus on reducing TB, the public sector assumes every cough to be TB unless proven otherwise, whereas the private sector looks for 'lesser' reasons, to reduce patient inconvenience and fear. As one expert pointed out, the chance of a cough being due to TB is one in 20.<sup>12</sup>

A study in Tumkur, Karnataka, identifies "diagnostic delay" as the delay faced by a TB patient and defines it as "the time interval between the onset of symptoms and labelling of the patient as a TB patient (TB diagnosis)" (Kumar et al. 2016). Important reasons for the delay are high expenditure on consultations before initial diagnosis and choosing to consult private health facilities.

Of course, diagnostic delay also is attributable to the delay in patients presenting themselves at any health care facility, but once this has been done, it is often found that many patients are not recognized as potential TB patients and therefore not offered or directed to efficient diagnostic testing. As an example, a study of smear-positive TB patients in Bangalore found that they had already visited an average of three health care providers before being correctly diagnosed (Pantoja et al. 2009). Similarly, a study conducted in the slums of 15 high-TB burden administrative wards in Mumbai found that there was a delay of 15 days or more from the time that the patient had first contacted a (any) health care provider to the time that s/he had received a diagnosis for TB (Mistry et al. 2016). Given this delay, it is reasonable to conclude that a significant proportion of TB patients fall off the patient pathway, dropping out of care during the diagnostic phase. MacPherson et al. (2014) identify this as "loss to follow-up during diagnostic period." Of all the sources of delay among the TB patient pathway, diagnostic delay has been found to be the most significant.

Availability of new technologies with respect to TB detection is a huge breakthrough in accurate TB diagnosis. Availability of tests like LPAs that aid the detection of DR-TB and GeneXpert are likely to improve the accuracy of diagnosis. Moreover, while TB tests are getting simpler, they continue to be expensive in the private sector – an important barrier to access by most patients. While GeneXpert is available for free in the public sector, private providers charge about Rs 1,800 for this test (Puri et al. 2016). Facilities equipped for testing are expensive to set up and if sharing of costs can be done by consortiums or nodal labs (and then be used on a revenue-sharing basis), this will provide economies of scale.<sup>13</sup> Another important challenge is ensuring the availability of effective, high-sensitivity diagnostic centers, particularly in poor, urban areas.

A study by Satyanarayana et al. (2015) describes that private practitioners rarely prescribe sputum microscopy test for their patients even if they suspect TB. Discussions with experts in TB care in India suggest that private health care providers often hesitate to diagnose TB, because of the stigma and a patient's fear of social exclusion. Patients themselves are often in denial and the private doctors fear that they will 'lose their patients' if they mention TB. By the time either side begins to accept the possibility of the disease, there has already been significant delay.<sup>14</sup>

Many private practitioners eventually refer patients to government hospitals, but this is often done after much delay, leading to increased cost to the patients and unsuitable treatment (Uplekar and Rangan 1993). This further strengthens the need for the RNTCP to engage more actively with the private health sector, including training them better to suspect TB.

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<sup>12</sup> KII-9

<sup>13</sup> KII-10

<sup>14</sup> KII-8

Even as facilities for sputum smear microscopy have greatly expanded under the RNTCP, the diagnosis of DR-TB continues to be of concern. Bhargava et al. (2011) note that facilities for culture and drug susceptibility testing (DST) in India are “grossly inadequate.”

### 2.2.3 Policy Issues

**Key actors:** Central TB Division, Drug Controller of India, funding and implementing partners

**Key issues:**

- Poor adherence to diagnostic protocols
- Ineffectual dissemination of Standards for TB Care in India
- Ineffective administrative machinery to regulate the TB market
- Lack of sufficient research and innovation for case diagnosis

The RNTCP was established with a target of detecting at least 70 percent of new smear-positive TB cases and curing 85 percent of these. With the advent of the National Strategic Plan (2012-2017), this has been revised to a new and ambitious target of “early detection of 90 percent of all TB cases.” This redefining of its goal of universal access has put the pre-diagnostic and diagnostic phases at the center of the RNTCP’s agenda. The National Strategic Plan lays out the commitment of the RNTCP to strengthen engagement with the private sector. It proposes to do this through a range of activities including the development and promulgation of Standards for TB Care in India, utilization of the existing health infrastructure, subsidizing quality TB diagnostic testing at private labs, social marketing of TB drugs, and flexible treatment options for private providers as per standards. Additionally, the RNTCP aims to establish systems for evaluation of new TB diagnostics and to support the establishment of minimum performance standards for licensure of TB diagnostic tests (Ministry of Health and Family Welfare 2012).

While the policies and guidelines are clear, gaps in their implementation remain. As per the Standards for TB Care in India, the first protocol for diagnosis of TB is a quality-assured sputum test with at least two samples. Chest X-ray should only be used as a screening tool and not for confirmation. Serological tests are banned and the tuberculin skin test and Interferon-gamma Release Assay (IGRA) are not recommended for diagnosing active TB. CBNAAT is preferred in the case of children and people living with HIV (WHO 2014). However, most private sector practitioners do not follow these diagnostic protocols. The signs of cough or fever are not taken to be TB in the first instance and the patients are initially treated with antibiotics. Only if the symptoms persist are chest X-rays recommended (Satyanarayana et al. 2015).

Dissemination of the Standards for TB Care in India is another challenge. These describe 26 standards of care regarding TB dealing with issues ranging from testing and screening of TB to addressing counseling needs (WHO 2014). However, a study conducted to review the knowledge of health care providers with regard to the standards showed major knowledge gaps. Adherence to the standards was found to be better in the public sector than in the private sector (Satyanarayana et al. 2015).

A concern expressed by several experts is that the government's 'stick' approach is a fundamental barrier to collaboration between private and public sectors. Private providers are often wary of RNTCP requirements, finding its documentation 'cumbersome.' An important strand that emerged from these discussions is that the government must see the private sector as partners and not agencies to regulate – and that a 'carrot, not stick' approach must be adopted so that they can be encouraged and trained to follow the established Standards for TB Care in India.<sup>15</sup>

At the same time, however, it is important that the program be strengthened. As the Pre-Conception and Pre-Natal Diagnostic Techniques Act gives the State the legal authority to intervene in the workings of private providers to attain a pre-defined goal, or as National AIDS Control Organization has worked on HIV tests to ensure that all HIV testing is standardized, the RNTCP needs to have stronger, more formal rules of engagement with the private sector that allow it to reasonably enforce its requirements.<sup>16</sup>

Examples of the research questions of concern in this phase of the patient pathway are how to introduce economies of scale into case diagnosis, and easier and cheaper algorithms for case diagnosis.

## 2.3 Treatment Phase

The third and final phase of the TB patient pathway is treatment. Once the patient is diagnosed with TB and told the diagnosis, s/he is in the treatment phase and the treatment must be initiated and continue as per the accepted standards of care. TB treatment is both time consuming and protracted.

### 2.3.1 Demand-side Issues

**Key actors:** TB patients

**Key issues:**

- Lack of awareness about TB and treatment protocols
- Inability of the patient to adhere to the treatment
- Notification requirement driving patients underground
- Patients uncomfortable with direct observation strategy

Lack of awareness among people about TB and TB treatment protocol is the most fundamental challenge in this phase. Not only does this directly affect demand generation, it compounds other issues as well. Two important consequences emerge at this stage of the patient pathway: (i) pre-diagnosis loss to follow-up, and (ii) loss to follow-up during treatment.

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<sup>15</sup> KII-4,5,10

<sup>16</sup> Engaging the Private Sector in TB Control: <http://www.thehindu.com/opinion/open-page/engaging-the-private-sector-in-tb-control/article5820015.ece>. Accessed April 1, 2017.

Pre-treatment loss to follow-up is defined as those individuals who are diagnosed as having TB but drop out of care *before* initiating treatment (MacPherson et al. 2014). This phenomenon is widely recognized as a prominent weakness in TB care initiatives and perpetuates the infection among those around the patient. It is estimated that an untreated smear-positive patient on an average can infect about 10 contacts annually and over 20 during the natural history of the disease until death (Thakur and Murhekar 2013). Studies have shown high rates of mortality among TB patients who test smear positive but don't initiate treatment (Squire et al. 2005). These patients present the additional challenges of failure to identify and count them – leading to an under-reporting of the severity and scale of the TB problem (Harris et al. 2009).

Many patients fail to initiate treatment for various reasons. The predominant one is low awareness. Another is high perceived treatment-related costs, especially for patients going to the private sector. These include the financial costs incurred for TB diagnosis and treatment, as well as the psychological and social costs associated with a long treatment process, adherence to the drug regimen, and simply being a TB patient. A common misconception that negative smears exclude TB also results in patients not getting the required treatment (Aslami et al. 2015; Kala, John, and Logaraj 2016).

For TB patients who do start treatment, it is not unusual that they fail to complete the treatment. Even within the public sector, TB patients go 'missing' after diagnosis. This loss to follow-up during treatment is defined as the phenomenon of patients dropping out of treatment *after* it has begun. It leads to the compounded challenges of relapse, treatment failure, or treatment after default – all of which are even harder to treat than original cases. The National Strategic Plan recognizes that decreasing the number of and improving the treatment outcomes for those previously treated for TB remains a significant challenge and notes that "one specific challenge is to decrease default among retreatment cases, which are currently more than twice that among New Smear Positive TB cases" (Ministry of Health and Family Welfare 2012).

Seventy-two percent of patients with TB were found to have been evaluated at government health facilities; 60 percent were diagnosed with TB, 53 percent started TB treatment, and only 39 percent achieved one-year recurrence-free survival (Subbaraman et al. 2016).

From the point of view of the patient, several reasons for failure to continue treatment emerge. Low awareness about the severity of the disease and the potential benefits of treatment, requirement for hospital attendance, the length of treatment and need for repeated visits, long waiting periods at clinics, inability to take time off from work and the opportunity costs involved in doing so, distance to the health facilities, and disease-related factors such as weakness and lethargy are some prominent reasons why TB patients often drop out (Bagchi, Ambe, and Sathiakumar 2010; Munro et al. 2007). Even when health care and diagnostic tests are available for free in the public sector, since most TB patients go to the private sector, the process also becomes costly. One way of ensuring that those diagnosed with TB take the next step toward treatment is to reduce these costs and time involved.

Treatment adherence also relates to patient compliance with TB testing and not only the drug regimen. Follow-up sputum microscopy – which needs to turn negative from positive after the initial two months of treatment – needs to be carried out again if it returns positive. Patient willingness to adhere to this system may also be a cause for concern, especially in areas where diagnostic centers and labs are located at a distance. Further, stigma associated with TB also has an impact on treatment adherence. Studies have shown that persons who default from treatment are ashamed of TB and are more likely to believe that it was a 'shameful disease,' and that receiving prescriptions for a larger number of medications was linked to greater shame (Comolet, Rakotomalala, and Rajaonarivoa 1998; Woith and Larson 2008). In a study of barriers to treatment adherence in Thailand, even though the association between perceived stigma and missed doses was minimal, felt experiences of stigma increased the rate of missed dosage among females and HIV-co-infected patients (Kipp et al. 2011).

Another issue is the low demand for case notification by patients and doctors. In a study in Pune about case notification in the private sector, many private practitioners expressed concern over case notification and public health staff visiting patients' homes to initiate treatment, especially without consent. Their concerns were a loss of patient confidentiality as well as a loss of trust and rapport between doctors and patients (Yeole et al. 2015). Similar studies point to the conscious decision by doctors of not notifying their patients to the government, fearing a privacy breach of their patients, discrimination against them by the community, and stigmatization and social ostracization of certain patients particularly unmarried females (Philip et al. 2015; Thomas et al. 2016).

Additionally, patients find the DOTS strategy uncomfortable and an invasion of privacy. Those patients who take DOTS particularly in public facilities face problems of travelling long distances to the health centers, inconvenient schedules, and mistreatment by the health services staff. This is seen to be better at private health care clinics where patients get more privacy, flexibility, and proximity to care, which points to the weakness of patient-centeredness in the DOTS program (Bhargava et al. 2011; Yelappa et al. 2016).

### 2.3.2 Supply-side Issues

**Key actors:** Individual doctors, doctors in small and corporate hospitals, small and corporate chemists

**Key issues:**

- Shopping for treatment
- Availability of drugs including FDCs in private sector
- Arbitrary treatment protocols in the private sector
- Qualification of treating providers

Kumar et al. (2016) compute 'treatment delay' as the time interval between the TB diagnosis and initiation of anti-TB drugs. Taken together with diagnostic delay, this constitutes the health system delay in the patient pathway. The researchers found that there was a longer health system delay when patients first consulted private providers compared with a government provider. Uplekar and Rangan (1993) found that many private practitioners ultimately refer patients to the government sector, but late and often after incomplete and inadequate treatment.

Mistry et al. (2016) attribute the bulk of the delay found in initiation to "referral-related movement." They found that in a survey of 15 high-TB burden wards in Mumbai, the majority of the patients with treatment initiation delay had been diagnosed with TB in the private sector but shifted (or were shifted) to the government sector for treatment initiation. This shift was also seen from non-allopathic doctors to allopaths (Mistry et al. 2016).

One of prime concerns for the treatment of TB is timely procurement and supply of drugs. Procurement and supply management is particularly important in TB prevention and care (Ministry of Health and Family Welfare 2012), because an interrupted supply of drugs is essential for TB treatment and care. The private TB drug market in high-burden countries including India is substantial, stable, and complicated. The reliable availability of drugs at private sector retail drug outlets suggests that they could be harnessed for TB prevention and care. The National Pharmacy Association could also be engaged in the National TB Program to ensure an uninterrupted drug supply to patients (Konduri, Delmotte, and Rutta 2017).

FDCs have advantages of their own like simplifying treatment by streamlining logistics management, preventing the occurrence of DR-TB, and reducing cost and pill intake for patients (Bloomberg et al. 2001). The rampant use of irrational FDCs in the private sector is a supply-side issue that needs to be managed. There is an urgent need to ensure introduction of rational FDCs that will not only increase drug compliance and encourage adherence to treatment but also ease logistical difficulties such as ordering, storage, handling, and delivery of drugs.

An important issue that emerges in the private sector is that the treatment protocols followed by private health care practitioners are found to be heterogeneous and suboptimal in nature. Murrison et al. (2016) found that out of 228 private practitioners' respondents in their survey, 160 listed 27 different treatment regimens for pulmonary TB and the other 68 referred all patients for TB treatment. When the treatment methods of these private practitioners were evaluated against Standards for TB Care in India standards, 16 prescriptions out of the 160 were found to be inconsistent with the standards in terms of treatment durations; 10 drug regimens lacked pyrazinamide and/or ethambutol and 10 included quinolones or injectable second-line agents. Prescription practices were found to be significantly poorer among chest physicians compared with other postgraduate and graduate allopathic practitioners. Only 40 percent of all private practitioners made use of DOTS-based approaches to ensure treatment adherence, including referral to the RNTCP DOTS program (Murrison et al. 2016).

Discussions with those working on TB care issues in India reveal that private sector physicians tweak the treatment regimen and prescribe 'random' antibiotics – mostly as per their own or the patient's convenience. While many attributed this mismanagement to a lack of awareness about Standards for TB Care in India, informants also indicated that even when health care providers are aware, private providers choose to follow their own regimes and are not willing to adopt accepted standards.<sup>17</sup> It was also pointed out that there is a need to train private doctors about daily regimen-based TB treatment.

The National Strategic Plan (2012-17) notes that the qualification of private practitioners prescribing these medications is also a problem. Practitioners of alternative forms of medicine are routinely found prescribing TB care medication without the qualification to do so. These poor prescribing practices cause prolonged morbidity, the spread of drug resistance, and a greater number of deaths from TB. Bhargava et al. (2011) identify the prescribing practices of the private health sector as 'most certainly' one of the reasons why India accounts for a high MDR-TB burden.

The threat from DR-TB looms large and needs to be addressed promptly. MDR-TB and XDR-TB develop because of the failure to take the appropriate combination of drugs consistently. DR-TB is deadly, difficult to diagnose and expensive to treat. It thus is all the more important to engage private providers in this regard, because a substantial number of MDR-TB patients are due to diagnostic delays and incorrect treatment protocols in the private sector (Ministry of Health and Family Welfare 2012).

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<sup>17</sup> KII-7

### 2.3.3 Policy Issues

**Key actors:** Central TB Division, Drug Controller of India, funding and implementing partners

**Key issues:**

- Lack of mutual trust between public and private sector
- Availability of drugs for MDR-TB
- Low case notification of TB from the private sector
- Unusually strict regulation by the public sector
- Dearth of research and innovation with reference to development of new drugs

Several policy issues regarding TB treatment remain to be addressed. There is a strong consensus among experts on building not only the capacity and awareness of the private sector, but also the trust between the public and private sector so that the private sector becomes more willing to engage with public sector.<sup>18</sup> In this regard, private sector acceptance of government-provided services and goods are at risk. A paper on the size and use pattern of the private TB drug market establishes that several non-public sector providers are fulfilling the needs of the consumers who choose to buy drugs in the private sector even though free drugs are available in the public sector (Wells et al. 2011).

Availability of drugs for MDR-TB is a concern. Treatment of MDR-TB requires the use of second-line drugs, which are more expensive, have more side effects, and are more difficult to obtain than those for drug-susceptible TB. Bedaquiline – hailed as the miracle drug that would cure TB – was introduced into the RNTCP in 2016, albeit with conditional access. It is still under trial and only six pilot sites in five cities (Ahmedabad, Chennai, Delhi, Guwahati, and Mumbai) can provide it to patients.<sup>19</sup>

Few patients with MDR-TB have the financial capacity needed to fight this disease over the two years of treatment. Many run out of funds, and even informed and committed patients are compelled to interrupt treatment while they arrange the financing (Gupta et al. 2015). Thus, provisioning and regulating the availability and pricing of drugs in the private sector, especially in case of MDR-TB and XDR-TB, is a critical issue.

Another area of concern is the notification of TB cases. The process of TB notification is crucial from the perspective of policy as it provides the rationale for evidence-based planning toward TB prevention and care (Srivastava et al. 2013). Although case notification is compulsory in the public sector, it is not in the private sector. Apart from private providers' own unwillingness to notify cases citing patient confidentiality, there is a lack of government incentivization, or monitoring through a robust mechanism to facilitate and encourage notification in the private sector. Mandating the notification of cases has been in place since 2012 and needs to be incentivized through a carrot-and-stick approach.

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<sup>18</sup> KII-4, KII-5, KII-12

<sup>19</sup> First Post: <http://www.firstpost.com/india/how-biased-and-irregular-availability-of-a-vital-tb-drug-hurts-women-patients-in-india-3199018.html>. Accessed July 1, 2016.

At the same time, it is important to note that government regulation of the private sector is usually dictatorial and unidirectional.<sup>20</sup> Even though TB case management practices of private practitioners in low- and middle-income countries are generally not in compliance with the government guidelines, regulatory mechanisms adopted by the government are unusually strict and rigid.<sup>21</sup>

Much research is required for better results in the treatment phase of the patient pathway; this could range from development of new drugs to population-based research on utilization of treatment services by vulnerable populations. An example of a successful intervention aimed at improving treatment adherence is the 99-DOTS program. The 99-DOTS package lists numbers concealed behind the medicines, which need to be dialed-in by the patient to register completion of that particular dose. If this call from the patient does not come within a stipulated timeframe, then reminders are sent to the patient; if these go unheeded, the DOT provider or health worker make a follow-up visit to provide the necessary support.<sup>22</sup> Information and Communication Technology-enabled innovations such as 99-DOTS can be further explored at the policy level to ensure effective TB treatment.

## 2.4 Stakeholder Analysis

The Government of India is committed to strengthening public-private partnership in TB care in India. This study seeks to understand the ways in which this policy commitment can be realized and identify potential barriers and blockers that may emerge as the reform agenda is rolled out. It also becomes imperative to identify opportunities and limitations of this process, allowing the State to fine-tune its policies and strengthen mechanisms of delivery.

It is recognized that the private sector is massive; however, services provided by this heterogeneous system are of variable quality. Thus a close look into the various 'actors' that constitute the private health care ecosystem becomes essential to understand the many moving parts of such a reform process.

This section presents a stakeholder analysis of actors in the TB ecosystem that captures their levels of 'interest' and 'power' in the process of reform. Any reform agenda will have a potential winners and losers and a stakeholder analysis is an effective tool to identify these and plan for change management. The stakeholder map that we constructed has 26 categories of stakeholders, which capture the views of 27 national- and state-level experts.

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<sup>20</sup> KII-4, KII-5, KII-10

<sup>21</sup> Ibid.

<sup>22</sup> Stop TB: [http://www.stoptb.org/news/frompartners/2015/fp15\\_072.asp](http://www.stoptb.org/news/frompartners/2015/fp15_072.asp). Accessed Jul. 21, 2016.

The World Bank defines a stakeholder analysis as “a methodology used to facilitate institutional and policy reform processes by accounting for and often incorporating the needs of those who have a ‘stake’ or an interest in the reforms under consideration.” It identifies this analysis as an important tool to understand how different forces would be affected by and respond to a reform, to point out divergent points of view, and to help strategize on dealing and negotiating with such divergence.<sup>23</sup>

For this stakeholder analysis, we identified a set of stakeholders in the reform agenda, i.e., individuals or institutions with a clear or possible stake in the changes that the reform is seeking to propose. A series of interviews were carried out with government officials at both national and state level, development partners, prominent academics, researchers, and practitioners of TB care in India to understand their view on how these actors would respond to a potential reform where the private-public interface would be strengthened to improve outcomes for TB patients. A Likert Tool was used to gather their responses on how they scored each of these stakeholders on their interest and power in the reform process. The Likert Tool that was used is in Annex B.

The ‘interest’ of a stakeholder is defined as the priority and importance the stakeholder attaches to the reform area. A high degree of interest does not necessarily mean the stakeholder would be supportive of the reform – a stakeholder can be strongly opposed to a reform and thus have high interest in blocking it.

The ‘power’ or level of influence depends on the quantity and type of resources and power the stakeholder can marshal to promote its position on the reform. This position can be supportive or opposing.

Using the World Bank methodology, this analysis allows us to classify stakeholders into four categories:

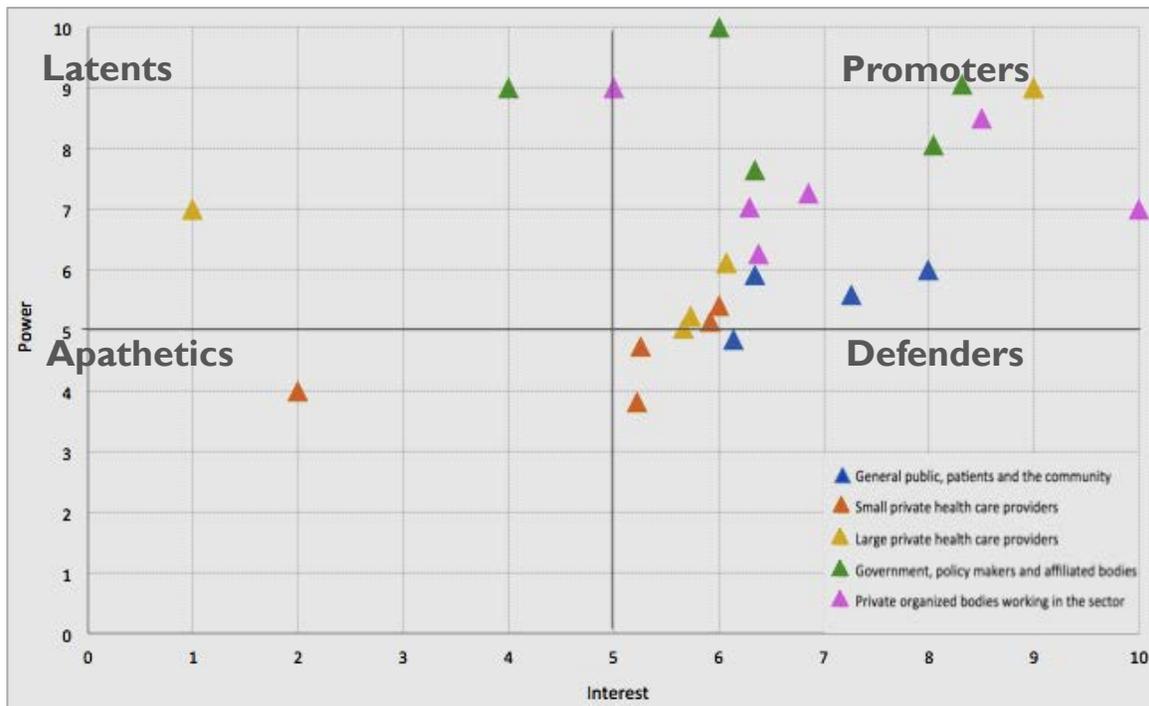
1. **Promoters:** Top right segment of the map. Stakeholders for whom the reform carries high priority and who can, by their actions, influence the reform or policy implementation.
2. **Defenders:** Bottom right segment of the map. Stakeholders for whom the reform carries high priority but who are not significant enough in the system to be able to influence change.
3. **Latents:** Top left segment of the map. Stakeholders who can directly or indirectly influence the policy reform and its implementation but for them, the reform agenda is not an important one.
4. **Apathetics:** Bottom left segment of the map. Stakeholders who neither care much about the reform, nor have the power to do anything to enable or block it.

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<sup>23</sup> World Bank Stakeholder Analysis:  
<http://www1.worldbank.org/publicsector/anticorrupt/PoliticalEconomy/stakeholderanalysis.htm> Accessed Jul. 21, 2016.

The stakeholder map (Figure 3) captures the average scores of the stakeholders, as scored by respondents in our interviews. It plots the key stakeholders on the interest-power matrix. Interest and Power are mapped in increasing order as we go up and to the right of the respective axes. (The response on interest and power of various stakeholders is in Annex C.)

**Figure 3: The Stakeholder Map**



At this stage, it is important to note that not all of these stakeholders received responses from all of the interviewees. Some of them were added by certain interviewees, highlighting their importance to their way of thinking. Presented below is an aggregation of all responses.

The key takeaways from the Stakeholder Analysis are:

- Promoters:** Government and its affiliates, and large private players and their organized bodies carry heavy weights and display high interest in the reform process: Expectedly, those with the highest power in the reform process are the government (Central TB Division) followed by funding, technical, and implementing partners. Organized bodies in the private health care ecosystem (Indian Medical Association, Indian Pharmaceutical Association, and Indian Chest Society) are the next in terms of power to influence the reform, and then come the large players such as corporate labs and doctors at large hospitals. This high power or influence over the reform process is matched with strong interest in it too – indicating a group of stakeholders that could be both strongly involved in the reform process as well capable of advancing or blocking it. If supportive of the agenda, this group can be identified as the strongest “Promoters” in the reform process.

- **Defenders:** Small chemists and small labs rank low in ability to implement change. An important lesson of this is that when the government does look to enhance partnerships, it should look into tapping the larger players first – not only will this enable them to exploit economies of scale but may also prove to be the most effective way to bring about change. However, individual doctors that work with institutions – however small – buck this trend and emerge as important players to partner with when reforms are put in place.
- **Very few Apathetics and Latents:** Interestingly, other than the Department of AYUSH practitioners, corporate hospitals, and other government ministries like finance, none of the stakeholders appear to attach a ‘low’ priority or interest to the reform (low being defined as five or less than five on the Likert Scale). This indicates that the reform process would have few Latents or Apathetics. It appears that those added to the list already prioritize the most important stakeholders.

The patients, symptomatics, and communities attach high priority to the reform since they are the ones directly affected by the disease. However, their ability to influence the reform is very limited. Community on the whole is more powerful in terms of influencing a reform compared with TB patients and symptomatics. Worth considering is whether – for a ‘medicalized’ disease such as TB – there is a need to leverage patients to enable change. This group, along with the small players such as the small chemists and labs could be potential “Defenders.”



## 3. POLITICAL ECONOMY ANALYSIS OF TB

PEA is neither strictly about politics nor about economics; rather, it is a science that maps out the local context, actors, and key relationships and allows for identification of recommendations to better engage the private sector to improve the quality of TB diagnosis, treatment, and care. By understanding the relationships between key actors and the 'bit players' in the subject area, it differs from other methodologies as it focuses on why the context is as it is and what the power dynamic between various actors is. PEA allows the relationships within the private sector in TB and of the private sector with the public, to become overt, thus bringing into focus the strategies that could be used to address the outcomes desired.

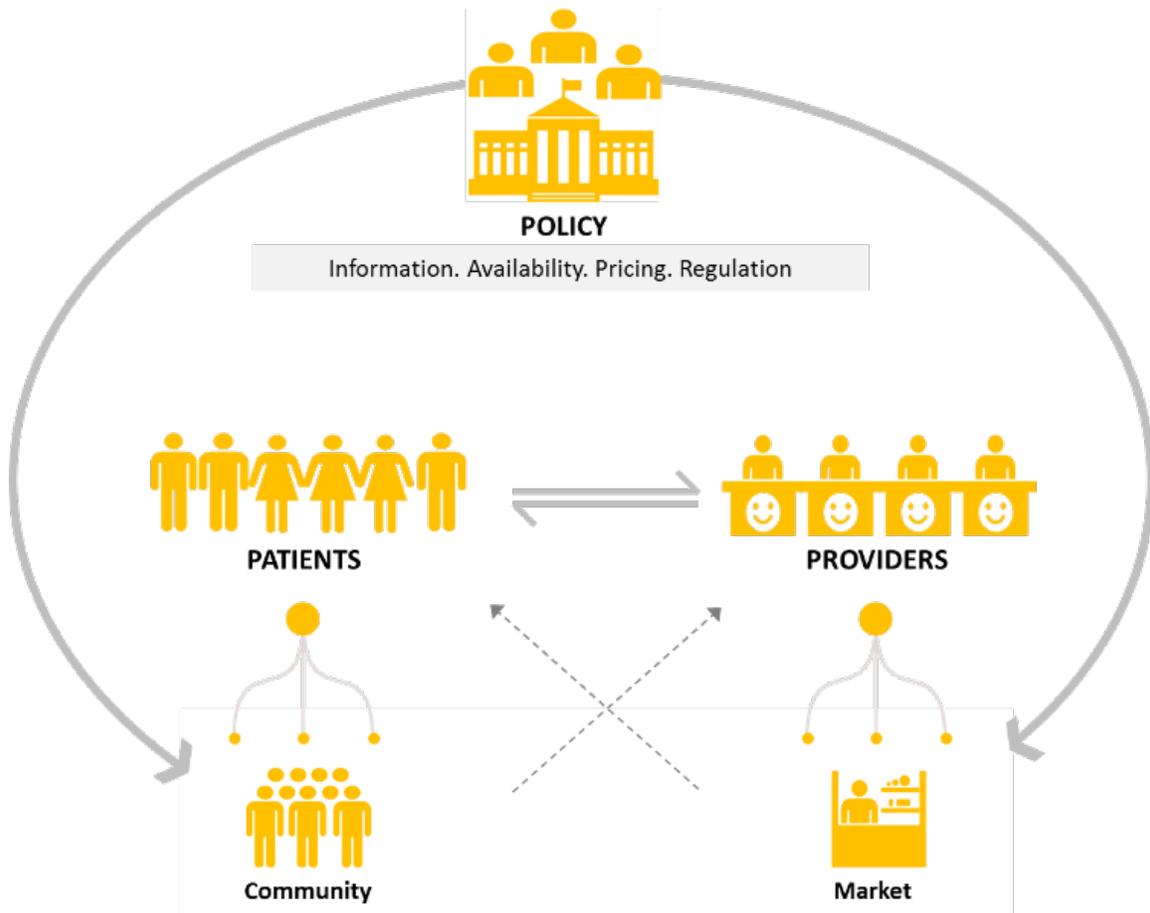
The PEA approach is a popular methodology in the international development field, with leading development partners adapting it to their requirements. We have based our use of the PEA methodology on the USAID's field guide.

### 3.1 A Framework for PEA

A simple but powerful framework has been used to discuss the political economy of private sector TB care. The framework, in Figure 4, has four important elements:

1. The first element comprises patients who form one end of the patient-provider dyad and the role that the community to which they belong plays in determining their care seeking attitudes and behaviors.
2. The second element comprises providers, the other end of the dyad, and the market forces that guide their actions.
3. The third element comprises the important cross linkages that have an impact on the behavior of the two prime actors – patients and providers – and that form a critical part of the substrate of relationships of the marketplace.
4. The fourth element is the policy environment, which modifies the incentives and disincentives that the prime actors have with respect to TB care.

Figure 4: The Political Economy Framework



### 3.1.1 Patients

Patients form one end of the political economy dyad of TB. They are the core individual units that represent the overall demand.

However, patients do not operate in isolation. The community establishes and governs social customs, which have a direct bearing on a patient's health seeking behavior. Issues such as stigma, social vulnerability, and prior community experience of the disease are important facets of patients' community life.

Patients also are steered by their personal situation to actualize (or not) the opportunities that they have. Factors such as the financial condition of the patient's family, opportunity cost, and expectation of cure has a large effect on their health care decisions.

### 3.1.2 Providers

At the other end of the political economy dyad of TB, the supply side, are providers. They operate in an environment of incentives and disincentives, which are guided by market forces. Since the study focuses on the engagement of the private sector, the issue of incentives and disincentives gains importance.

India has a great heterogeneity of providers, who range from NQPPs, AYUSH doctors, chemists, and GPs, to specialists including those specialized in TB and chest diseases. Providers enter the market to provide a social good, but also to make a living through the practice of their profession. Hence, economic considerations play a big role in their decision making. The medical fraternity is well networked – it includes relationships between providers of clinical and laboratory services and between allopaths and NQPPs. This network is held together by a well-organized web of transactional relationships.

Factors that play an important role in decision making include the need to build reputation which primarily works on the basis of word of mouth, retention of patients and their extended group, availability of tests and drugs, and last but not least, profits. These factors offer incentives and disincentives that steer provider choices.

### 3.1.3 Patient and Provider Cross Linkages

There are several cross linkages between the factors that determine patient and provider behavior. The first that demands considerable attention is between the patient and the provider. This linkage establishes the relationship between the two prime actors, which ultimately decides the course of the patient pathway.

Another cross linkage that needs to be studied closely is between the provider and the community. Providers are drawn from the same society as their patients. Hence, even though their profession may have a substantial effect on their attitudes and norms with respect to TB, their background attitude to the disease, which is determined by community norms, cannot be discounted.

The other important interaction in this framework is the linkage between the patients and the market. Incentives or disincentives guided by the market play a significant role in determining the behavior of patients – the pricing of tests or the prices of the medicines for example, can affect a patient's decisions.

### 3.1.4 Policy Environment

Policy intervenes in the relationship between patients and providers by altering the incentive-disincentive equilibrium between them. The incentive and disincentive structure is guided by market forces; hence, policy to some extent intervenes in the market and directs its operation.

The policy environment in which the patient-provider interaction takes place works by four broad means: changing information symmetry, changing availability, changing price, and changing regulations. The changes can be explicit or implicit. Each change can affect the decision-making considerations of the two prime actors.

By providing an advantageous environment for patients and providers, policy can facilitate their choices in a way that improves patient detection, supports rational testing, reinforces the use of standardized TB treatment protocols, and ultimately promotes better TB care.

The political economy of TB can best be approached by understanding the (i) drivers of demand-side issues, (ii) market forces that influence supply-side issues, and finally (iii) policy and strategy elements designed to improve the delivery of high-quality TB treatment. The rest of this chapter discusses the interplay of these aspects that constitutes the political economy of private sector involvement in TB treatment and care in India.

## 3.2 Patient Pathways

A Patient Pathway is the track that a patient chooses from the point of first contact until the completion of treatment. Patients take different pathways through the pre-diagnosis, diagnosis, and treatment phases, depending upon their personal choices and environment. Every TB patient is likely to experience symptoms such as cough (the most common symptom), fever especially in the evening, and weight loss.

In this study, Patient Pathways were observed in four settings: Kolkata, West Bengal; Mehsana, Gujarat; Mumbai, Maharashtra; and Patna, Bihar are described below and visualized in Figures 5, 6, and 7.

### 3.2.1 Pre-diagnosis Phase

The pre-diagnosis phase involves decision making by the patient based on his awareness of TB, his trust in his first contact providers, and the index of suspicion of the provider. TB, which is relatively uncommon (at least in the experience of most first contact providers), presents as a symptom complex that must be decoded with the right lab tests for a diagnosis, and requires responsible long-term treatment and follow-up. First contact providers play a critical role in putting the patient on the right path to cure.

In most cases, the patient approaches his usual local provider, because cough is not seen to be *badi* (big) enough to warrant a change in the usual practice. The providers of first contact could range from a specialist, a GP, and a chemist to even an NQPP or a quack. Patients are found to move from one provider to another based on the relief that they experience in their symptoms or not, guidance from others in their inner circle, and prevailing wisdom. Patient Pathways chosen by rural and urban patients might also be quite different.

### 3.2.2 Diagnosis Phase

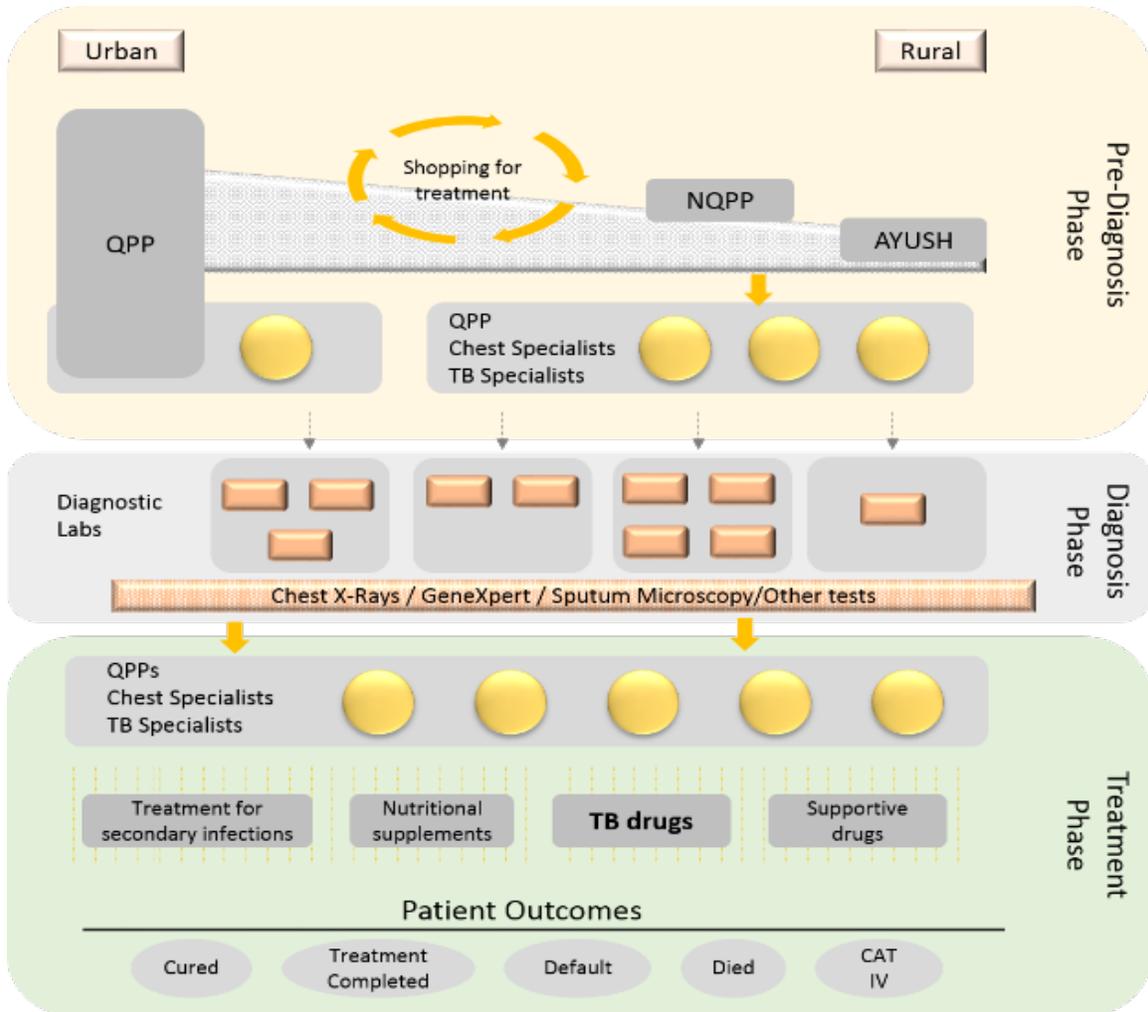
It is only when the patient first entertains the notion that s/he might have TB that the locus of care seeking might shift from the local provider to an allopath who has a reputation for treating lung diseases or specifically TB. The patient is asked to undergo tests to identify the specific sickness that afflicts him. Tests can range from blood tests and X-rays to more specific tests for the diagnosis of TB such as sputum testing, LPAs, and GeneXpert. In addition, providers may ask the patient to get tested for other associated conditions, and for baseline studies of liver and kidney functions, which may be affected by the subsequent intake of TB drugs.

### 3.2.3 Treatment Phase

Finally, the patient is put on treatment based on clinical and laboratory evidence that s/he has TB. The prescription of TB drugs is expected to always be done by a qualified allopath at a minimum, and often is seen as the preserve of specialists, especially specialists in TB and chest diseases, internal medicine, or orthopedics/gastroenterology/gynecology. In this phase, the main challenge is to ensure adherence to the full course of treatment so as to cure the patient and prevent MDR/ XDR-TB. This does not always occur.

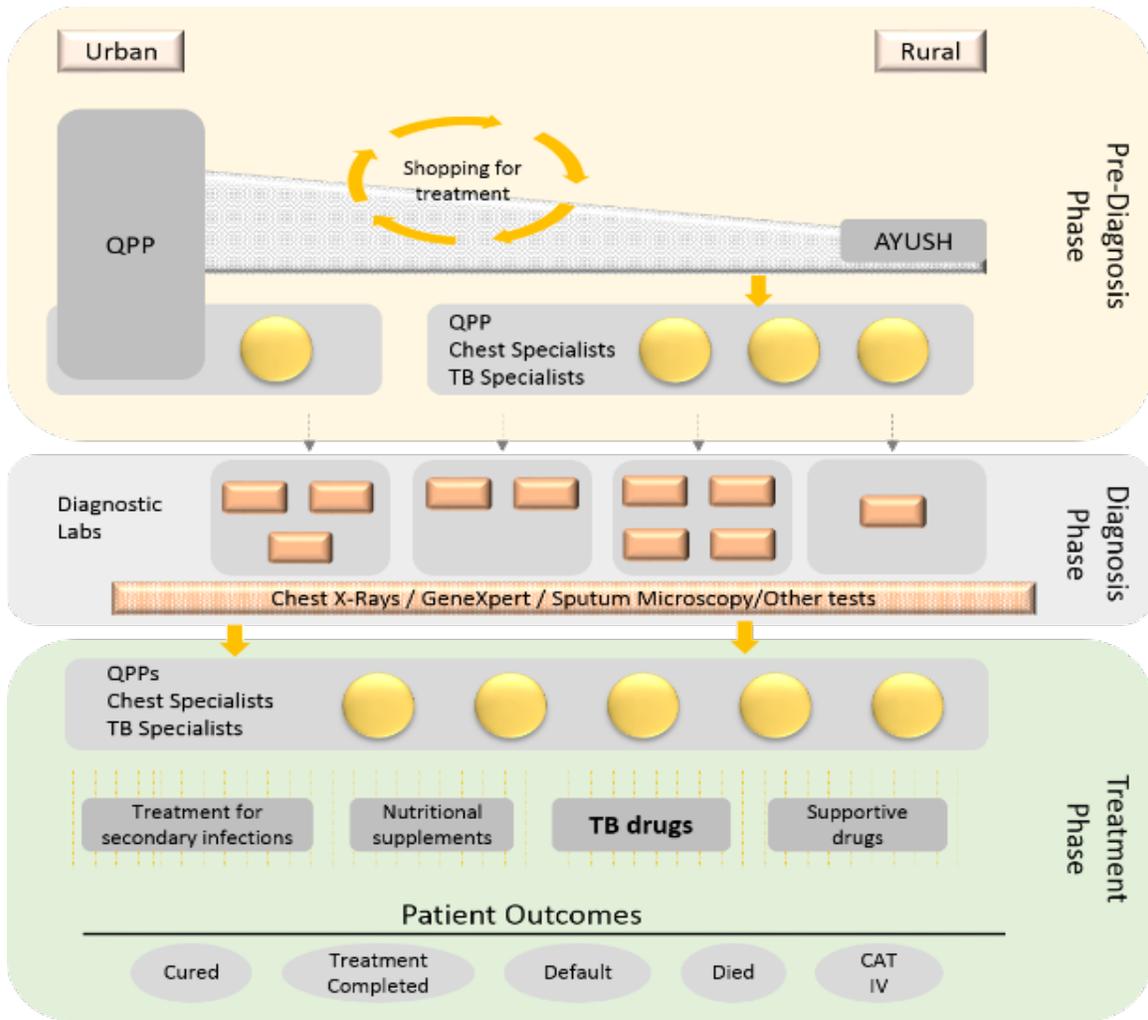
In Kolkata and Patna, Patient Pathways were quite similar (see Figure 5). Symptomatics usually visit a qualified private practitioner (QPP) in urban areas and an NQPP or AYUSH doctor in rural areas as their first point of contact.<sup>24</sup> The patients who visit a QPP mostly stay with him or move to other QPPs while shopping for treatment for their symptoms. However, patients who visit an NQPP or AYUSH doctors as their first point of contact are referred to a QPP. Determination of diagnostic labs to do the tests prescribed by the practitioner for confirmation of their diagnosis is by that physician. After the diagnosis has been confirmed, the patients usually go back to the same QPP for further treatment. The patient is then put on treatment, being prescribed TB drugs and other supportive drugs or nutritional supplements for their recovery.

**Figure 5: Patient Pathway in Kolkata and Patna**

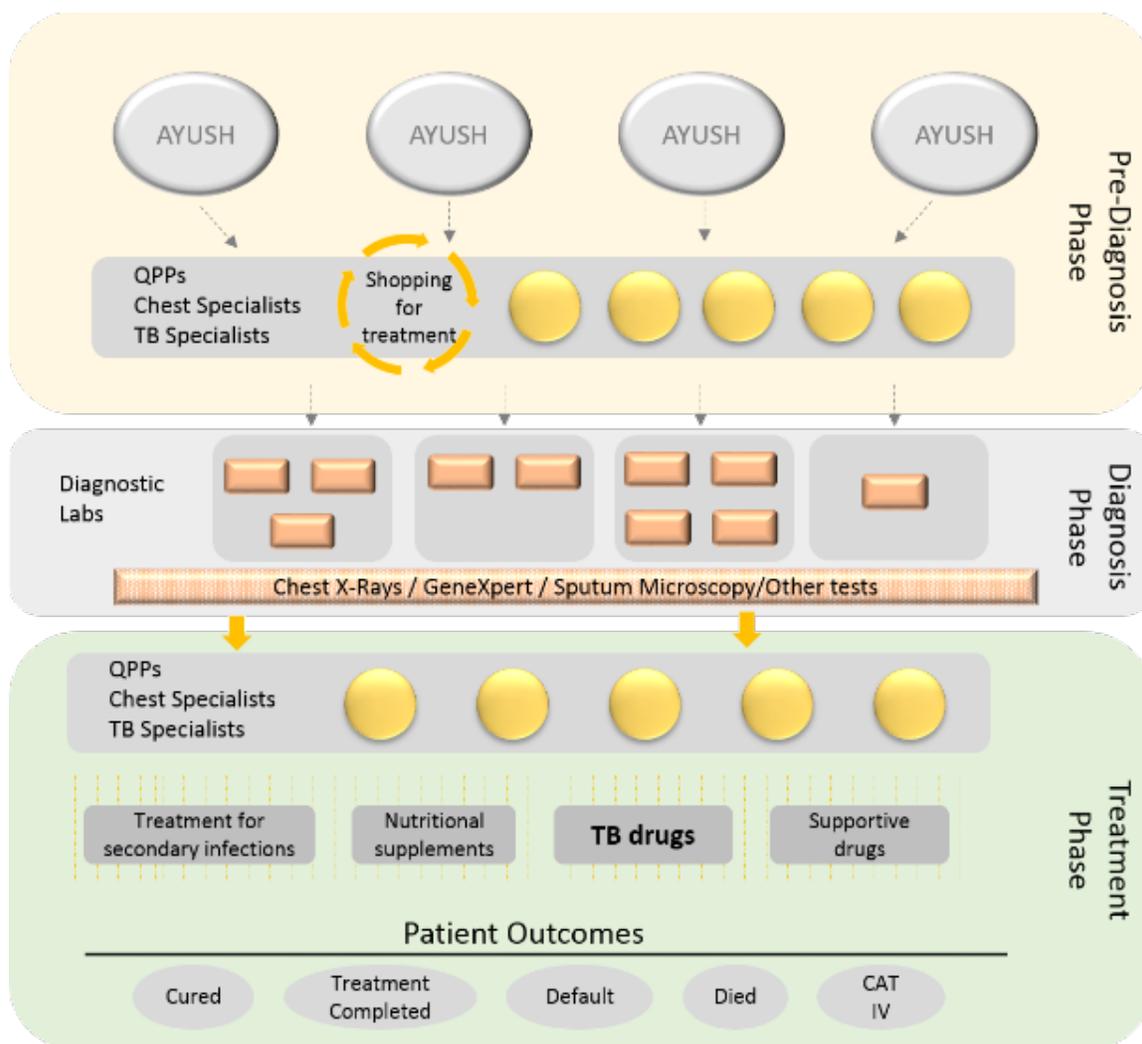


<sup>24</sup> KII- 7, 9, 26, 32

**Figure 6: Patient Pathway in Mehsana**



**Figure 7: Patient Pathway in Mumbai**



Persons with presumptive TB in Mehsana visit a QPP in urban areas and AYUSH doctors in rural areas (see Figure 6).<sup>25</sup> NQPPs have not been involved in the program. AYUSH doctors refer the patients to QPPs for treatment. The diagnosis and treatment phase are similar to those in Kolkata and Patna. In Mehsana, QPPs prescribe tests for confirmation of TB diagnosis and the patient is generally sent to a nearby private lab or primary health center where these tests are available for free. Once the diagnosis is confirmed, the patient is prescribed TB drugs and the treatment begins. Supportive drugs may be prescribed, although it seemed to be less common and expensive than in Mumbai.

<sup>25</sup> KII- 17,19,21

In Mumbai, first contact providers are usually AYUSH doctors (see Figure 7). These doctors as well as first contact QPPs are localized in their place of operation and have a limited catchment area of a 2–3 km radius. Their clients generally see them for most ailments that they might get, and the doctor-patient relationship is based on trust. AYUSH doctors refer the patients to a QPP, chest specialist, or TB specialist for definitive treatment of TB.<sup>26</sup> In the diagnosis phase, persons with presumptive TB do not generally approach diagnostic laboratories directly to ask for TB tests. Their pathway is determined primarily by the consulting physician. After the confirmation of diagnosis, the patient goes back to the same practitioner who provides further treatment.

### 3.3 Demand-side Issues

Demand for services is the self-motivated need for services experienced by patients. The personal circumstances of the patient are the main considerations that drive their decision making – when and how they assume the ‘sick role,’ their financial situation, their difficulty in reaching medical help, their expectation of length of life, their work situation, and so on. Some of it is derived from the perceptions of the community in which they grew up and reside, and the community experience of the disease. Demand is an important determinant of loss to follow-up as well as to delays in care seeking. The actors are the patients themselves, of course, but also community and patient groups, patients who have completed treatment, and so on.

Health seeking behavior is the action taken by an individual to seek a cure for an illness or to better their state of health if it is perceived to be less than optimal. It is important to understand the health seeking behavior of an individual in order to understand when in the course of ill health and where they seek care so that appropriate interventions can be designed for them. Many aspects influence these actions. Several health seeking behavior studies have documented that patients are generally conscious of the gravity of their symptoms and titrate their care seeking accordingly. In India, conditions felt to be less serious are generally addressed by a local chemist or less-qualified practitioner, while conditions felt to be more serious and longstanding result in visits to qualified practitioners, frequently specialists (Courtwright and Turner 2010).

TB usually presents with cough – often mild to begin with, then both persistent and more debilitating as time passes. Its course is affected by the immune status of the patient, which in turn is determined by a range of factors such as nutritional status, overall health, ventilation, and overcrowding in housing and the workplace (Pai 2016).

Our desk review showed that the health seeking behavior of patients and persons with presumptive TB in India is impacted by patient delay, which poses an obstruction to early detection of TB (Kumar et al. 2016). The literature also indicates that delay on the part of patients is an important behaviour that affects health outcomes. Our findings suggest that awareness plays a very important role in determining the health seeking behavior of patients. Lack of awareness about TB and its presentation as cough results in the patient taking their own cough lightly and/or choosing to self-medicate, leading to both delay and worsening of their condition.

*“Cough is not taken as a serious problem. Patients generally go to a nearby chemist and ask for a cough syrup”*

- Informal Provider

<sup>26</sup> KII- 47, 50

Increased awareness of TB being a curable disease has led to a reported increase among patients in Mumbai, Mehsana, and Patna seeking medical care earlier than previously.<sup>27</sup> In contrast, poor awareness levels in Kolkata means people do not necessarily relate cough to TB. Increasing awareness and the consequent readiness to seek care improves the overall business of first contact providers, diagnostic facilities, and TB specialists. This makes for a greater interest among caregivers about TB, demonstrating the interplay of demand- and supply-side factors in the political economy of private provision of TB care.

### 3.3.1 Pre-Diagnosis Phase

The pre-diagnosis phase of TB is marked by the onset of symptoms that are suggestive of TB. This phase is intricately linked with the health seeking behavior and often determines the Patient Pathway adopted by the patient. It is during the pre-diagnosis phase that patients seek medical care for their symptoms. An early diagnosis of TB is considered to be an important step to preventing the transmission and lowering the incidence of this disease. The National Strategic Policy on TB prevention and care recognizes the importance of the pre-diagnosis phase and points out that timely identification of TB cases is a pre-requisite for effective disease prevention and care (Ministry of Health and Family Welfare 2014).

According to our desk review, major issues that are of concern in the pre-diagnosis phase are lack of awareness of TB in the community and the stigmatization and social exclusion related to TB. Patients do not take their symptoms seriously and rely on self-medication or over-the-counter medication, which more often than not worsens their condition. Even after suspecting that their cough might be due to TB, some patients do not visit a doctor because they are in denial and resist seeking care due to the fear of social exclusion (Courtwright and Turner Norris 2010). As a result, shopping for treatment is prevalent wherein the patient sees two or three providers before receiving definitive treatment for TB. This is an extra cost for the already poor patient.

We found that increased awareness about TB has led persons with presumptive TB to actively seek medical care earlier and generated demand for diagnostic tests in Mehsana, Mumbai, and Patna.<sup>28</sup> In Kolkata, the community is largely unaware and many people do not relate cough to TB.<sup>29</sup> This highlights the importance of awareness, the absence of which results in slower care seeking.

Our findings suggest that increased awareness has increased demand for private services for TB in states like Gujarat. In contrast, in places like Kolkata, where awareness was reported to be quite low, stigma surrounding TB was high.<sup>30</sup> Fear of social exclusion discourages patients from discussing their symptoms.<sup>31</sup> This reluctance to talk about the disease prevents persons with presumptive TB from seeking care. Despite free services being available in the public sector, privacy in that sector is less trusted, and it is assumed that the information shared by patients is less secure.

*“People now know that TB is a fatal disease, and this fear is why they have started taking their symptoms more seriously.”*

-Patient

<sup>27</sup> KII-2, 3, 9, 23, 25, 43

<sup>28</sup> KII-2, 3, 9, 23, 25, 43

<sup>29</sup> KII-18,20,23

<sup>30</sup> KII-27,29

<sup>31</sup> KII-28

### 3.3.2 Diagnosis Phase

The diagnosis phase usually begins when the patient has accepted the possibility of serious disease and seeks expert diagnosis. An important aspect of this phase is provider-patient interaction. The major concerns of the patients as discussed above are driven primarily by two factors: social stigma associated with having TB and cost of the diagnostic tests and related opportunity costs. Demand for tests is determined by the prescribing physician. Diagnostic protocols are established on the basis of provider advice and not by patient choice.

Our desk review suggests that the diagnostic protocols prescribed by patients are determined primarily by the perception of self-stigma of the patients. As the reasons for the cough are worked through, diagnostic tests for TB might be delayed because the physician feels that the patient is not ready to accept TB as a diagnosis. Although in this phase the patient has accepted the possibility of a serious disease, a diagnosis of TB is unwelcome on account of the associated social stigma (Courtwright and Turner Norris 2010).

Another factor with a large impact on progression to definitive diagnosis is cost. It figures largely role in the patient's choice of provider. Our informants reported that access to free, high-quality diagnostic tests is an enabler for diagnosis. It has significantly reduced delays related to cost of the test. The rate of diagnosis has improved in all the states, i.e., Bihar, Gujarat,

Maharashtra, and West Bengal; this is seen to be the result of free availability of high-quality tests.<sup>32</sup> However, cost here includes not only the cost of TB tests themselves but also other items like transportation and food, since the diagnostic center might be far away. And there are opportunity costs: patients usually forgo work, and wages, on the day they have the TB tests. Our findings suggest that these opportunity costs are unacceptably high and prevent patients from taking up and (sometimes) continuing TB treatment.

Environmental factors such as the schedule of the diagnostic center and the distance of the private provider play a crucial role in determining the demand for TB services. A private facility has more flexible timings, which help the patient to access services without sacrificing a day's earnings.

*“Most of the people who come for diagnosis are poor and free diagnostic tests are very helpful for them. The rate of diagnosis has improved.”*

-Diagnostic Lab

### 3.3.3 Treatment Phase

The treatment phase of TB begins once diagnosis is confirmed and treatment must be initiated as per the accepted standards of care. In this phase, the key issues are lack of awareness about TB treatment and protocols and factors that prevent the patient from adhering to treatment. Lack of awareness is a fundamental challenge, as it leads to lack of demand for treatment.

There is also loss registered in terms of follow-up; these are of two kinds. The first is loss to follow-up at the pre-treatment phase, which is when the patient is diagnosed with TB but falls out of the patient pathway before any treatment begins. The second is loss to follow-up during the treatment phase, when patients are unable to complete treatment (MacPherson et al. 2014).

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<sup>32</sup> KII- 8,10,20,23,33,52

In our findings, community attitude plays a vital role in awareness generation and ensuring adherence to treatment. In rural areas, the community is close knit and has considerable influence on the behavior of the patient. While changing community attitudes supports network formation and adherence to treatment, this has been a slow process. Greater awareness of TB throughout the community – in both urban and rural settings – has resulted in more patient readiness to accept a TB diagnosis and adhere to treatment.

Cost also plays a major role in treatment adherence. The cost of seeking treatment remains high in all the states. High consultation fees charged by private providers prevent poor patients from approaching them.<sup>33</sup> High opportunity costs may prevent patients from taking up and continuing TB treatment. Although access to quality-assured free drugs has decreased the financial burden of patients and enabled poor patients to access quality treatment, sometimes the line of treatment prescribed adds to the overall financial burden on patients. For example, doctors might prescribe costly nutritional supplements, and/or supplementary antibiotics to treat other infections. Even though TB drugs are free, these additional expenses often make the difference between a patient continuing TB treatment or not.

*“The high consultation fees and the cost of supplementary medication forces patients to default.”*

- Private Provider

Hence adherence, critical to better cure rates, was reported to be a challenge in all the states.<sup>34</sup> The generally poor financial condition of patients and the long time span of TB treatment results in non-compliance. In Bihar, the pre-conceived notion about ‘English’ medicine generating excessive heat is another factor that results in reluctance to take drugs over a long period and prevents patients from completing treatment.<sup>35</sup>

### 3.3.4 Incentives and Disincentives

It is quite evident from the discussion that patient decisions regarding their treatment are determined by a number of factors. Some factors encourage them to seek care, and others discourage them from doing so. Paying heed to these factors can be used to incentivize patients to seek timely and appropriate care.

Much of the discussion in the preceding paragraphs was about the disincentives to treatment and care: social stigma, cost, and adverse environmental factors. Stigma discourages patients to seek early care and treatment. Cost is a very significant factor when it comes to patient’s choice of provider, shopping for treatment, ability to undertake prescribed diagnostic tests, and adherence to treatment. Our review found that the cost of seeking treatment remains high in all states. This results from the shopping for treatment prevalent among most patients and the high consultation fees charged by the private providers. Supplementary antibiotics and nutritional supplements prescribed by doctors are often expensive and increase patient costs. Environmental factors such as the timing and the distance of the facility also increase costs.<sup>36</sup>

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<sup>33</sup> KII- 11,13,23,27,30,49

<sup>34</sup> KII- 13,17, 31, 52

<sup>35</sup> KII-9,12

<sup>36</sup> KII-10,17,27,32

Incentives to treatment seeking were greater awareness and subsidy of diagnosis and treatment costs through provision of free services. Increased awareness about TB being curable has led persons with presumptive TB to actively seek early medical care in Mehsana, Mumbai, and Patna.<sup>37</sup> A positive community attitude to TB diagnosis and treatment can be a major incentive for stigma reduction and demand generation. Changing community attitudes makes it easier for patients to access and adhere to treatment. Greater awareness among community also ensured patient's readiness to accept a diagnosis of TB.<sup>38</sup> Access to free high-quality diagnostic tests was found to be an enabler for diagnosis as it reduced the delays associated with the tests. Consequently, the rate of diagnosis has improved in all the states studied (Bihar, Gujarat, Maharashtra, and West Bengal).<sup>39</sup> Similarly, access to free drugs from the private sector has also enabled demand, helping poor patient to access quality treatment and considerably reducing the overall financial burden.

### 3.4 Supply-side Issues

Supply is the provision of goods and services needed to fulfill the purpose of the program. Supply-side actors may be in the public and private health care systems. These sectors act in tandem and sometimes substitute for each other by patients who shop for services in both, or by the providers themselves, who may work in both sectors. This study focused on how the private health sector can meet the needs of TB prevention and care. Relevant actors include individual doctors and those with small and large hospitals/ clinics (institutions), and the diagnostic laboratory system including X-ray facilities. Pharmacies (individual and corporate) also are an integral part of the private sector system for TB care. Professional associations' play an important role in aggregating the voices of professional groups, especially doctors.

Private providers play a crucial role when it comes to seeking TB care. More than 60 percent of TB symptomatics and patients approach a private provider as first point of contact (Uplekar et al. 1998). They use private providers more often because the private providers are more accessible (nearer to their place of residence, open for longer hours), and are perceived to be of superior quality and more considerate than their public sector counterparts. The private sector is highly fragmented in nature. The provider of first contact ranges from a highly qualified chest specialist, to a GP, to an NQPP. The private providers operate at different levels and cater to different clientele. For example, an urban dweller is more likely to visit a QPP while rural residents have more access to an informal provider. It is not surprising that the treatment prescribed varies. The Standards for TB Care in India are not well known. In spite of all these issues, one thing remains clear; the market capture of private providers is too large to be ignored by policymakers.

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<sup>37</sup> KII-2,3,9,22,37

<sup>38</sup> KII-20,26,32

<sup>39</sup> KII-4,14,29,46

### 3.4.1 Pre-Diagnosis Phase

The key actors in the pre-diagnosis phase are the providers of first contact in small and private hospitals, NQPPs, and small and corporate chemists. A major issue is the low index of TB suspicion among providers – this primarily relates to low awareness among the providers regarding TB and their reluctance to consider TB as a primary diagnosis. The provider of first contact is usually a local practitioner who treats everything from diarrhea to the common cold. He may be unsure about treating TB or reluctant to suggest that diagnosis to the patient given the stigma that surrounds the disease. At the very least, he would like to rule out other (less alarming) diagnoses of cough before considering TB.

*“Jhola Chaap Doctors are playing a very crucial role therefore engagement with them is a must”*

-Councillor

Our findings revealed that lack of expertise and limited awareness of appropriate diagnostic protocols limits the detection of TB in a timely manner. It was reported that first contact providers are often motivated by the fear of ‘losing their patient’ to another provider.<sup>40</sup> Persons with presumptive TB often shop for treatment of their symptoms, with each patient generally having been to two to three providers on average.<sup>41</sup> Providers fear that suggesting a diagnosis of TB would result in the patient moving on to another provider in order to avoid coming to terms with a definitive diagnosis of TB.

### 3.4.2 Diagnosis Phase

One of primary issues faced by the providers in this phase is their lack of awareness about diagnostic protocols and procedures. There has been little diffusion of the Standards for TB Care in India. Nor has much effort been made to educate service providers to raise their index of suspicion regarding TB.

The underutilization of newer and sophisticated diagnostic techniques, which can stem from lack of awareness and the absence of infrastructure, is a concern.<sup>42</sup> As a result, TB diagnosis is time consuming and expensive, and does not yield much profit for the providers. However, adoption of new and appropriate diagnostic techniques has spread rapidly. The use of GeneXpert, a highly accurate and sensitive test, has increased among private providers. Providers have also moved (albeit incompletely) toward microbiological testing for TB treatment. CBNAAT machines are available in most districts of all the states. It is reported that the use of one or two sputum samples by private providers is most common. Side by side, the reliance on chest X-rays continues.

*“The use of GeneXpert testing in the private sector has increased, as more providers are becoming aware of the new developments in diagnosis”*

-State Official

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<sup>40</sup> KII-9,18,27

<sup>41</sup> KII-23,37,42

<sup>42</sup> KII-13,33

Schedules and distance of the testing centers also affect utilization. It was reported that private sector centers are more accessible and convenient in Mumbai and Patna.<sup>43</sup> Public sector facilities are open only between 10 am and 6 pm, whereas the extended hours of the private providers increase their accessibility. Availability and accessibility of allopathic service providers is generally limited to urban centers; symptomatics in rural areas still rely on informal providers as their first point of contact.<sup>44</sup>

Information asymmetry between the patient and the provider has several consequences. Moral hazard influences physicians' choices regarding diagnosis. A provider may choose not to completely disclose/delay revealing the diagnosis in order to make a profit. A well-established transactional relationship between providers and private labs results in a large number of diagnostic tests being prescribed to patients.<sup>45</sup> Doctors and physicians actively advocate expensive testing methods to their patients in place of other, less expensive, but equally conclusive tests (Pai 2013). Thus, financial considerations play a role in the choice of tests prescribed resulting in extra financial burden on patients.

There is also no uniformity in the diagnostic protocols that formal providers prescribe.<sup>46</sup> Some recommend a variety of tests while others directly prescribe a course of antibiotics for a trial period. The varying approaches adopted by different (and sometimes the same) providers increases patients' confusion and doubt, encouraging them to shop for treatment.

*“Private doctors rely more on X rays than on sputum microscopy or GeneXpert. There are still 60 percent patients who have not been microbiologically tested”*

- Interface Agency

### 3.4.3 Treatment Phase

TB patients can be cured when appropriate drugs are taken for the optimum period, while inadequate intake or inappropriate regimens can result in chronic illness and development of DR-TB. The main providers during this phase are doctors (individual doctors and from small and corporate hospitals) and chemists (small and corporate chemists).

Lack of provider awareness of the Standards for TB Care in India results in disparate treatment practices which, as during the diagnosis phase, adds to patient confusion.<sup>47</sup> According to study informants, arbitrary treatment practices and prescription of irrational medicines are common. For example, patients often are prescribed antibiotics to suppress symptoms, but these work for only a short time. Some of this is influenced by patient demand although irrational practices are not.

Moral hazard persists into this phase. It influences treatment practice in that pecuniary considerations sometimes determine the choice of brands of drugs and supplements. Thus, while anti-TB drugs may be free of cost, additional prescriptions – of expensive antibiotics and nutritional supplements – add to the burden of already financially constrained patients.

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<sup>43</sup> KII-11,19,38,52

<sup>44</sup> KII-15

<sup>45</sup> KII-46,48

<sup>46</sup> KII-9,49,52

<sup>47</sup> KII-17,24,37

rapport between treatment providers and patients is crucial not just for the early detection of the disease but also for treatment completion. As mentioned by informant in all four states, maintaining future clientele is critical for providers' professional life.<sup>48</sup> Forming a personal connection with the patient is important not just to improve the likelihood of successful diagnosis of TB and adherence to treatment but also to ensure future references. A major gap in this regard is the absence of a system for retrieval of patients lost to follow-up. With the systems available through the projects studied, it was found that cure rates in the four locations had increased to about 70 percent in Kolkata, 90 percent in Mehsana, 70 percent in Mumbai, and 74 percent in Patna.

### 3.4.4 Incentives and Constraints

Understanding and leveraging the incentives and disincentives of providers results in better cure rates, better adherence to treatment, and better collaboration with the providers. A primary incentive for the providers is profit. While a provider might have chosen to practice medicine for mostly altruistic reasons, once in practice, providers become business owners, and a primary concern becomes generating profits. Profits can be realized through increasing demand, transactional relationships for laboratory and X-ray services, and referrals. Moral hazard poses challenges to professional probity in all phases of the care cycle.

Having a certain degree of autonomy incentivizes providers to engage better with the TB program. Private providers feel that the program is a one-way process whereby the government heaps demands on them but gives them no space to voice their concerns. They find the government's approach dictatorial rather than collaborative. For example, they feel the time they would spend in maintaining program records should be compensated if it is to be undertaken by private providers. According to our findings, giving autonomy to private providers – including freedom to prescribe the drugs of their choice – helped smooth implementation of the program in Mehsana and other locations.<sup>49</sup>

A major disadvantage that private providers face is the lack of a system for tracking and retaining the patients. As has been noted, many patients shop for treatment. There is no mechanism by which prescribing physicians or laboratories can check if patients actually get the tests that they have been prescribed done. There is no mechanism for retrieval of patients lost to follow-up.<sup>50</sup> Some patients provide incorrect addresses, while others move back to their home towns during their course of treatment.

*“Patients are not given the right information because there are a lot of doctors whose benefits lie in TB being a highly critical disease. Therefore they don't want it to be destigmatised.”*

- Partner

*“There is no record of migrant population. Around 20-25 percent patients who are from other cities or districts are not followed up”*

-Private Provider

<sup>48</sup> KII-7,9,18,24,32,45

<sup>49</sup> KII-20,23,25

<sup>50</sup> KII-7,10,18,24,30,41

Despite these disincentives, association with the National TB Program also is an incentive for private providers. It boosts their reputation, leading to an increase in TB clients; being seen as a ‘good doctor’ in the community in turn leads to an increase in their business overall. Some private providers like to work with the program because they believe it is a social good; some are self-motivated to identify and treat TB patients.<sup>51</sup> It was reported that treating TB is seen to be as satisfying as social work for physicians in Mumbai and Patna.

## 3.5 The Policy Sphere

The policy sphere sets the rules of the game and the policy agenda within which TB demand and supply operate. Policy is as good as its implementation; the means and thoroughness of implementation is crucial to its success.<sup>52</sup> It has been pointed out that policy making is not complete unless there are financial and human resource to deliver it, and a strategy and planning for its delivery has been articulated.<sup>53</sup> The policy space comprises primarily government bodies and regulators, but also includes professional associations, which can play an important role in multiplying dissemination and providing voice to the professional community.

The sphere of policy – here, the RNTCP’s strategy and program design – is committed to finding cases early, achieving prompt reporting of TB cases diagnosed in the private sector, and improving the quality of care in the private sector. In 2012-17, the strategic vision of the RNTCP was to develop and deploy engagement models that will help overcome barriers of mutual mistrust and conflicting market forces and fragmentation, and to accept, encompass, and improve TB care provided by the private sector.

### 3.5.1 Availability

As per the Standards for TB Care in India, the primary diagnostic protocol for TB is to get a quality assured sputum test with at least two samples. Acceptance of sputum samples from the private sector at sputum collection centers and arrangements for transportation of samples has made the use of laboratories easier and reduced patient inconvenience. The government has instituted free chest X-rays for patients in the private sector to encourage screening and early identification of TB, and it reimburses the costs to radiology clinics. CBNAAT/ GeneXpert is freely available in the private sector, even for primary diagnosis purposes, unlike in the public sector where use is restricted to cases that do not respond to treatment. With CBNAAT machines now available in most districts in all states, diagnosis of children and people living with HIV is also more convenient (WHO 2014). However, availability of cartridges was observed to be an issue in Mehsana and Kolkata, with Mehsana prioritizing public sector patients when the stock of cartridges is limited.<sup>54</sup> Serological tests have been banned, and the tuberculin skin test and Interferon Gamma Release Assay are not recommended for diagnosing active TB.

*“Patients were hesitant to take free drugs from the TB hospitals as they doubted the quality. However they are very satisfied now since free medicines are available in the private sector.”*

-Private Provider

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<sup>51</sup> KII-11,16,26,34

<sup>52</sup>

<sup>53</sup> KII-12

<sup>54</sup> KII-15,16,20

Advocacy, communication and social mobilization for TB control projects are being run by the government to actively screen socially and clinically vulnerable populations. Special 'Active Case Finding' projects are presently being carried out in 50 districts spanning 18 states. Kolkata also conducted a workshop to address people from jail, hawkers, and migratory population groups.

Timely availability and procurement of drugs for drug-susceptible TB is a problem. Although free drugs are theoretically available in the public sector, stock-outs have reduced confidence in public sector systems. Patients prefer the private sector because of the ease of access and trust.

Treatment of MDR-TB requires the use of second-line drugs, which are more difficult to obtain than the first-line drugs used for drug-susceptible TB. Government policy limits treatment of DR-TB to the public sector. In any case, private providers prefer not to treat it, especially as cure rates are of the order of 50 percent.

Bedaquiline – hailed as the miracle TB drug – was introduced into the RNTCP in 2016, albeit with conditional access. While the government seeks to restrict its availability, it is available in the grey market. Most patients with MDR-TB lack the financial capacity needed to fight this disease over the two years of treatment. The majority run out of funds and even informed and committed patients are compelled to interrupt treatment while they arrange the finances (Gupta et al. 2015). Thus, provisioning and regulating the availability and pricing of drugs in the private sector, especially in case of MDR-TB and XDR-TB is critical.

### 3.5.2 Pricing

Most patients seeking TB care lack the financial capacity to get complete treatment in the more expensive private sector. Thus, making diagnostic tests and drugs in the private sector free helps patients both to seek care and to adhere to treatment.

The National Strategic Plan lays out the commitment of the RNTCP to strengthen engagement with the private sector. Government subsidizing of quality TB diagnostic testing (sputum microscopy and GeneXpert) at private labs has increased acceptance of these tests among the private providers and reduced patients' financial burden. This has increased willingness of persons with presumptive TB to undergo diagnosis and has, in turn, reduced the delay in diagnosis.

*“Poor patients have benefitted a lot from the free diagnostic tests and they feel less burdened.*

- Diagnostic Lab

Free first-line drugs have also been made available in the private sector. The use of an intermediary agency that collates and disburses funds means that reimbursements are not delayed, unlike in the past when distrust marked private-public relationships. This has reportedly led to greater adherence to treatment, also seen in TB indicators published by state governments.

### 3.5.3 Regulation

Efforts are being made to regulate the private sector and align it to government norms to achieve the goals of the END TB strategy.

An important gain has been in the notification of TB cases, which is seen as crucial to provide data for evidence-based planning for TB prevention and care (Srivastava et al. 2013). Case notification has been mandatory since 2012 in both public and private sectors, but because the provision is not strictly enforced, notification is practiced more in the breach by the private sector, which continues to view it with suspicion. There is a lack of incentivization by the government, or indeed monitoring, through any mechanism.

*“There is a need to regulate the private sector, but in a approachable manner”*

-State Official

While our desk review and interviews at the national level suggest that government regulation has in the past been dictatorial and unidirectional, this in contrast to prevailing views in the states, which suggest that there is good coordination between public and private sector.<sup>55</sup> Nevertheless, this has been due, at least in part, to the projects being willing to close their eyes to the transactional nature of relationships that form the substratum of the private system and the moral hazard that plays out in the form of additional financial burden on the patient.

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<sup>55</sup> KII-4, KII-5, KII-10

## 4. CONCLUSION AND RECOMMENDATIONS

### 4.1 Conclusion

TB poses one of India's greatest health threats. The private sector is today seen as the key to winning a war begun 55 years ago against one of the country's most devastating diseases.

The PEA methodology has provided an in-depth view of the relationships between patient and provider and of each – and both together – with the policy environment in which these relationships play out. One in four persons in India is infected with the TB bacillus and about 1.6 per one thousand has active disease and is capable of spreading TB. In 2016, 1.75 million TB patients were notified from the public and private sectors. Of the total cases notified, 83 percent had pulmonary TB and 17 percent had extra-pulmonary TB (Ministry of Health and Family Welfare 2017b). The rate of DR-TB has been rising steadily and in 2016 represented 2 percent of the new TB cases notified, or about 0.03 million persons.<sup>56</sup>

TB begins with a simple cough, most often among the poor and undernourished living in crowded homes and/ or working in crowded places. Persons with TB first present to their local provider with a cough that is 'not going away.' As the cough persists, they and their providers begin to consider the possibility that the cough may be a symptom of TB. Many patients move from provider to provider as they battle the pernicious cough and fever that mark the disease – on average, a patient has seen two or three providers before being diagnosed. About 60 percent of TB patients in India have seen a private sector provider in their quest to get well, even if they eventually take treatment in the public sector. Delay in diagnosis is due to lack of information about and the stigma associated with TB. First contact providers are either unaware of how to diagnose or are reluctant to progress to a definitive diagnosis of TB due to stigma and fear of losing the patient. These delays on both sides, patient and provider, means it takes about two months for the person with TB to get a diagnosis – by which time their disease has worsened and they have spread their infection to others.

The private sector has long relied on chest X-rays to develop a differential diagnosis and establish TB, though recently introduced diagnostic tools such as CBNAAT and sputum microscopy have caught on, especially with their wide availability and test costs being underwritten by the government. Many first contact providers refer the patient to a QPP known for TB care for diagnosis and treatment. Additional tests such as blood pressure, liver function, and sometimes kidney function are prescribed, presumably to rule out other conditions that might cause persistent cough or obtain a baseline of these functions before drug use.

Patients are generally prescribed anti-TB drugs in FDCs available from private chemists. Protocols for both diagnosis and treatment vary widely. Patients are also prescribed a number of additional drugs and nutritional supplements. Patients who can afford all the tests and drugs are generally motivated to complete treatment. Those who cannot afford it may drop out. Cure rates in the private sector hover around the 70 percent mark, approaching cure rates in the public sector. This is heartening. However, the rate also shows that about a third of patients are either not motivated or unable to afford the treatment requirements. This is a cause for concern.

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<sup>56</sup> The data that have been presented are not all from the same time period and have been used to give a general picture.

## 4.2 Recommendations for Policy

Policy tools can be employed to make changes that will improve TB care through more detection, appropriate testing, and use of standardized TB treatment. Policy tools are used to alter the incentive-disincentive equilibrium between patients and providers by explicitly and/or implicitly altering the considerations that direct decision making by patients and providers.

The policy toolkit has four primary instruments: information, availability, pricing, and regulation. These constitute the policy environment in which the patient-provider interaction takes place. Policy may change information asymmetry by ensuring that patients are aware that TB is a cause of a long-standing cough, leading them to put pressure on first contact providers to carry out diagnostic tests early in the course of the disease. It might change the availability of a service by installing GeneXpert machines in all districts of the country. Policy might also change the price at which certain tests or drugs are available through alterations in custom tariffs or subsidy of cost. And finally, policy might regulate through such means as requiring notification.

It is important to recognize that the likelihood of the private sector to independently undertake awareness generation is low. Awareness generation is generally the purview of government or of an agency charged with creating awareness and undertaking counseling. Environmental factors have much to do with patients' readiness to make use of services. Ease of private provider and patient access to CBNAAT has changed the game, and even increased patient readiness to do sputum microscopy. Pricing works by reducing prices through subsidy (full or partial) or increasing them through taxes. This has already been applied to availability of diagnostics such as chest X-ray. Regulation and monitoring systems are well-known preserves of public policy. It is important to recognize that use of differential (non-uniform) diagnosis and cure in the public and private sectors could garble data, making it difficult to interpret in the medium term. Control of the emerging DR-TB epidemic is critical before it gets out of hand and could benefit from application of regulation.

The government has introduced public-private mix efforts to reach private providers and work with them to increase identification, increase diagnosis and notification, and improve treatment outcomes in the private sector. This is being done indirectly through an interface agency like those in Kolkata, Mumbai, and Patna or directly as in Mehsana. These efforts are yielding results, with notifications from the private sector rising to 60 percent of all notifications and treatment completion rates in the region of 70 percent.

Broader interventions in the country include active case detection among high-risk populations, mandatory notification, an incentive for notification, availability of free CBNAAT test and chest X-ray as initial diagnostic tools, and free supply of FDC drugs in at least five states

Provided below is a discussion of the possible use of these four tools to improve patient detection, support rational testing, and reinforce the use of standardized TB treatment protocols by altering the incentive-disincentive equilibrium of the patient-provider dyad.

## 4.2.1 Addressing Information Asymmetries

### *Pre-Diagnosis Phase*

- Awareness generation in the general population
  - Findings suggest that patient expectations of getting well have a lot to do with their readiness to begin and motivation to complete treatment. A demotivating factor is the length of treatment and the difficulty of taking rest during treatment. Family support is important. By ensuring that the population believes in the results that can be obtained by complete treatment, the patient-community link is activated, as well as the cross-linkages to the (first contact) provider.
  - Important messaging is thus that the success of TB treatment leading to better survival rates; TB drugs are strong medicines that can knock out strong bacteria (with its subliminal link to treatment of DR-TB); and the need to care for TB patients so that they can go back to work.
- Counseling of patients
  - Our findings indicate that there could be missed opportunities for patient counseling during the pre-diagnosis phase, which could support early diagnosis and prevention of transmission of the disease.
  - Information that would be useful includes awareness about dos and don'ts and the need for specific tests for TB, which can provide a definitive diagnosis.
- Provider motivation and training
  - Several providers were motivated by altruistic reasons to provide treatment to TB patients; others recognized the value of providing treatment to their personal reputation and practice size. Also found was a need to encourage private providers to adopt standardized diagnostic and treatment protocols.
  - Key issues that could be covered in training are Standards of TB Care in India and platforms to showcase private provider efforts to adopt diagnostic and treatment protocols; success of TB treatment by private sector doctors, leading to the patient's better chance for survival; market expansion of private providers as successful treatment builds reputations; and participation in a social and national good.

### *Diagnosis and Treatment Phases*

- Counseling of patients
  - Missed opportunities for patient counseling were also obvious during diagnosis and treatment. Counseling could support prevention of transmission, encouragement to seek diagnosis, and adherence to treatment protocols.
  - Information that would be useful includes awareness about dos and don'ts; the need for TB testing; that supplementary drugs need not be expensive; that nutritional supplementation need not be expensive; and the need for follow-up and adherence.
- Provider education
  - In the diagnosis and treatment phases, our findings show that providers were motivated by altruistic reasons to provide treatment to TB patients. The value of providing treatment to physicians' personal reputation and practice size was noted. There is also a need to encourage private providers to adopt standardized diagnostic and treatment protocols.

- Key issues to be covered are Standards of TB Care in India and platforms to showcase private provider efforts to adopt diagnostic and treatment protocols; success of TB treatment by private sector doctors, leading to the patient's better chance for survival; market expansion of private providers as successful treatment builds reputations; and participation in a social and national good.
- Reminder messaging for patients
  - Without the deep penetration that public systems have through frontline workers, reminder messaging is seen to be essential. Reminder messaging uses phone/ web technology in each of the models studied. It is presently being carried out through third-party providers in all four project sites with good results.
  - Reminder messaging systems for private sector patients need to be continued where in place and expanded to cover private sector initiatives once begun.

## 4.2.2 Availability of Diagnostic and Treatment Services

### *Pre-Diagnosis*

- Capacity expansion
  - The role of providers at first contact is critical to reduce the time available for transmission of the disease and make diagnosis early in the course of the disease with possibly better results. Recognizing the role of first contact providers to screen out patients of TB from a larger set of respiratory and other conditions is required for the successful implementation of TB control, but this is distorted by moral hazard issues.
  - It may be worthwhile to consider conditional payments to first contact providers who make a definitive diagnosis of TB.

### *Diagnosis*

- Diagnostic sample transportation
  - Patients living at a distance from the district headquarters are less able than those living nearby to benefit from free diagnostic services such as CBNAAT. Wider availability of such laboratory services could help. Making diagnostic services accessible can play an important role in ensuring that diagnosis is not delayed.
  - One solution might be to increase the total number of CBNAAT machines in order to meet an exploding demand for the test. The possibility of a hub-and-spoke model for collection of diagnostic material and transport of it to a hub for testing could be considered using a third-party administrator to ensure optimum utilization of these machines.

### *Treatment*

- Listing of private sector providers
  - Treatment providers who are well versed in the Standards of TB Care in India are a critical resource. A short, easy-to-complete training course with online and offline modalities could help to build capacity in the private sector. Private sector providers value their connections with the government sector; this sort of initiative could yield practical benefits in terms of better compliance with diagnostic and treatment protocols.

- Private providers who have completed such a course could be listed on the government website as alternative sources of treatment for patients who prefer using the private sector.

## 4.2.3 Pricing of Services

### Diagnosis

- Subsidized diagnostics
  - A major impediment to early diagnosis is poor compliance with diagnostic protocols on the part of the patient. The cost of diagnosis – direct and indirect – causes delay. Where a subsidy has been provided, projects report greater compliance and earlier diagnosis.
  - Making free diagnostics available to patients in the private sector would greatly aid in early diagnosis and notification of the disease. While it may be worthwhile to relate this to completion of treatment, periodic rewards carry their own beneficial effects.

### Treatment

- Free or subsidized treatment
  - A key constraint to completion of treatment is the cost of drugs. Many patients discontinue treatment when they feel somewhat better due to the high cost of drugs and supportive medications.
  - Providing free or subsidized treatment would shift the financial burden of treatment away from patients, making it more likely that they complete treatment.
- Patient adherence incentive
  - Our findings and the literature indicate that opportunity costs constrain patient adherence to treatment. These are often hard to estimate in advance but require considerable outlay by the patient over the period of treatment. Programs such as the Beti Bachao campaign provide incentives to families to achieve a result. These incentives are held in escrow until the result – in this case of Beti Bachao, a girl attaining majority – are achieved.
  - A conditional cash transfer program linked to achieving a critical TB treatment milestone could be considered. Rewards should be linked not to achievements such as completion of the intensive phase but rather to adherence beyond that phase.
- Nutritional supplements
  - Consumption of additional nutrients has been shown to significantly improve patient outcome. This is particularly so since TB is a disease that occurs disproportionately among the poor. There have been calls from the Prime Minister's Office to begin such supplementation, and programs have been put in place for HIV and in the case of Severe Acute Malnutrition among under-five children.
  - Supplements may be worthwhile investments, possibly through tie-ups with corporates under their Corporate Social Responsibility initiatives.
- Physician's treatment completion incentive
  - It is argued that physicians incur opportunity costs associated with patient counseling and would need to be incentivized to regularly and systematically counsel patients regarding diagnosis and adherence to treatment. Physicians also incur opportunity costs linked to notification that must be done by them or someone in their office.

- Offering incentives to physicians for ensuring that their patients complete treatment would compensate for the additional demands the program puts on them such as doing notification, sharing patient information, and requesting reimbursement.

## 4.2.4 Strengthening government regulation and systems

### Diagnosis

- Uniform definition of diagnosis and treatment closure
  - If two datasets are to be treated as the same, or if comparisons are to be made between two sets of data, it is important to have data that show the same information. Thus common definitions for diagnosis and treatment closure in both public and private sectors are required. Use of uniform definitions for diagnosis and cure/ completion would make comparability of the results possible at this point in piloting private sector initiatives.
  - Establish appropriate indicators for definitive diagnosis of TB and closure of treatment.
- NIKSHAY initiative
  - The NIKSHAY effort has the potential to reduce duplicate registration/ counting. This is critical if reliable numbers of those on treatment are to be gathered and if robust data on shopping for treatment, drop-out of treatment, and re-entry into treatment are to be tracked. Presently, reliance is placed on field officers to remember each patient and remove duplications within the system; this is not good enough to ensure data validity.
  - Registration would be more dependable if it were linked to a unique ID number such as the Aadhar which is widely available.

### Treatment

- Crackdown on the grey market for Bedaquiline
  - Ensuring that there is rational use of bedaquiline is critical to tackling DR-TB and success in India's TB control efforts. Reserving the use of bedaquiline through regulation is already in place. Ensuring implementation of such regulation and close-down of the grey market for the drug is an essential step in this direction.
  - Effectively reserve the use of bedaquiline for treatment of DR-TB in the public sector.
- Management of private sector initiatives
  - The private sector is the port of first call for most persons with TB. It plays an important part in directing persons toward definitive care and takes much of the burden of treatment off the public sector. For India to achieve control of TB, it is clear that the private sector must play a responsible and considerable role. As has been demonstrated in existing public-private mix projects, significant economies of scale can be achieved in managing such efforts, with sizeable gains in case detection.
  - Private sector initiatives should be extended and expanded through third-party administrators. Government capacity to manage such administrators must be built. Operational learning from present day pilots would be an important resource.

# ANNEX A: DISCUSSION GUIDE

Respondent Name \_\_\_\_\_

Designation \_\_\_\_\_

I	TB
	<p><b>1. Landscape the problem of TB in your state</b></p> <ul style="list-style-type: none"><li>a. What are the ways in which you engage the private sector?</li><li>b. Does this have political support? In what way?</li></ul>
II	Pre-Diagnosis Phase
	<p><b>1. How do people with cough seek care?</b></p> <ul style="list-style-type: none"><li>a. Are they aware that cough could be due to TB? Any specific education measures?</li><li>b. What are their constraints?</li><li>c. Are there any incentives for specifically asking for the TB test?</li><li>d. How can demand be increased?</li></ul> <p><b>2. Who are the most important private sector actors (in this phase)?</b></p> <ul style="list-style-type: none"><li>a. How does each contribute in achieving public health goals?</li></ul> <p><b>3. How does the private sector identify TB?</b></p> <ul style="list-style-type: none"><li>a. Are they aware that cough could be due to TB? Any specific education measures?</li><li>b. What are incentives for primary care physicians to identify TB?</li><li>c. Any moral hazard issues?</li><li>d. What constraints do they face in identifying TB?</li><li>e. Are they aware of the STCI guidance on TB identification?</li></ul> <p><b>4. What specifically does the public sector do to support TB identification?</b></p> <ul style="list-style-type: none"><li>a. Communication efforts</li><li>b. Financial support e.g. incentives to align to government norms?</li><li>c. Private sector regulation/monitoring</li><li>d. Any policy constraints to private sector participation?</li></ul> <p><b>5. What opportunities are there for better cooperation between public and private sector?</b></p> <ul style="list-style-type: none"><li>a. Notification of TB</li><li>b. Dissemination of STCI</li><li>c. Research</li></ul> <p><b>6. Are there any additional roles that you think private sector can play/play better</b></p>

- 1. How does a TB suspect seek diagnosis?**
  - a. *How aware are patients about various methods to diagnose TB? Do they seek specific methods? If so, on what basis?*
  - b. *What are their constraints? Is cost an important factor?*
  - c. *Do patients have any incentives for undergoing TB diagnosis?*
  - d. *Are there any specific efforts to increase awareness about various tests for diagnosis among patients?*
  - e. *What additional efforts could be undertaken to boost demand for TB diagnostics?*
- 2. Who are the most important private sector actors (in this phase)?**
  - a. *How does each contribute in achieving public health goals?*
- 3. How does the private sector diagnose TB?**
  - a. *How do referrals usually take place in the private sector?*
  - b. *On what basis do doctors choose diagnostic methods? Are there any incentives for them to choose one method over another?*
  - c. *Is their choice of diagnostic methods different from that used in public sector?*
  - d. *Are they aware of STCI and do they follow the diagnostic protocols?*
  - e. *Does the private sector face constraints in diagnosing TB?*
- 4. How does the public sector support diagnosis of TB?**
  - a. *Are any incentives provided for the private sector to align to government norms?*
  - b. *Probe for infrastructure development support*
  - c. *Probe for development of innovative technologies*
  - d. *Are there penalties in case of non-adherence to standards?*
  - e. *What are the policy constraints to private sector participation?*
- 5. Do you see any opportunities for better cooperation between public and private sector?**
  - a. *Notification of TB*
  - b. *Dissemination of / applying STCI*
  - c. *Research*
- 6. Are there any additional roles that you think private sector can play/play better?**

- 1. Do TB patients adhere to treatment?**
  - a. What are the constraints to adherence?
  - b. Do they have any specific incentives for adherence?
  - c. Are specific measures being taken to increase awareness about adherence?
  - d. What additional efforts can be undertaken to boost demand for standard TB treatment?
- 2. Who are the most important private sector actors (in this phase)?**
  - a. How does each contribute in achieving public health goals?
- 3. How does the private sector undertake TB treatment?**
  - a. How do referrals usually take place in the private sector?
  - b. On what basis do doctors choose treatment to be given? Are there any incentives for them to choose one method over another?
  - c. Is the choice that they make different from the treatment protocols in public sector?
  - d. Are they aware of STCI and do they follow the treatment protocols?
  - e. Does the private sector face constraints in treating TB?
- 4. How does the public sector support treatment of TB?**
  - a. Are any incentives provided for the private sector to align to government norms?
  - b. Probe for infrastructure development support
  - c. Probe for development of innovative technologies
  - d. Are there penalties in case of non-adherence to standards?
  - e. What are the policy constraints to private sector participation?
- 5. Do you see any opportunities for better cooperation between public and private sector?**
  - a. Notification of TB
  - b. Application of STCI
  - c. Research
- 6. Are there any additional roles that you think private sector can play/play better?**



## ANNEX B: STAKEHOLDER ANALYSIS TOOL

**Let us assume that the government wants to institute reforms at the public – private interface in order to improve outcomes for TB patients. These reforms would be based on the recommendations that you have just made to us.**

1. Please score on a scale of 0 – 10, the interest that the following stakeholders might have in the reform. A score of 0 means that the stakeholder has no interest in the issue while a score of 10 would mean that the stakeholder has a lot of interest in the issue – positive or negative.

Note to interviewer: Use the Likert Tool]

**Can you identify any actors in the private sector (of those listed above) who will strongly oppose this reform you suggest? If yes, who?**

2. Next we'd like to ask you to score on a scale of 0 – 10, the power of the stakeholders to influence the uptake of the reform. A score of 0 means that the stakeholder has no power or influence in uptake of the reform while a score of 10 would mean that the stakeholder has a lot of influence over the uptake of the reform.

[Note to interviewer: Use the Likert Tool]

**Of the actors likely to strongly oppose the reforms, can you identify actors who have the power to block this reform you suggest? If yes, who? Can you elaborate on what makes them powerful?**

*Probe for: strong unions/lobbies, political strength, large share of the market etc.*

Thank you for your time. May I get back to you for any further thoughts or clarifications?

Name	Organization										
0 indicates no interest in reform 10 indicates a high level of interest in reform – positive or negative											
	0	1	2	3	4	5	6	7	8	9	10
Community	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
TB suspects (those with signs and symptoms of TB who have been advised diagnosis).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
TB patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Small labs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Corporate labs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Individual doctors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Doctors with small institutions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Doctors at large institutions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Small chemist shops	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Corporate chemist shops	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Government – Central TB Division	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Government – Drugs Controller of India	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Funding/ Technical/ Implementing partners (USAID, WHO, BMGF, PATH, NGOs etc).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Indian Medical Association	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Indian Pharmaceuticals Association	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Indian Chest Society	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Specify	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Specify	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						

Name	Organization										
0 indicates no interest in reform 10 indicates a high level of interest in reform – positive or negative											
	0	1	2	3	4	5	6	7	8	9	10
Community	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
TB suspects (those with signs and symptoms of TB who have been advised diagnosis).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
TB patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Small labs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Corporate labs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Individual doctors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Doctors with small institutions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Doctors at large institutions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Small chemist shops	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Corporate chemist shops	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Government – Central TB Division	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Government – Drugs Controller of India	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Funding/ Technical/ Implementing partners (USAID, WHO, BMGF, PATH, NGOs etc).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Indian Medical Association	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Indian Pharmaceuticals Association	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Indian Chest Society	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
<i>Specify</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
<i>Specify</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						



## ANNEX C. STAKEHOLDER ANALYSIS RESPONSES

Stakeholders	Interest	Power
<b>Demand</b>		
<b>General public, patients and the community</b>		
TB patients	7.3	5.6
Treatment Providers	8.0	6.0
TB symptomatics	6.1	4.9
Community	6.3	5.9
DOTS legacy community*	0.0	8.0
<b>Supply</b>		
<b>Private health care providers (Small)</b>		
Individual doctors	5.9	5.1
Doctors with small institutions	6.0	5.4
AYUSH	2.0	4.0
Small labs	5.2	3.8
Small chemist shops	5.3	4.7
<b>Private health care providers (Large)</b>		
Corporate hospitals	1.0	7.0
Pulmonary physicians	9.0	9.0
Corporate labs	5.7	5.2
Corporate chemist shops	5.7	5.0
<b>Policy</b>		
<b>Government, policy makers and affiliated bodies</b>		
Government- Central TB Division	8.3	9.1
Government- Drugs Controller of India	6.3	7.7
Funding/Technical/Implementing partners	8.0	8.1
Other government ministries (Finance, Industry etc.)	4.0	9.0
Political leadership (Centre, State)	6.0	10.0

Stakeholders	Interest	Power
<b>Private organized bodies working in the sector**</b>		
Indian Medical Association	6.9	7.3
Indian Pharmaceuticals Association	6.3	7.0
Indian Chest Society	6.4	6.3
Indian Academy of Pediatrics	8.5	8.5
Other medical associations (API, FOGSI etc.)	5.0	9.0
CSOs (NGO, CBO, rights based organizations)	10.0	7.0

\*DOTS legacy community comprises patients who have completed treatment and act as community volunteers to build compliance with DOTS treatment.

\*\*The private organized bodies might play a role on the supply side as well.

## ANNEX D. LIST OF RESPONDENTS

### NATIONAL LEVEL

#	Interviewees	Organization
1	Geetanjali Sharma	PwC
2	Heman Sabharwal	PwC
3	Jamie Tonsing	The Union
4	Jorge. A Coarasa	World Bank
5	Kavita Aiyagiri	The Union
6	Puneet Dewan	BMGF
7	Ramesh Bhat	IIM-A (retd.)
8	Ramya Ananthakrishnan	REACH
9	Sanjay Sarin	FIND
10	Shibu Vijayan	PATH
11	Sreenivas Achuntan Nair	WHO
12	Sunil Khaparde	CTD
13	Suresh Kunhi Mohammad	World Bank
14	Venkat Raman	RNTCP task group on private sector engagement

### STATE LEVEL

#	Interviewees	Designation
<b>Patna, Bihar</b>		
1	K.N. Sahai	State TB Officer
2	Lavkush Kumar	Patient
3	Manuj	PPIA Project Staff
4	Mrityunjay	PPIA Project Staff
5	Naushad Ali	QPP
6	Niti Jha	PPIA Project Staff
7	Paramjeet Kumari	NQPP
8	Pranati Das	PPIA Project Staff
9	Rizwanat Tauheed	Lab Technician
10	Santosh Kumar	Lab Technician
11	Sarvesh Suman	Chemist

#	Interviewees	Designation
12	Sonu	Chemist
13	Suman	NQPP
14	Vijay Kumar	QPP
<b>Mehsana, Gujarat</b>		
15	Harshida Ben	Patient
16	Harun	WHO Consultant
17	Hiren Patel	Chemist
18	Jignesh	Patient
19	KK Patel	District TB Officer
20	Narendra Patel	QPP
21	ND Tapodhan	PPIA Project Staff
22	Pankaj Ojha	Chemist
23	Pramukh Swamy	QPP
24	PS Patel	Chemist
25	Ram Bhai Patel	QPP
<b>Kolkata, West Bengal</b>		
26	Anjali Nath	PPIA Project Staff
27	Alivia	PPIA Project Staff
28	Dilip Singh	Chemist
29	S Ghosh	Central TB Officer
30	S. Parthiban	PPIA Project Staff
31	Ishita	PPIA Project staff
32	Kunal Kati Dey	Deputy CMOH II
33	Md. Ashraf Ali	NQPP
34	Neelofar	TOUCH Agent
35	Niraj	PPIA Project Staff
36	Satyendra Nath Dey	Councillor
37	Shamsuddhi Ahmed	QPP
38	Shatabdi	PPIA Project Staff
39	Shurusha Nursing Home	Diagnostic Lab
40	Subhro	PPIA Project Staff
41	Tanusree	PPIA Project Staff
42	Vikram Khaitan	Chemist

#	Interviewees	Designation
<b>Mumbai, Maharashtra</b>		
43	Ghanshyam	PPIA Project staff
44	Amit Shobhawat	AYUSH
45	Dakshah Shah	District TB Officer
46	Eknath Patel	AYUSH
47	Gaurav Ghatawat	QPP
48	Guddu	Lab Technician
49	Mubashirin	AYUSH
50	Omprakash Gurjar	AYUSH
51	Parvez Sheikh	AYUSH
52	Rehman	AYUSH
53	Sameer	Patient
54	Yunus	PPIA Project Staff



# ANNEX E. DOSSIERS

## Bihar

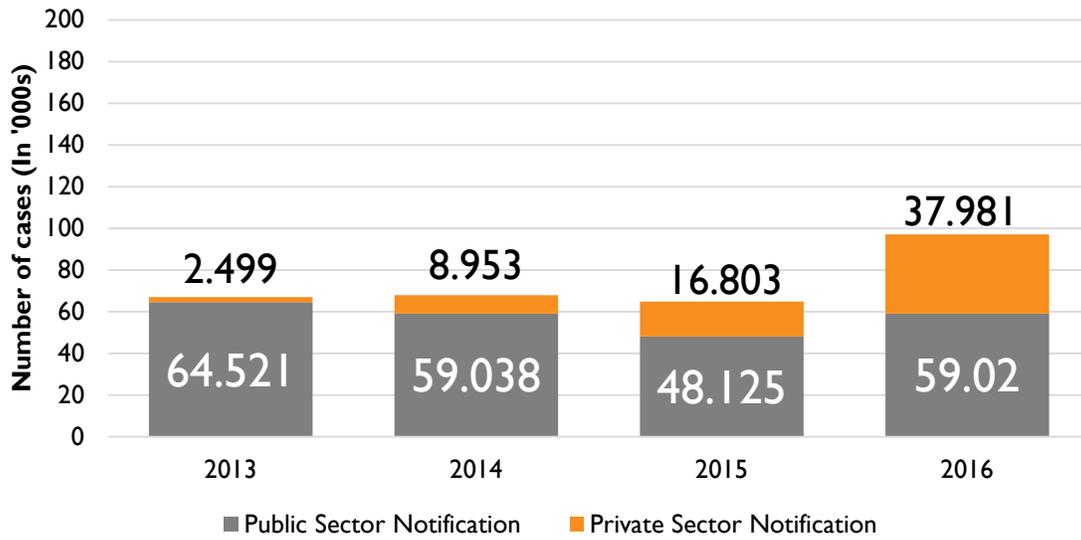
### Context

- Bihar is 3rd most populous state in India with 104.1 million people.
- Only 11.3% live in urban areas.
- Land area ~94,163 sq. km with a population density of 1,106 per sq. km. Population density is 1,806 in the Patna.
- Life expectancy is 68.1 years. Women's life expectancy is higher than that of men (68.4 years vs 67.8 years).
- 21.9% live below the poverty line, more in rural areas (25.7%) than in urban areas (13.7%).
- ~40% of the households in urban areas live in houses with only one room.
- Rs 8,234 crore were allocated to the National Health Mission in 2016-17, an increase of 65.2% from the allocation in 2015-16.
- There are substantial gaps in health sector infrastructure in Bihar in terms of manpower, equipment, and drugs.

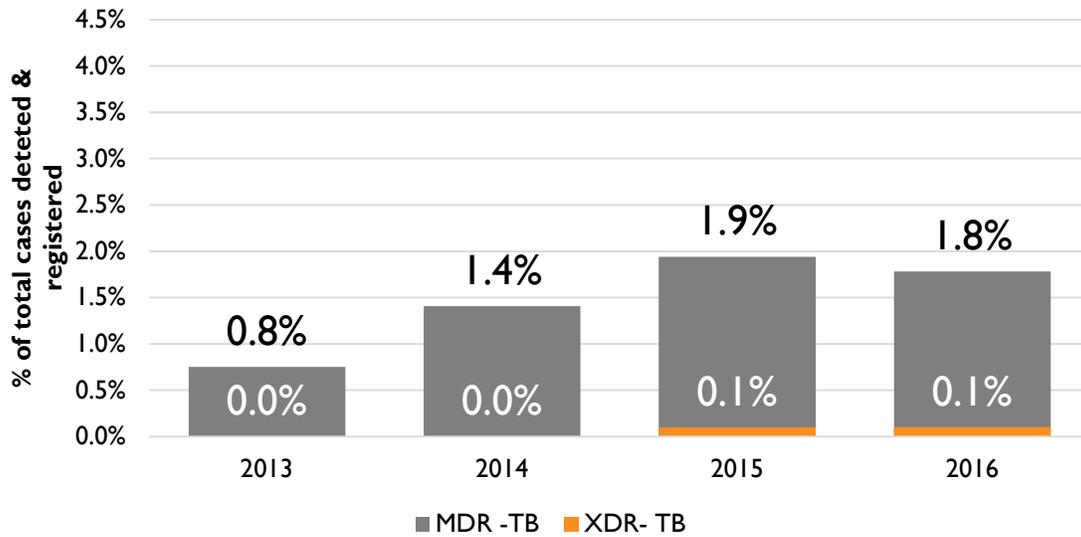
### Problem of TB in Bihar

- Bihar has seen an upsurge in the number of TB patients in the last four years from 67,020 to 97,001.
- In 2016, 97,001 TB patients were notified. Of these, 84% were new TB cases and 16% were previously treated. Patna itself reported over 28,330 TB cases; these represent ~30% of all cases in the state.
- 37,981 (39%) of total cases in 2016 were notified by the private sector.
- In 2015, of 32,057 microbiologically confirmed new TB patients registered, 77% were cured, 6% defaulted, 3% died, and 14% transferred out or moved to CAT IV. Of the 20,073 clinically diagnosed new TB cases, 91% completed treatment, 5% defaulted, 2% died, and 2% transferred out or moved to CAT IV.
- There has been an increase in the notified cases of DR-TB. In 2016, 1,762 MDR-TB and 102 XDR-TB cases were registered and initiated on treatment.

**Figure A1. Notifications in Public and Private Sector - Bihar**



**Figure A2. Cases of DR TB Detected and Registered - Bihar**



# Public-Private Interface Agency Model

World Health Partners

<http://www.worldhealthpartners.org>

## Location

Patna, Bihar

## Other Partners

- Government of Bihar
- RNTCP
- The Bill and Melinda Gates Foundation
- World Health Partners

## Background

- TB causes two deaths every three minutes in India. In 2015, as many as 58,814 new TB cases were registered in Bihar. Out of these, 1,010 cases were of MDR-TB and 25 cases were of XDR-TB.
- More than half of the TB patients are estimated to seek care in the private sector. These providers are often the first point-of-care even for patients who are eventually treated in the public sector.
- Given that the private sector treats a significant number of TB patients, its engagement is essential to achieve universal access to quality diagnosis and treatment.
- World Health Partners has worked in Patna since 2014 as a Private Provider Interface Agency (PPIA). It works with the Government of Bihar to help strengthen TB prevention efforts in Patna district.
- They have been engaging and networking existing qualified and informally qualified providers, chemist shops, and diagnostic facilities under the ambit of Universal Access to TB Care, using a technology-based reporting platform and an inclusive system of financial and service incentives.

## Objectives

- Facilitate early and accurate diagnosis of TB in the private sector
- Facilitate notification of cases diagnosed and treated in the private sector
- Ensure appropriate treatment of cases in the private sector as per Standards for TB Care in India
- Ensure treatment completion and improved cure rates of TB patients in the private sector

## How it Works

- A QPP notifies a TB case diagnosed or treated outside the RNTCP. The doctor calls a toll-free number at the contact center to notify the TB patient.
- Additionally, in Patna:
  - AYUSH/other informal providers are engaged and trained to refer presumptive TB/TB cases to a QPP.
  - In order to facilitate accurate TB diagnosis, a provider engaged under PPIA sites registers a case and simultaneously issues an electronic diagnostic voucher with a unique serial number. The voucher number is delivered to the patient via SMS.

- On receiving the prescription from the provider and diagnostic voucher number, the TB patient/presumptive TB patient will produce the same to the engaged laboratory.
- The laboratory validates the authenticity of the voucher number by calling the toll-free number at the contact center. On successful validation, the laboratory provides the assigned diagnostic services.
- After the test results are out, the laboratory service provider calls on the toll-free number at the contact center to update the test results.
- On receiving the diagnostic results, the QPP calls the toll-free number to notify the case.
- The payments are made through e-transfer directly to the chemists against the vouchers validated by them. The chemists are reimbursed 3% of the cost in addition to the manufacturer suggested retail price of the drugs.
- A patient is contacted by the contact center for confirmation of receipt of free TB medicines. During the confirmation call, the patient is also counselled, informed about adherence mechanisms, and the adherence plan is decided.
- Further patient monitoring is managed through missed calls from patients to the contact center, SMS reminders to patients from the contact center, weekly phone calls to patients whose adherence is not marked in a week, voucher refilling monitoring, and visit to patients based on information from the contact center on adherence.

### Coverage

So far, in Patna, the World Health Partners has engaged with:

- 597 doctors
- 461 informal providers
- 127 laboratories and imaging centers.
- 698 chemists

### Impact

- The networks of private providers have notified 40,331 cases of TB till date.
- Approximately 37,296 patients have initiated free drugs.
- 13,292 patients were reported to have completed treatment by the end of 2015.
- 963 cases of DR-TB diagnosed.
- Availability of rapid and high-sensitivity tests, support to accessing them, and constant monitoring has dramatically improved the use of sputum testing in the private sector.
- The use of CBNAAT has contributed significantly to MDR-TB case findings in the private sector.
- Adherence support is extended to TB patients treated in the private sector and their treatment outcomes are systematically ascertained.
- Out-of-pocket expenditure by patients has decreased considerably because free diagnosis and drugs are now available in the private sector.

## Challenges

- Preventing the misuse of free diagnostic tests.
- Procuring drugs. It was reported that a few medicines have been out of stock for the past 6 months.
- Getting private providers to follow Standards for TB care.
- Changing the prescribing behavior of practitioners.
- Increasing the institutional coordination and capacity of public sector staff to manage the program to increase effectiveness of the intervention through the PPIA.
- Following up migrants since many move to their home towns soon after diagnosis.

# GUJARAT

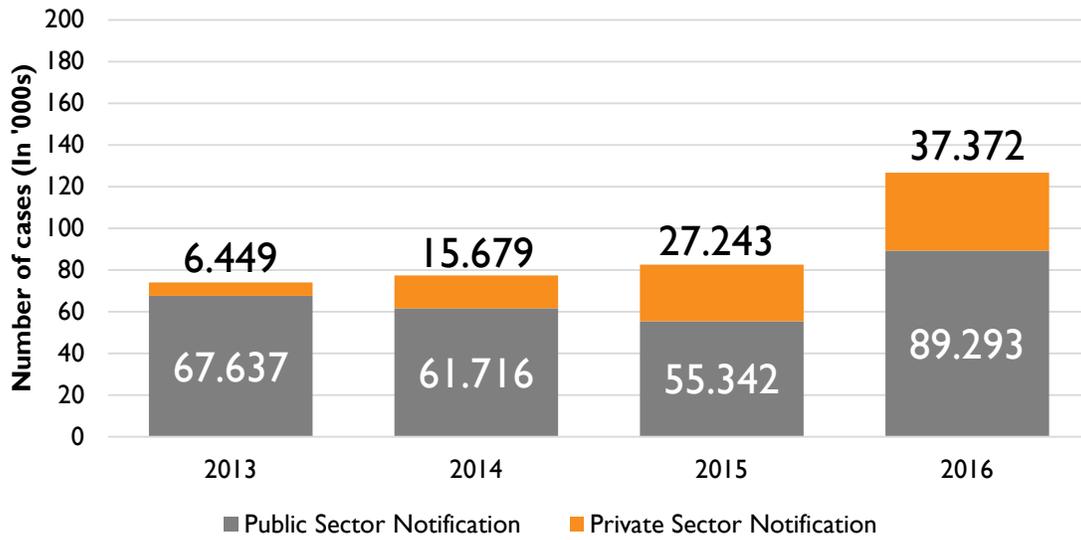
## Context

- Gujarat is 10<sup>th</sup> most populous state in India with 60 million people.
- 43% live in urban areas.
- Land area ~ 190,000 sq km with a population density of 308 per sq km. Average population density in urban areas is 400. Population density is approximately 462 in Mehsana district.
- Life expectancy is 68.7 years. Women's life expectancy is higher than that of men (71 years vs 66.6 years).
- 16.4% live below the poverty line, more in rural areas (22%) than in urban areas (10%).
- Rs 1323 crore were allocated to the National Health Mission in 2015-16.
- Gujarat's health infrastructure in both urban and rural areas is quite good. However there is a shortage of human resources at all levels.

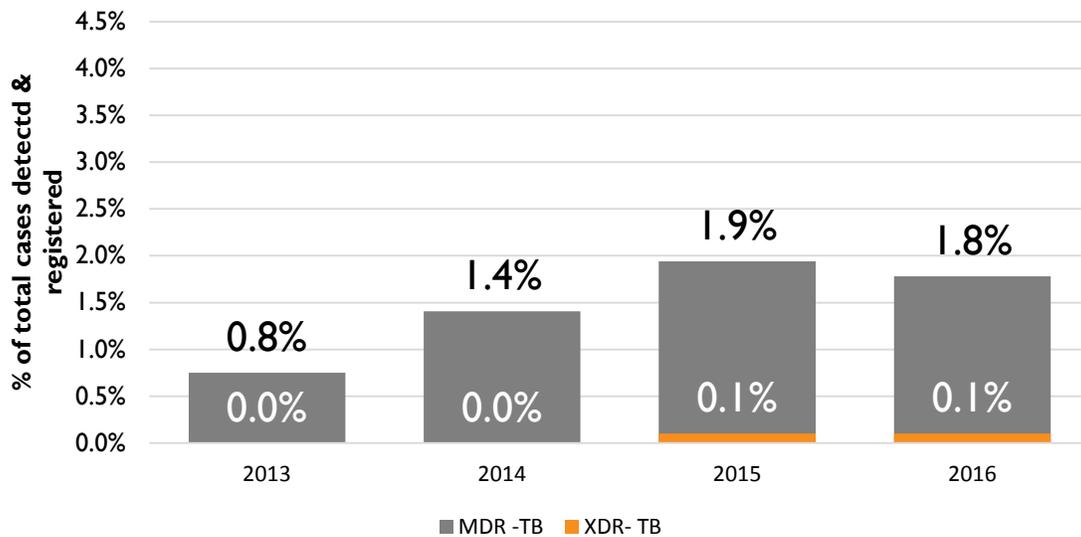
## Problem of TB in Gujarat

- Gujarat ranks 7<sup>th</sup> among Indian states with regard to number of TB cases.
- In 2016, 126,665 TB patients were notified. Of these, 72% were new TB cases and 28% were cases that were previously treated. Mehsana notified over 6,000 TB cases, about 4.5% of all cases.
- Of cases notified in 2016, 64% were microbiologically diagnosed and 36% were clinically diagnosed.
- 37,372 (30%) of total cases in 2016 were notified by the private sector.
- In 2015, of the 39,093 microbiologically confirmed new TB patients registered, 88% were cured, 3% defaulted, 5% died, and 4% transferred out or moved to CAT IV. Of the 20,907 clinically diagnosed new TB cases, 93% were completed, 2% defaulted, 4% died, and 1% transferred out or moved to CAT IV.
- There has been an increase in the notified cases of DR-TB. In 2016, 2,222 MDR-TB and 245 XDR-TB cases were registered and initiated on treatment, constituting ~2% of notified TB cases.

**Figure A3. Notifications in Public and Private Sector - Gujarat**



**Figure A4. Cases of DR TB Detected and Registered - Gujarat**



## Public-Private Mix Model

Government of Gujarat  
<http://www.gujaratindia.com>

### Location

Mehsana, Gujarat

### Other Partners

- Central TB Division
- Government of Gujarat
- The Bill and Melinda Gates Foundation
- World Health Partners
- Vertex
- Ernst and Young

### Background

- There has been a steady rise in the number of TB cases registered in the state, from 74,086 cases in 2013 to 89,047 in 2016.
- Even though an estimated 60% of Gujarat's TB cases seek care in the private sector, only 20% of TB notifications were made each year by that sector until 2013.
- A need was felt to have an effective engagement with the private sector to improve overall TB outcomes.
- Multiple prior efforts by the RNTCP to engage the private sector have had limited success due to factors such as mutual mistrust, conflicting market forces, and the immense scale and fragmentation of the private health sector.
- The RNTCP recommended redesigning the existing strategies and developing and implementing innovative models for engaging the private sector to overcome the challenges in service delivery gap in TB care
- In Mehsana, the RNTCP staff were encouraged to manage the service delivery intervention for a small number of private providers.

### Objectives

- Facilitate early and accurate diagnosis of TB in the private sector
- Facilitate notification of cases diagnosed and treated in the private sector
- Ensure appropriate treatment of cases in the private sector as per Standards for TB Care in India
- Ensure treatment completion and improved cure rates of TB patients in the private sector

## How it Works

The Mehsana model does not use a PPIA. RNTCP staff alone carry out field operations.

Following is the process of engagement adopted in Gujarat:

- Standard Operating Procedures (SOP) for drug voucher generation and a TB Manual is given to all the engaged QPPs and chemists for their reference. The documents are in both English and Gujarati.
- A QPP notifies a TB case diagnosed or treated outside the RNTCP. The doctor calls a toll-free number at the contact center to notify the TB patient.
- As soon as a TB case is notified, an electronic drug voucher with a unique serial number is generated for first-line anti-TB drugs prescription.
- A master list of all the preferred drugs for TB with their prices has been created and distributed to private providers and chemists. Private providers have the freedom to choose from this list.
- On receiving the prescription from the doctor and the drug voucher number, the TB patient produces the same to the chemist.
- The chemist validates the authenticity of the voucher number by calling the toll-free number at the contact center. If the voucher number is valid, the chemist gives a one-month supply of free anti-TB drugs to the patient based on the prescription and voucher.
- The payments are made through e-transfer directly to the chemists against the vouchers validated by them. The chemists are reimbursed an additional 3% of the cost and MRP of the drug.
- A patient is contacted by the contact center for confirmation of receipt of free TB medicines. During the confirmation call, the patient is also counselled, informed about adherence mechanisms and the adherence plan decided.
- Further patient monitoring is managed through missed calls from patients to the contact center, SMS reminders to patients from the contact center, weekly phone calls to patients whose adherence is not marked in a week, voucher refilling monitoring, and visit to patients based on information from the contact center on adherence.

## Coverage

So far in Mehsana:

- 123 MBBS doctors have been engaged and are active in prescribing anti-TB treatment.
- Diagnostic labs have not been engaged because it was not a part of the mandate initially. However, in 2015 this component was added.
- 99 chemists have been engaged and are actively participating in the project.

Informal providers have not been engaged in Mehsana. However, most rural residents with presumptive TB visit AYUSH and homeopathic doctors. Efforts have been made to train them in order to improve the referral mechanism.

## Impact

- Approximately additional 8241 cases of TB have been notified since implementation.
- Notification from the private sector has more than doubled, from 20% in 2013 to 58% in 2016. Public sector notification has not decreased over the same period.
- The treatment completion rate among TB patients has reached 83%.
- The number of TB notifications has greatly increased from just ~1/3 of practitioners who were sensitized and enlisted under the intervention, indicating the importance of intentional prioritization and targeting of providers.
- The changes have facilitated monitoring and improvement of quality of care in the private sector.
- The process of enlisting of providers, prioritizing them based on their potential to contribute to TB case notification, and updating the priority list for prescribing doctors through pharmacy surveillance has been tested and found to be robust.
- Systems and strategies were developed for sensitization, which led to active recruitment of key providers.
- Processes related to customer service interface were employed, which kept providers engaged.
- Adherence support was extended to TB patients treated in the private sector and their treatment outcomes were systematically ascertained.
- The project has reduced or subsidized the cost of care that patients incur specifically on treatment and drugs

## Challenges

- Not all targeted key providers have been successfully engaged and out of those who are engaged, only about half are active.
- Improving microbiological confirmation without subsidized or free high sensitivity diagnostic tests is difficult.
- There were initial discrepancies in drug reimbursements due to miscommunication between the chemists and the call centers. This has been resolved.
- Following up with the migrant population is an issue. Most of them move back to their home town once they are diagnosed with TB. There is no mechanism to keep track of these patients.
- Effectiveness of the intervention requires closer institutional coordination and capacity of the public sector staff to manage the program. However, since there is no help from outside, the RNRCP staff gets burdened with the additional work.
- Even though the program is functioning well, sustainability is an issue. As per the Gates Foundation calculations, current expenditure per patient is about \$66. Thus, it will be very difficult to sustain the program after the funding period ends in December.

# WEST BENGAL

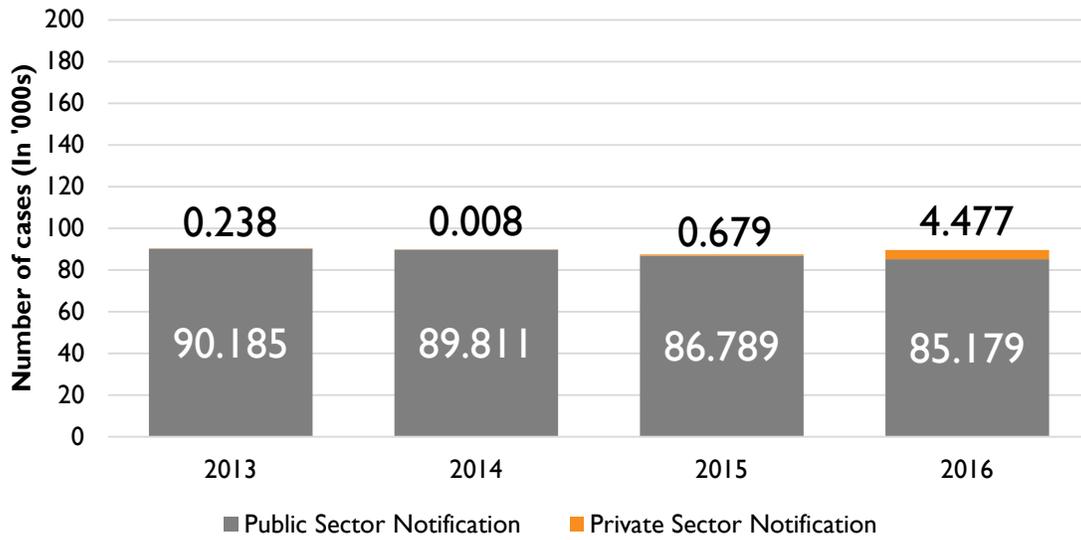
## Context

- West Bengal is the 4<sup>th</sup> most populous state in India with 91.3 million people.
- ~32% live in urban areas.
- Land area ~88,752 sq. km with a population density of 1,028 per sq km. Population density goes up to 1806 in Kolkata.
- Life expectancy is 70.7 years. Women's life expectancy is higher than that of men (72.1 vs 69.2 years).
- 26.7% live below the poverty line, more in rural areas (28.8%) than in urban areas (22.0%).
- Rs 3058.86 crore were allocated to the National Health Mission in 2016-17, a decrease of 13% from the allocation in 2015-16.
- There has been a paradigm shift in health care infrastructure from a mainly urban and clinic based one to the creation of preventive and rehabilitative services by strengthening the primary, secondary, and tertiary care institutions and linking them through appropriate referral systems.

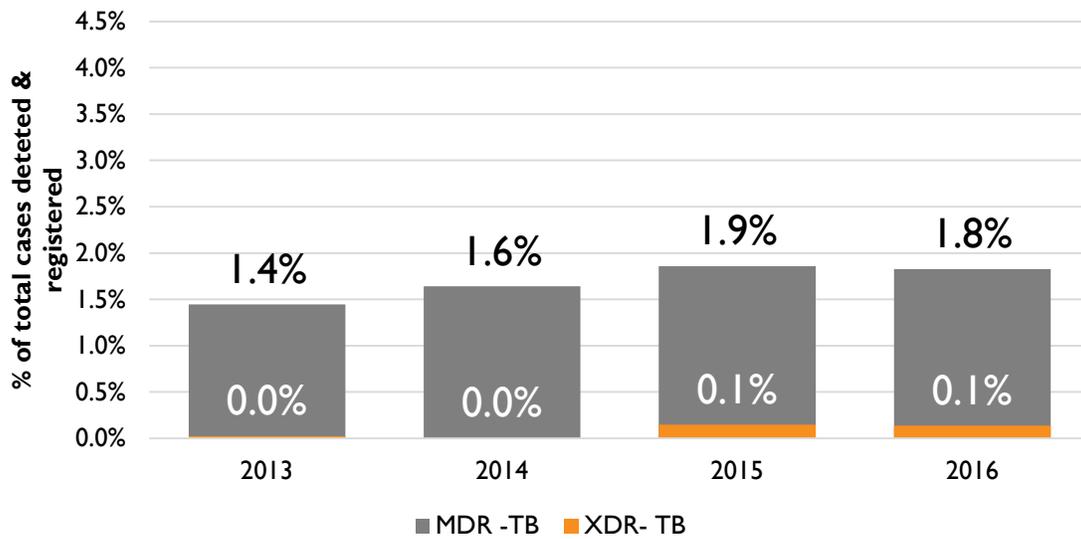
## Problem of TB in West Bengal

- Despite efforts to control TB, it continues to be the most dangerous epidemic in West Bengal.
- In 2016, 89,656 TB patients were notified. Of these, 84% were new TB cases and 16% were previously treated cases. Kolkata reported over 4,000 TB cases.
- Of cases notified in 2016, 60% were microbiologically diagnosed and 40% were diagnosed clinically.
- Only 4,477 (5%) of total cases in 2016 were notified by the private sector.
- In 2015, of 43,242 microbiologically confirmed new TB patients registered, 85% were cured, 6% defaulted, 4% died, and 5% transferred out or moved to CAT IV. Of the 29,764 clinically diagnosed new TB cases, 90% completed, 5% defaulted, 4% died, and 1% transferred out or moved to CAT IV.
- There has been an increase in the notified cases of DR-TB. In 2016, 1962 MDR-TB and 161 XDR-TB cases were registered and initiated on treatment.

**Figure A5. Notifications in Public and Private Sector – West Bengal**



**Figure A6. Cases of DR TB Detected and Registered – West Bengal**



# Public Private Interface Agency Model

World Health Partners

<http://www.worldhealthpartners.org>

## Location

Kolkata, West Bengal

## Other Partners

USAID implementing partners that support the TB Health Action Learning Initiative (THALI) include:

- World Health Partners (WHP)
- Child In Need Institute (CINI)
- John Snow India (JSI)
- Global Health Strategies (GHS)

## Background

- Around 150,000 fresh cases of TB occur in West Bengal each year and thousands die of the disease.
- The number of MDR-TB cases has increased from 1,284 in 2013 to 2,222 in 2016.
- An estimated 60% of persons with presumptive TB in West Bengal rely on private providers and informal providers as their first point of contact.
- Even though private sector treats more than half of the TB patients in West Bengal, notifications from the private sector have been only 19% of the total notifications, i.e., 5 per lakh population.
- Stigma attached to the disease continues to play a significant role in delaying diagnosis and continuance of the treatment.
- Therefore a need was felt to facilitate TB notification and adherence monitoring for private sector patients and create community awareness on TB prevention and care.
- Therefore the four-year USAID-funded THALI project was put in place. It is aimed at improving TB services by supporting the private health sector and increasing TB notification through community engagement.

## Objectives

- Increase community engagement
- Improve private sector delivery in TB prevention and care
- Catalyze Innovations to address challenges in case finding and treatment adherence
- Strengthen evidence-based decision making
- Engage with government and associations
- Increase investment for urban TB prevention

## How it Works

- Field volunteers called 'Touch Agents' have been appointed to sensitize and increase community engagement. They also are to identify persons with presumptive TB from within the community. They are paid Rs. 250 for each suspect referral and notification, Rs. 250 for follow-up of patients during treatment, and Rs. 300 for treatment completion.
- A QPP notifies a TB case diagnosed or treated outside the RNTCP. The doctor calls a toll-free number at the contact center to notify the TB patient. An incentive of Rs. 300 is paid to the compounder of the practitioner to ensure patient adherence support.
- Additionally, in Kolkata:
  - Informal providers are engaged and trained to refer presumptive TB/TB cases to QPP. An incentive of Rs. 300 is paid to the informal providers as an incentive for case referral and treatment supervision.
  - In order to facilitate accurate TB diagnosis, a provider engaged under PPIA sites registers a case and simultaneously issues an electronic diagnostic voucher with a unique serial number. The voucher number is delivered to the patient via SMS.
  - On receiving the prescription from the provider and diagnostic voucher number, the TB patient/presumptive TB patient will produce the same to the engaged laboratory.
  - The laboratory validates the authenticity of the voucher number by calling the toll-free number at the contact center. On successful validation, the laboratory provides the assigned diagnostic services.
  - After the test results are out, the laboratory service provider calls the toll-free number at the contact center to update the test results. The only incentive for the lab is an increased clientele.
  - On receiving the diagnostic results, the QPP calls the toll-free number to notify the case.
- The payments are made through e-transfer directly to the chemists against the vouchers validated by them. The chemists are reimbursed 3% in addition to the MRP of the drugs.
- A patient is contacted by the contact center for confirmation of receipt of free TB medicines. During the confirmation call, the patient is also counselled, informed about adherence mechanisms and the adherence plan is decided.
- Further patient monitoring is managed through missed calls from patients to the contact center, SMS reminders to patients from the contact center, weekly phone calls to patients whose adherence is not marked in a week, voucher refilling monitoring, and visit to patients based on information from the contact center on adherence.

## Coverage

So far, in Kolkata, World Health Partners has engaged with:

- 191 doctors
- 27 informal providers
- 7 laboratories and imaging centers
- 96 chemists

## **Impact**

- Even though the program was established in 2016, engagement with private providers started only in January 2017. Since then, the network of private providers has notified approximately 465 cases.
- Approximately 300 patients have initiated treatment with free drugs.
- Availability of rapid and high-sensitivity tests has dramatically improved the use of sputum testing in the private sector. However a few private providers continue to rely on chest X-rays to confirm the diagnosis of TB.
- The use of CBNAAT has contributed significantly to MDR-TB case finding from the private sector. 28 CBNAAT machine have been put in place in West Bengal. Out of these, 7 are in Kolkata and 2 in Howrah.
- Out-of-pocket expenditure for the patients has reduced considerably.

## **Challenges**

- Chemists are not satisfied with the process of reimbursement: because voucher validation takes 10-15 days, their payment is delayed. There is also a communication gap between chemists and the call center.
- Engaging with private sector providers to change in their prescribing practices to align with government norms is a challenge.
- Bringing patients lost to follow-up back to the system is cumbersome.
- Keeping track of the migrant population is a major challenge since they move to their home towns soon after diagnosis.

# MAHARASHTRA

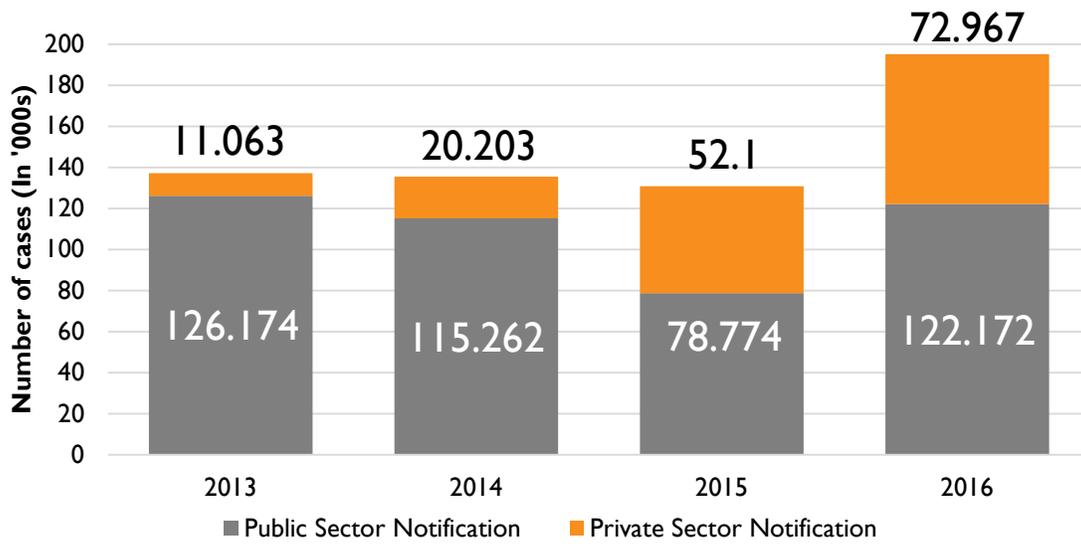
## Context

- Maharashtra is 2<sup>nd</sup> most populous state in India with 112.4 million people.
- 45.2% live in urban areas.
- Land area ~307,713 sq. km with a population density of 365 per sq. km. Average population density in urban areas is 400. Population density goes up to 277,136 per sq. km in the Dharavi slum area of Mumbai.
- Life expectancy is 67.2 years. Women's life expectancy is higher than that of men (68.4 years vs 66.0 years).
- 17.3% live below the poverty line, more in rural areas (24.2%) than in urban areas (9.1%) in urban areas.
- ~40% of the households in urban areas live in houses with only one room.
- Rs 970 crore allocated to that National Health Mission in 2016-17, a decrease of 51.4% from the allocation in 2015-16.
- The state has a three-tier health infrastructure to provide comprehensive health services. However, poor implementation of the National Urban Health Missions remains a key policy challenge.

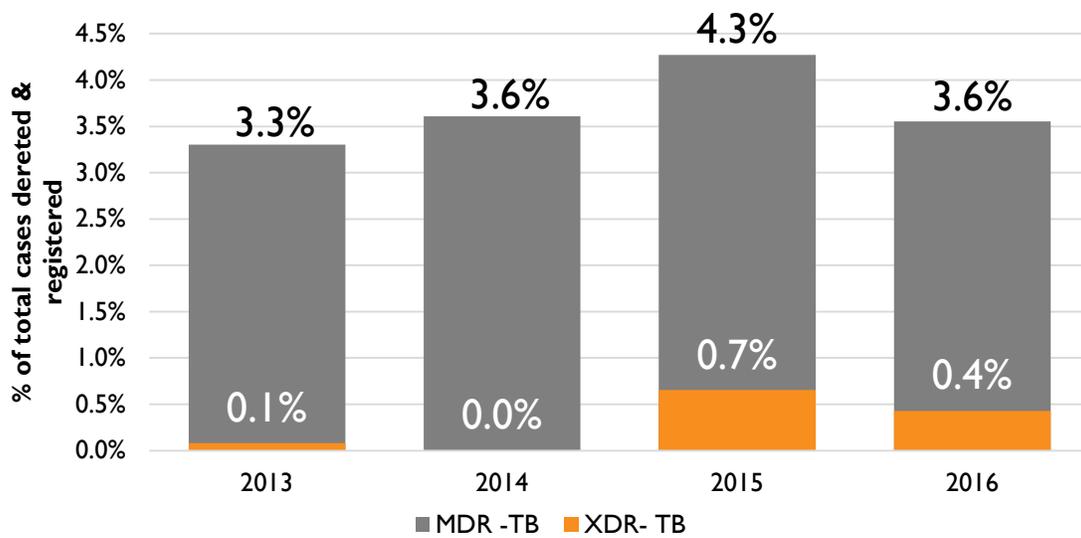
## Problem of TB in Maharashtra

- Maharashtra has the highest incidence of both drug-sensitive and DR-TB in India.
- In 2016, 195,139 TB patients were notified. Of these, 79% were new TB cases and 21% were cases that were previously treated. Mumbai itself reported over 50,000 TB cases.
- Of cases notified in 2016, 49% were microbiologically diagnosed and 51% were clinically diagnosed.
- 72,967 (37%) of total cases in 2016 were notified by the private sector.
- In 2015, of 49,108 microbiologically confirmed new TB patients registered, 82% were cured, 5% defaulted, 5% died, and 8% either transferred out or moved to CAT IV. Of the 52,106 clinically diagnosed new TB cases, 89% completed, 4% defaulted, 4% died, and 3% either transferred out or moved to CAT IV.
- There has been an increase in the notified cases of DR-TB. In 2016, 7,221 MDR-TB and 873 XDR-TB cases were registered and initiated on treatment.

**Figure A7. Notifications in Public and Private Sector - Maharashtra**



**Figure A8. Cases of DR TB Detected and Registered - Maharashtra**



## Private Provider Interface Agency, Mumbai

PATH, India

<http://www.path.org/our-work/india.php>

### Location

Mumbai, Maharashtra

### Other Partners

- Municipal Corporation of Greater Mumbai
- Central TB Division
- The Bill and Melinda Gates Foundation
- World Health Organization
- Maharashtra Janavikas Kendra
- Association for Leprosy Education, Rehabilitation, and Treatment

### Background

- India has more cases of TB than any other country. Many of these cases are found in urban slums, such as those in Mumbai.
- Mumbai is a heavily populated, densely packed city. Water and sanitation facilities are poor, and there is widespread indoor and outdoor air pollution and malnutrition and illness, all predisposing causes of TB. There is stark inequality of income. Health care providers are many and highly heterogeneous.
- Mumbai houses 12% of the population of Maharashtra state, but accounts for 22% of notified cases of TB and – significant in regard to potential drug resistance – 50% of people undergoing retreatment after relapse.
- The emergence of DR-TB in Mumbai is alarming. Reports have consistently shown higher levels of MDR-TB in Mumbai than in other parts of India.
- Engagement with the private sector in TB care has been limited, and policy is silent on how to effectively incorporate informal or AYUSH providers who are the point of first contact for about 50% of Mumbai's population.
- Efforts to manage the private sector to improve TB prevention in Mumbai have resulted in the adoption of a Private Provider Interface Agency (PPIA).
- A hub-and-spoke model has been adopted with integrated efforts to provide standardized and quality TB care to patients in an affordable and timely manner by engaging with key stakeholders.

## Objectives

The broad objectives of PPIA are:

- To achieve early diagnosis of TB in the private sector
- To bring about a considerable increase in case notification from the private sector and subsequently increase total case notification
- To encourage uptake of microbiological tests in the private sector
- To provide standardized TB diagnosis and treatment in the private sector (including formal and informal providers, laboratories, chemists, and hospitals) as per the Standards of TB Care in India
- To facilitate implementation of free drugs at private pharmacies
- To support patients for treatment completion and improve treatment success rate in the private sector

## How it works

PPIA offers a variety of services to ensure quality TB care and treatment to patients:

- *Private provider mapping:* A mapping of private health care facilities including formal and informal providers, labs, chemists, and hospitals is conducted under PPIA. This is done to ascertain the private provider universe and relevant target groups.
- *Provider engagement:* PPIA reaches out and engages with private providers practicing in slum areas, including informal providers, and offers patient benefits to them for early referrals. It engages the 'hub' hospitals by identifying the doctors and chest physicians as the key trouble-shooters for treatment.
- *TB diagnostic services in the private sector:* PPIA engages with laboratories for quality chest X-rays and microbiological tests for referred persons with presumptive TB. It further leverages IPAQT labs to provide subsidized GeneXpert testing, and establishes sputum collection and transportation systems wherever needed.
- *Patient services:* Subsidized diagnostic tests and free first-line anti-TB drugs are offered to patients, making access to otherwise unaffordable doctors and chest physicians easier.
- *Voucher reimbursement mechanism:* To ensure affordability of care, PPIA has established and implemented a voucher system for diagnostic subsidies and free anti-TB medication, while simultaneously reimbursing labs and chemists for the services they offer free of cost.
- *Treatment adherence:* Adherence is a crucial aspect of TB care; it is ensured through timely reminders about drug intake and follow-up diagnostic tests. For this purpose, PPIA has partnered with dedicated NGOs working at the community level – the Association for Leprosy Education, Rehabilitation, and Treatment, and the Maharashtra Janavikas Kendra – to promote awareness about TB and TB prevention, and to provide counseling support for treatment completion and contact tracing.
- *Drug-resistant patient referral:* PPIA also undertakes pre-treatment evaluation and drug susceptibility tests for rifampin-resistant patients, and refers them to the public sector for treatment.

## Coverage

So far, in Mumbai:

- 475 hospitals have been identified as hub-hospitals providing quality TB care to patients.
- 1,315 MBBS doctors have been engaged and are active in prescribing TB treatment.
- 2,115 AYUSH doctors have been networked to ensure timely referral of persons with presumptive TB.
- 1,977 GPs have been engaged to provide TB treatment.
- 227 laboratories provide chest X-rays free of cost and subsidized GeneXpert testing.
- 326 pharmacies have been networked to provide free anti-TB medication to patients.

## Impact

- Under the project, 30,500 free chest X-rays and 22,779 GeneXpert tests have been conducted.
- PPIA network physicians have initiated 26,199 TB patients on treatment, and 11,095 patients have successfully completed treatment. This has been realized through the systematic monitoring of treatment adherence and alliances with community based organizations.
- PPIA network providers have also diagnosed 2,711 MDR-TB patients and guided them to public health facilities for treatment.
- PPIA has enabled a four-fold increase in TB case notification rate from the private sector from 53 per 100,000 in 2014 to 227 per 100,000 in early 2016.
- The project has reduced or subsidized the cost of care for patients incurred specifically on drugs and diagnostics.

## Challenges

- Substantial ground remains to be covered in terms of consolidating the process of engaging the providers in the remaining wards of Mumbai, as there are still a large number of private providers who are not part of the intervention project.
- Practitioners not engaged in the program perceive that patients may not return to their clinic, which will jeopardize their income. Incentives provided also are perceived as insignificant. Chemists who are not active have expressed their disinterest, fearing paperwork, inspection, and payment delays. Hence, at this time they are not willing to participate.
- Lack of a grievance redressal mechanism, which can help ensure prompt action to support private practitioners, chemists, and patients, is a challenge to strengthening customer service and procedures for private providers.

## ANNEX F: DOCUMENT LOG FOR DESK REVIEW

#	Document
1	USAID – Political Economy Assessment
2	UNDP – Institutional and Context Analysis
3	UKAID – Applied Political Economy Analysis
4	DLP (Research Paper) – From Political Economy to Political Analysis
5	DFID – Political Economy Analysis How To Note
6	IDS - A Combined Approach to Political Economy and Power Analysis
7	CTD TB India Annual Report Part III
8	Annex A - Tools for Political Economy Analysis
9	RNTCP - National Strategic Plan (2012 -2017)
10	BMGF - Tuberculosis Strategy Overview
11	PATH - Private Provider Interface Agency
12	WHO - The End TB Strategy
13	WHO - Global Tuberculosis Report 2016
14	WHO - Implementing The End TB Strategy (The Essentials)
15	International Journal of Infectious Diseases - Public Private Mix for Tuberculosis Care and Control (Review)
16	World Bank - Project Appraisal Document
17	Clingendael Institute - Framework for Strategic Governance and Corruption Analysis
18	Swedish International Development Cooperation Agency - Power Analysis
19	An Analytical Framework for Understanding the Political Economy of Sectors and Policy Arenas
20	European Commission - Analyzing and Addressing Governance in Sector Operations
21	Rethinking Governance in Water Services
22	DFID - Understanding the Politics of the Budget
23	World Bank - Problem Driven Governance and Political Economy Analysis
24	World Bank - The Political Economy of Policy Reform
25	International Institute for Environment and Development - Stakeholder Power Analysis
26	Stakeholder and Power Analysis
27	WHO - Stakeholder Analysis Guidelines
28	World Bank - Stakeholder Analysis
29	A Public Private Partnership to control TB in an Urban Setting, Kampala Uganda

#	Document
30	An Analysis of the implementation of the RNTCP in India
31	Global Fund - Expansion of Effective Public and Private Sector Intervention in HIV, Tuberculosis and Malaria Prevention and Treatment in India
32	Improving Tuberculosis through Public Private Collaboration in India
33	Mukund Uplekar - Private Practitioners and Public Health
34	Mukund Uplekar - Tuberculosis Management by Private Practitioners in Mumbai, India
35	Mukund Uplekar - Tuberculosis Patient and Practitioners in Private Clinics in India
36	Public-Private Mix Tb Activities in Meerut, Uttar Pradesh, North India (Delivering Dots via Collaboration with Private Providers and Non-Governmental Organizations)
37	RNTCP - National Guideline for Partnership 2014
38	RNTCP - Training Module for Community Pharmacists 2013
39	Strategic Guide for Building Public Private Mix (Partnerships to support Tuberculosis Control )
40	WHO - Best practices in engagement of all health care providers in the management of drug resistant tuberculosis
41	WHO - Framework for engagement of all health care providers
42	WHO - Laboratory Strengthening under END TB strategy
43	WHO - Public Private Mix for TB
44	WHO - Public-Private Mix for TB Care and Control (Toolkit)
45	WHO - Report of a WHO consultation meeting to enhance the engagement of communities, NGOs and civil society organizations
46	WHO - Toolkit for developing a national TB research plan
47	Mismanagement of Tuberculosis in India
48	Tuberculosis Prescription Practices in Private and Public Sector in India
49	CTD TB India Annual Report Part I
50	CTD TB India Annual Report Part II
51	WHO - Standards for TB care in India
52	Patients Charter
53	TB management by private practitioners
54	Tuberculosis control
55	Privatization of Health Care in India
56	Innovative health service delivery models in low and middle income countries
57	Performance-Based Incentives for Health
58	Quality of Private and Public Ambulatory Health Care in Low and Middle Income Countries
59	Private vs. Public
60	Quality of Primary Care in Low-Income Countries

#	Document
61	In urban and rural India a standardized patient study showed low levels of provider training and huge quality gaps
62	Use of standardized patients to assess quality of tuberculosis care (A pilot, cross-sectional study)
63	Quality and Accountability in Healthcare Delivery
64	Barriers to Point-of-Care Testing in India
65	Global Fund - Enhancing Private Sector Contribution to TB Care in India
66	Blurring of Boundaries (Public-Private Partnerships in Health Services in India)
67	Evaluation of Results Based Financing Strategies for Tuberculosis care and Control in India
68	Global Policy (Eradicating TB in India - Challenges, Perspectives, Solutions)
69	Partnerships with the Private Sector in Health
70	The relative efficiency of public and private service delivery
71	IMS - Understanding Healthcare Access in India
72	India Needs a National Policy to Control Tuberculosis
73	India should screen all tuberculosis patients for drug resistant disease at diagnosis
74	How Did the TB Patients Reach DOTS Services in Delhi (A Study of Patient Treatment Seeking Behavior)
75	Engaging for-profit providers in TB control lessons learnt from initiatives in South Asia
76	How to hinder tuberculosis control (five easy steps)
77	Let's talk TB (A series on Tuberculosis)
78	Using standardized patients to evaluate hospital-based intervention outcome
79	Mapping Medical Providers in Rural India (Four Key Trends)
80	Alternative medicine an ethnographic study of how practitioners of Indian medical systems manage TB in Mumbai
81	Unregulated and Unaccountable (Private Health Providers)
82	The End TB Strategy (India can blaze the trail)
83	Antimicrobial resistance and the growing threat of drug-resistant tuberculosis
84	TB control (challenges and opportunities for India)
85	Tuberculosis control needs a complete and patient-centric solution
86	Testing and Treating the Missing Millions with Tuberculosis
87	The Paradox of Tuberculosis Case Notification by Private Practitioners in Alappuzha District of Kerala, India
88	USAID - Public Private Mix (PPM) Models for the Sustainability of Successful TB Control Initiatives
89	Private versus public strategies for health service provision for improving health outcomes in resource-limited settings
90	World Bank - Public Ends, Private Means
91	Public-Private Partnership in the Health Sector in India
92	Are India's quacks the answer to its shortage of doctors

#	Document
93	Xpert MTB-RIF for tuberculosis testing (access and price in highly privatized health markets)
94	'Multiple-test' approach to the laboratory diagnosis of tuberculosis -perception of medical doctors from Ujjain, India
95	Tuberculosis Care in India (How Can Private Practitioners Make a Difference)
96	Regulating the private health sector
97	Role of private sector in health care in India with special role in Cancer
98	The Importance of Implementation Strategy in Scaling Up Xpert MTB-RIF for Diagnosis of Tuberculosis in the Indian Health-Care System (A Transmission Model)
99	Quality of tuberculosis care in India (A systematic review)
100	Clinical Social Franchising Compendium (An Annual Survey of Programmes)
101	What Is the Role of Informal Healthcare Providers in Developing Countries (A Systematic Review)
102	Disease Control Implications of India's Changing Multi-Drug Resistant Tuberculosis Epidemic
103	Survey using incognito standardized patients shows poor quality care in China's rural clinics
104	Financial burden for tuberculosis patients in low- and middle-income countries (A systematic review)
105	Diagnosis and Treatment of Childhood Pulmonary Tuberculosis
106	TB Diagnostics Market in Select High-Burden Countries (Current Market and Future Opportunities for Novel Diagnostics)
107	Tuberculosis in India
108	MDR, XDR, TDR tuberculosis - ominous progression
109	Private Health Insurance in India (Promise and Reality)
110	Global antibiotic consumption 2000 to 2010 (An analysis of national pharmaceutical sales data)
111	Achieving Systemic and Scalable Private Sector Engagement in Tuberculosis Care and Prevention in Asia
112	Size and Usage Patterns of Private TB Drug Markets in the High Burden Countries
113	Mehsana (Snapshot)
114	Mumbai (Snapshot)
115	Patna (Snapshot)
116	Terms of Reference for Public Private Interface Agency (PPIA)
117	Terms of Reference for Public Private Interface Agency (PPIA)
118	Tuberculosis control in postcolonial South India and beyond. (1948-1960)

## ANNEX G. REFERENCES

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