

## REACHING ALL TUBERCULOSIS PATIENTS IN INDIA WITH QUALITY CARE: CHALLENGES, OPPORTUNITIES AND THE WAY FORWARD TO ADDRESS THE MISSING MILLIONS

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TB is an ancient scourge that has caused untimely death of millions of people in the world, over several generations. The diagnosis of the disease using a microscope was demonstrated by Robert Koch over a century ago and medicines for cure have been available for over four decades. Yet, almost one million people die of TB globally each year, and an additional 0.3 million deaths occur due to tuberculosis in HIV positive people<sup>1</sup>. In India alone nearly 0.3 million deaths occur annually due to TB. While efforts are ongoing for research and development of an effective vaccine, early detection and effective treatment remains the mainstay for preventing mortality, interrupting transmission and reducing the risk of further emergence of drug resistance.

India bears the highest burden of TB among all countries. Out of the estimated 8.6 million new cases of TB occurring annually, 2.2 million, i.e. more than one-fourth occurs in India alone<sup>1</sup>. The decline in incidence of TB in India observed after 2005 is insufficient and it is unacceptable that a curable disease continues to kill hundreds of thousands of Indians during their economically productive years of life leading to considerable economic loss to the country<sup>2</sup>.

### The missing millions of TB patients

India's Revised National Tuberculosis Control Programme started in 1997 and rolled out the internationally recommended DOTS strategy in a phased manner, reaching pan state and district coverage in 2006 ([www.tbindia.nic.in](http://www.tbindia.nic.in)). Thereafter, efforts were made to improve access to TB care under the RNTCP while simultaneously launching and expanding services for drug resistant TB and HIV-associated TB. Private sector care delivery models were developed<sup>3</sup>, awareness campaigns were launched and increased service delivery points were made available in areas

with concentrated tribal population as well as urban poor population.

Results demonstrated increasing numbers of people tested for TB, increased number of patients diagnosed and registered for treatment and overall reasonably good treatment success rates<sup>4</sup>. However, the increasing trend in case detection of incident TB cases (i.e. new and relapse cases) showed signs of stagnation in the late 2000s, remaining more or less flat, and even fell from 2011 to 2012<sup>1,4</sup>. Meanwhile, the numbers of people with symptoms of TB that were tested with smear microscopy increased year-on-year, with a fall in smear positivity rate denoting greater effort being made to detect cases yet less cases actually detected<sup>4</sup>. Under routine circumstances, this implies good progress in TB control, however there are three important factors that need to be kept in mind while interpreting these trends. First, this data and trend at the national level hides several different trends in data of states and districts and therefore cannot be interpreted with such simplicity. Second, and more importantly, the RNTCP has not been able to detect and treat a large number and proportion of the TB burden in the country. In the last few years, RNTCP has notified about 1.2 to 1.3 million incident TB cases annually leaving behind nearly one million incident TB cases from the estimated annual incidence of 2.2 million cases<sup>1,4</sup> (Table). This nearly one million missing cases is an

**Table:** Incidence, notification and missing cases of TB

Year	Estimated annual incidence	Notified incident cases (new & relapse)	Missing cases
2010	2,200,000	1,339,866	860,134
2011	2,200,000	1,323,949	876,051
2012	2,200,000	1,289,836	910,164

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underestimate because this is only among incident TB cases and if prevalent TB cases are added this becomes even a higher number. These large numbers of TB patients are either managed by the non-RNTCP affiliated care providers, including a large and diverse private sector, or are not diagnosed and treated. In either case their diagnosis, treatment and outcomes remain undocumented and unknown. Third, the notification data from India shows a large proportion and numbers of TB patients that are being treated again (re-treatment cases) which is unlike any other high TB burden country<sup>1</sup>. A number of studies have explored this issue but more information and understanding is required before we can concretely interpret the reasons for the increased numbers of retreatment cases.

While plans are being made in India to achieve universal access to quality services across all states and districts and services for drug resistant TB are being scaled up<sup>5</sup>, the issue of over a million TB patients missing from the notification and care services in India is a worry and presents a gigantic challenge, which if not addressed rapidly will be one of the major reasons for failing in the fight against TB.

This paper highlights the reasons and possible solutions for the missing millions of TB patients in India.

### **Reasons for missing patients**

There are two broad reasons for missing TB cases from the notification system in India.

First and foremost is the fact that a substantial proportion of patients are managed by care providers that do not notify to RNTCP<sup>6</sup>. These care providers are mostly private sector care providers but could also be public sector care providers. The private sector care providers are diverse, ranging from individual clinicians to large hospitals, from unqualified practitioners to specialist doctors, and also include private laboratories and pharmacies. The public sector care providers who do not notify TB cases are more likely to be hospitals that are outside the primary

health care system, especially in the urban areas, and health facilities that are under other government ministries or departments. Compounded to this problem is the reality of a large number of public sector doctors who also do private practice in their free time, and interestingly their prescription and notification practices in private practice are quite different.

Secondly, a number of TB patients fail to access appropriate care and in them TB is never diagnosed or treated. This could happen for people who are unable to access care because of barriers like distance to health facility, inability to pay for care or high opportunity cost for accessing free health care, elderly people who are immobile, people who do not for many reasons believe in modern medicine and populations with low awareness about TB. In addition, TB could be missed as a diagnosis in patients who seek care if the providers do not think about TB or do not rely on the correct diagnostics for TB. The widespread use of inaccurate and expensive serological tests for the diagnosis of TB is one such example which led to the Government of India ultimately issuing an order to ban them<sup>4</sup>. However, these tests are now quickly getting replaced by Interferon-Gamma Release Assays (IGRAs) which are again expensive and are not useful in the diagnosis of active TB disease. There are also patients who either drop out during the diagnostic process or after diagnosis of TB are not initiated on treatment<sup>7</sup>.

Detecting all cases alone is not enough, detecting them early and initiating them on effective treatment is what is needed to make an impact on transmission. A number of studies have pointed out the late diagnosis and treatment of TB in India and the related shopping for care which results in excessive out-of-pocket expenses for patients<sup>8</sup>.

To increase case detection and notifications, RNTCP has implemented several initiatives and some of them have been reasonably successful, but not enough to address the enormous challenge of the missing cases.

One such example is the involvement of all care providers through different models of



public-private collaborations. This initiative, started in early 2000s, did increase case detection and notifications in targeted population and some of the projects are still ongoing<sup>3,9</sup>. But progress was limited because the models could not be scaled up and compliance of all providers of care could not be ensured due to a variety of reasons linked to the characteristics and drivers of the private sector health care market in India. Even a large number of government doctors during their private practice often resorted to treating TB without notification. It is a well-established fact that most patients, including the poor, in India first seek care in the private sector with willingness to pay out of pocket. From the patient's perspective, care provided free of cost by the government is often not perceived as good quality, is sometimes difficult to access and comes with an opportunity cost of lost wages. In contrast, care provided by the private sector is readily available and easy to access in terms of time, place and choice of care providers. The quality of TB care provided by the private sector care providers varies considerably. Diagnosis is often delayed, missed or comes at a high cost due to unnecessary and inappropriate tests<sup>8</sup>. Treatment is complicated due to prescription practices, drug quality issues and lack of a system for treatment adherence. RNTCP collaborated with the Indian Medical Association to train practitioners and more recently made TB a disease that is mandatorily notifiable. It is interesting to note that a year after the policy of mandatory notification case detection did not increase but actually fell marginally<sup>4</sup>. This points to the fact that in a country like India regulatory mechanisms alone are not sufficient because policies and regulations are difficult to implement and enforce. More recently the National Strategic Plan of RNTCP has proposed a new approach of working with the private sector care providers with minimal disruption to the private sector market principles and allowing an interface agency to bridge the gap between RNTCP and the private sector care providers.

Other initiatives of RNTCP included additional service delivery points and provision of additional human resources in urban areas and tribal

areas. This has helped in providing greater access to the urban poor and indigenous populations. However, there are many more vulnerable and underserved groups that are yet to be systematically identified and reached.

### **Actions needed to detect and notify all TB cases in India**

The actions that are needed to detect and notify all TB patients in India are numerous. However, the top three action points are notification, private sector business models and active case finding.

**1. Notification:** The mandatory TB notification policy needs to be implemented. This will require education of care providers, incentives for notifications and user-friendly electronic and mobile phone based tools for notifications. The government has started an excellent web-based notification system called "NIKSHAY" (<http://nikshay.gov.in/User/Login.aspx>). Considering the widespread use of mobile phones in India and relative difficult access to computers the next step is to develop a mobile phone based data entry and retrieving system which should be simple and friendly. Such a notification system should include doctors, laboratories and pharmacies. Positive results in diagnostic laboratory tests such as the Xpert MTB/RIF tests should trigger automated notifications and such systems are today available (<http://www.stoptb.org/global/awards/tbreach/xpertsms.asp>). In clinics, doctors making a diagnosis of TB should be able to notify using mobile phone based applications or messaging systems. Further work is needed to trigger notifications from pharmacies on sale of anti-TB medicines, again using mobile phone based applications.

**2. Private sector business models:** Innovative, sustainable and scalable business models for TB care in the private sector are urgently needed. The traditional RNTCP models of public-private collaborations have relied heavily on referral of patients to the public sector, use of only RNTCP drug regimen and provision of free services in



the private health care sector. New models are required where the private sector manages the TB cases themselves, using the best available diagnostics and standard internationally recommended drug regimen, and notifies the patients to the government through the NIKSHAY system. To be sustainable and effective such models should work with, and not against, the principles and forces of the private sector market. Separate business models may be required for laboratories, pharmacies and clinics. There are examples of such models taking shape in India on laboratories<sup>10</sup> and elsewhere on clinics<sup>11</sup> and this is an opportunity to think out-of-the-box. The anti-TB medicine market in the private sector in India far exceeds that of the public sector<sup>12</sup>. This is an opportunity for intervening in the private sector market by introduction of quality assured patient-wise TB drug box to ensure correct dosage and complete treatment. This could not only improve quality and affordability of TB drugs in the private market but also has the potential of triggering notification as a drug box moves from the shelf of the private pharmacy to the patient. To implement any of these models a private sector interface agency will be required and it is encouraging to note that the RNTCP national strategic plan recognized this. One such model with an interface agency has just started to function in Mumbai and there is much to be learnt from this project.

**3. Active TB case finding.** Active screening and case finding needs to be considered as a strategy to increase case detection and more importantly to diagnose TB patients early in their course of illness. This should be prioritized for high risk, vulnerable and underserved population groups. New approaches in care delivery needs to be planned and implemented for key affected population groups such as migrants, urban slum dwellers, indigenous population groups, mining affected population, etc. These approaches include systematic screening<sup>13</sup>, mobile outreach and effective use of community volunteers in care delivery<sup>14</sup>.

In addition to the above three important action points, diagnosis and treatment of all forms of TB need to be included in the package of services under the

Universal Health Coverage agenda of India<sup>15</sup>, and the government budgetary allocation for TB prevention and care should be increased.

In May 2014, the World Health Assembly will consider a new post-2015 strategy with bold targets.

**By bold innovations in care delivery, India can make rapid progress towards early and enhanced TB case detection and has an opportunity to lead the fight against TB globally, along with other BRICS countries which account for more than half of the TB burden globally.** ([http://www.stoptb.org/news/stories/2013/ns13\\_003.asp](http://www.stoptb.org/news/stories/2013/ns13_003.asp)).

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## THE TUBERCULOSIS ASSOCIATION OF INDIA

### NATCON 2014

The 69<sup>th</sup> National Conference on Tuberculosis and Chest Diseases

(NATCON 2014) will be held in association with the Maharashtra State Anti-TB Association at Mumbai.

The timings and other details will be announced in due course.