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Mismanagement of tuberculosis in India: Causes, consequences, and the way forward

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India leads the world in its burden of tuberculosis (TB) due to the neglect of TB as a public health problem, and mismanagement of TB patients in both public and private sectors. The original National Tuberculosis Programme (NTP) failed because of low rates of case detection and cure. The Revised National Tuberculosis Control Program (RNTCP) has reversed these trends in the public sector, with expanded access to improved diagnosis, short–course regimens and high cure rates. The RNTCP is yet to adequately address the challenge of drug resistant TB. The private sector in India, which manages more than half of all TB patients, is a continuing source of mismanagement of TB, and is largely outside the scope of the RNTCP. Diagnostic and treatment practices in the private sector are often not evidence based. As RNTCP enters its new phase (2012 – 2017), there is an urgent need to engage, incentivize and integrate the private sector into national TB control, to facilitate universal access and to curb mismanagement of TB which threatens India's TB control efforts.

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Introduction

Tuberculosis in India: magnitude of the problem

INDIA, A COUNTRY WITH OVER 1.21 BILLION PEOPLE, has the highest burden of tuberculosis (TB) in the world, accounting for 20% of the global incidence of TB, and an even higher share of global incidence of multi–drug resistant (MDR) TB (1). Thus the success of any global effort to control TB and MDR–TB is critically dependent on the success of such an effort in India. The Indian National TB programme (NTP) was launched in 1962, but suffered from inadequate program funding, managerial weaknesses, irregular drug supply and multiplicity of treatment regimens (2). With low rates of case detection and treatment completion (30%), high rates of default (40–60%), and continuing high mortality (50 per 100,000) the NTP failed (2). Acknowledging this reality, a Revised National Tuberculosis Control Programme (RNTCP) was launched by the Government of India in 1997, based on the global DOTS (Directly Observed Treatment, Short course) strategy which aimed to have an epidemiologic impact by achieving 70% case detection and 85% cure rates. By 2006, 100% of the Indian population was covered by the DOTS programme, making this scale–up one of India's most significant public health accomplishments. The RNTCP has resulted in impressive improvements in cure rates (currently >80% in new infectious cases), substantial decline in death rates with low rates of default (<10%) (3,4).

Despite this success, India continues to have an estimated annual incidence of more than 2 million TB cases. While the problem of TB in India is characterized by high incidence, high prevalence, and high rate of transmission of TB infection (5), available estimates of the TB burden have been inconsistent. The most recent World Health Organization (WHO) estimates of TB morbidity and mortality for India are shown in Figure 1 (1). In contrast, the Tuberculosis Research Centre (TRC) in India estimated the burden to be substantially higher, with 8.5 million cases of TB of all forms in the year 2000, including 3.8 million smear–positive cases, 3.9 million smear–negative cases and 0.8 million cases of extra–pul-

Population 2009 (millions) 1 198

Estimates of burden * 2009	Number (thousands)	Rate (per 100 000 pop)
Mortality (excluding HIV)	280 (160–430)	23 (14–36)
Prevalence (incl HIV)	3 000 (1 300–5 000)	249 (105–419)
Incidence (incl HIV)	2 000 (1 600–2 400)	168 (137–202)
Incidence (HIV-positive)	130 (54–240)	11 (4.5–20)
Case detection, all forms (%)	67 (56–83)	

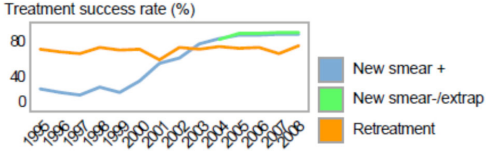
Case notifications 2009					
New cases		(%)	Retreatment cases		(%)
Smear-positive	624 617	(50)	Relapse	108 361	(37)
Smear-negative	384 113	(31)	Treatment after failure	18 870	(7)
Smear unknown			Treatment after default	73 549	(25)
Extrapulmonary	233 026	(19)	Other	88 976	(31)
Other	1 796	(<1)			
Total new	1 243 552		Total retreatment	289 756	
Total < 15 years	13 577				

Total new and relapse	1 351 913	(88% of total)
Total cases notified	1 533 308	

Drug regimens	
Rifampicin used throughout treatment	Yes
% of patients treated with fixed-dose combinations (FDCs)	0
Paediatric formulations procured	Yes

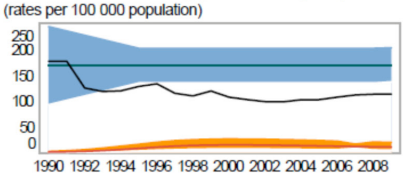
Treatment success rate 2008 (%)	
New smear-positive	87
New smear-negative/extrapulmonary	89
Retreatment	74

Treatment success rate (%)

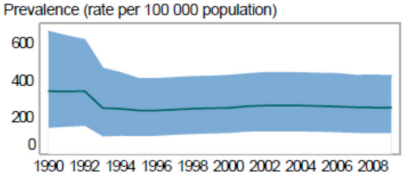


MDR-TB, Estimates among notified cases * 2008	
% of new TB cases with MDR-TB	23 (1.8–2.8)
% of retreatment TB cases with MDR-TB	17 (15–20)
Estimated MDR-TB cases among new pulmonary TB cases notified in 2009	23 000 (18 000–28 000)
Estimated MDR-TB cases among retreated pulmonary TB cases notified in 2009	50 000 (43 000–57 000)

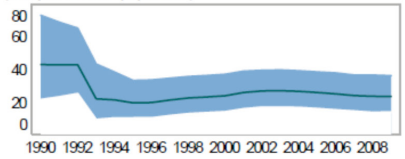
Incidence (HIV+TB in orange), notifications (black) (rates per 100 000 population)



Prevalence (rate per 100 000 population)



Mortality excluding HIV (rate per 100 000 population)



TB/HIV 2009	
TB patients with known HIV status	258 037
% of TB patients with known HIV status	17
TB patients that are HIV-positive	31 058
% of tested TB patients that are HIV-positive	12
% HIV-positive TB patients started on CPT	
% HIV-positive TB patients started on ART	
HIV-positive people screened for TB	280 903
HIV-positive people provided with IPT	

CPT (orange) and ART (green) for HIV-positive TB patients (blue)

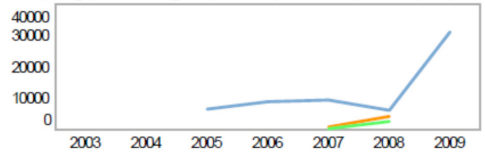


Figure 1 | Estimates of tuberculosis burden in India (1). *(reproduced with permission from WHO)*

monary TB (6). This was based on surveys conducted in India, where the prevalence of culture–positive and smear–positive pulmonary TB were found to be 605 per 100,000 and 323 per 100,000 respectively, considerably higher than the WHO estimates (7).

The problems of drug resistant TB, HIV co-infection, and the social costs of TB in India are staggering. With an estimated annual incidence of 99,000 cases of MDR–TB (1), the highest in the world, drug resistant TB is a serious threat to control of TB in India. Currently, less than 1% of MDR–TB patients have access to effective treatment, and there is an urgent need for scale–up of access to MDR–TB treatment (1, 8). India has an estimated 2.27 million people who are HIV infected, and at high risk of developing TB (9). Although case fatality rates have declined, the number of persons dying from TB is unacceptably high (1). TB has a devastating impact on patients and families. The mean costs (direct and indirect) can be as high as 40% of the annual income, pushing poor families into further debt and destitution (10). The costs of TB to the nation have been computed to be $3 billion per year (11).

Why is TB such a big problem in India, despite the success of the DOTS program? TB is a disease of poverty, with several known social determinants (e.g. malnutrition and tobacco smoking) that are not adequately addressed

by the DOTS strategy. Furthermore, early detection and successful treatment of patients with TB is the cornerstone of TB control. If TB diagnosis and/or treatment is delayed or mismanaged, it can have serious consequences for not only the patient, but also the country in terms of continued TB transmission, and worsening of the epidemic.

Under the RNTCP, the network of diagnostic and treatment services for TB has undergone substantial expansion and now covers the entire nation. However, universal coverage refers only to availability of RNTCP services throughout the country, and fails to reflect the fact that more than half of all TB patients access private healthcare for the management of their disease (12). In this article, we examine the problem of mismanagement of TB in India, in diagnosis as well as treatment, in both the public sector and the private sector, which contributes to the present epidemiologic situation, and the challenges that RNTCP will need to address in its next phase (2012 – 2017). We also discuss the often–ignored role of the private sector in the management of TB, and the need for its integration into national TB control efforts to minimize the mismanagement of TB.

There is a large amount of published literature that consistently show that serological tests for TB are inaccurate and have no clinical role in the diagnosis of either pulmonary or extra–pulmonary TB.

TB diagnosis and treatment: past errors and present challenges

Mismanagement in case diagnosis

i. Under–utilization of sputum microscopy and over–reliance on chest radiography

Sputum smear examination is the most reliable way to diagnose patients with pulmonary TB, as it has a high specificity though lower sensitivity, while chest radiographs for the diagnosis of pulmonary TB have higher sensitivity but lower specificity (13). The positive predictive value of sputum smear result is more than 90%, while that of chest X-ray is around 66% (13).

The erstwhile NTP did emphasize sputum examination of patients as the basic tool for diagnosis of pulmonary TB, with chest radiography playing a secondary role. It envisioned integration of TB diagnostic and treatment services into the general health services, and availability of sputum microscopy in the most peripheral health institutions, with radiological facilities available at the district level. This approach was technically and operationally appropriate for India, where 70% of the population resides in rural areas. However, health services did not expand in the rural areas commensurate with the rise in population, as the NTP covered only 50% of the peripheral health institutions, and even in these institutions only a fraction of those presenting with cough were subjected to smear microscopy as per NTP guidelines (14, 15).

Chest radiographs, done on all patients presenting to the District TB Center, before they submitted a sputum sample (13), were over–utilized for TB diagnosis. As a result 78% of the cases of pulmonary TB were diagnosed on the basis of chest radiography alone, resulting in the unwarranted administration of anti–TB treatment to a large number of patients (16). This pattern of under–utilization of sputum microscopy and over–reliance on radiology has been documented in the private sector as well. In a survey of general practitioners in New Delhi, only 12% of private practitioners opted for sputum examination for diagnosis of pulmonary TB, with 88% relying on chest radiology (17).

Apart from preference for radiology, this low utilization of sputum microscopy also reflects the poor availability of quality–assured sputum microscopy services in private laboratories. It is a big concern than only a tiny fraction of Indian laboratories have any sort of laboratory accreditation or certification. This lack of quality assurance in laboratories is clearly a major hurdle for improving TB diagnosis.

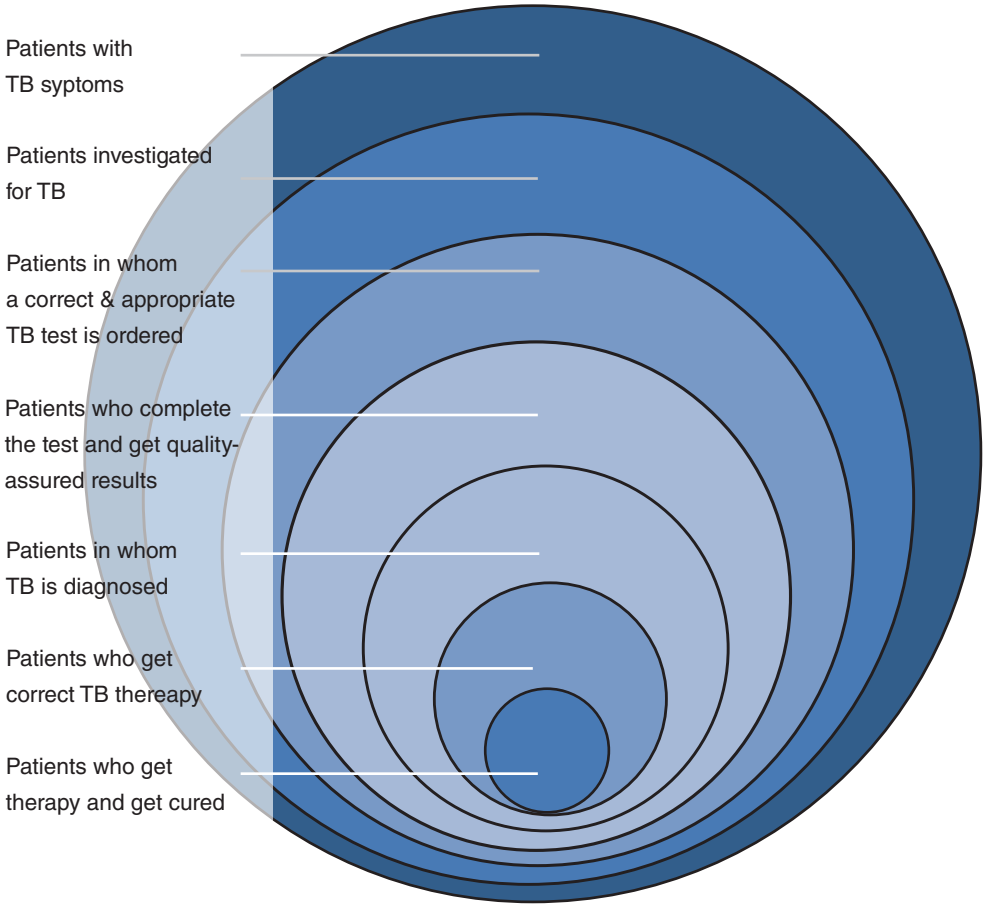


Figure 2 | Misdiagnosis and mismanagement can result in only fraction of TB patients getting correct diagnosis, appropriate therapy, and positive outcomes

ii. Use of suboptimal diagnostics in the private sector

While the private sector underutilizes reliable tools for diagnosis of pulmonary TB, a disturbing trend is the widespread abuse of suboptimal diagnostic tests, such as serological (antibody–detection) tests for active TB. There is a large amount of published literature that consistently show that serological tests for TB are inaccurate and have no clinical role in the diagnosis of either pulmonary or extra-pulmonary TB (18, 19). There are no international guidelines supporting their use; in fact, the International Standards for TB Care discourage the use of these tests (20). Despite this, 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. This has prompted the WHO to issue a policy against their use (21).

Treatment in the private sector is often started based on serology results, with potentially disastrous consequences for patients (22). As diagnostics for TB are mostly unregulated, there is no system in place to keep such tests off the market. Such poor diagnostic practices lead to wrong and/or delayed diagnosis, inflate costs of care, could explain the delays of 1 – 2 months before a TB patient gets diagnosed (23, 24), and the reason why even those patients who do reach a DOTS centre do so after initially visiting 6–9 healthcare providers (25). Thus, undiagnosed TB, delayed diagnosis and mismanaged TB continues to fuel the TB epidemic.

iii. Achievements and diagnostic challenges in the era of drug resistance

Through the RNTCP, facilities for sputum microscopy have been greatly expanded and one microscopy centre is now available per 100,000 residents. Also quality assurance of

microscopy is being addressed and assured within the RNTCP. This has improved case detection (to >70%) as well as the quality of diagnosis; as the ratio of smear positive cases to smear negative cases is now approximately 50:50, rather than 22:78 within the earlier NTP.

However, a major gap still exists for the diagnosis of drug resistant TB. Facilities for culture and drug susceptibility testing (DST) in India are grossly inadequate. As of 2008, there were only 17 accredited facilities for doing culture and DST (which works out to 0.1 facility per 10 million residents, against a minimum of 1 per 10 million), although efforts are underway to increases the number to 43 laboratories with DST capacity. Indeed, by 2011, 27 accredited laboratories are operational, including 8 private/NGO sector laboratories. Expansion of laboratory capacity is critical to ensure that patients with suspected drug resistant TB can be diagnosed early and treated appropriately. The RNTCP has begun to incorporate recent, more rapid methods of performing culture and DST (e.g. liquid culture and molecular assays) and this is important to avoid unnecessary delays in the management of patients with MDR–TB.

"Successful treatment of TB depends more than the science of chemotherapy. To have the highest likelihood of success, chemotherapy must be provided within a clinical and social framework, based on an individual patient's circumstances"

Mismanagement in treatment

The availability of standardized short–course regimens free of cost and in an uninterrupted manner for patients with TB represents a big step forward in the control of TB in India. However, since half of all TB treatment occurs in the private sector, access to standardized effective short–course regimens is not uniform because of their treatment practices.

The other current challenge is treatment of MDR–TB. This problem is linked to the poor organization of TB treatment in the past NTP, coupled with the use of less effective regimes, which needed prolonged administration. Short–course chemotherapy, which was the standard of care worldwide, was introduced late in the NTP, and became available to all patients with TB in India only by 2006 when RNTCP achieved universal coverage. In the NTP, less than a quarter of patients (those who were smear positive) were put on short–course chemotherapy, while the rest were given long-duration drug regimens such as INH and thiacetazone, which were less effective and more toxic. It is not surprising that treatment completion and cure rates were low during the NTP. These partially treated cases contributed to both the lack of decline in prevalence of TB, and increasing drug resistance seen in longitudinal studies (26, 27).

A. Poor treatment practices in the private sector

In 2006, out of the total market of $94 million for first–line anti–TB drugs in India, the public sector purchased drugs worth $24 million while the private sector accounted for the remaining (28), underscoring the importance of the private sector in TB treatment.

The private sector in India is highly unorganized, with a lack of regulation in both prescribing practices as well as the qualifications of those prescribing these medications. Practitioners of various alternative forms of medicine often prescribe anti–TB drugs without being qualified to do so. Apart from causing prolonged morbidity and increased mortality from the disease, poor prescribing practices also fuel the emergence and spread of drug–resistant organisms, and are most certainly one of the reasons why India accounts for over a fifth of the global MDR–TB burden, with indicators showing a rising trend (29).

A study from Mumbai published in 2010 found that when 106 private practitioners in an urban slum were asked to write a prescription for a patient with pulmonary TB, 63 different

drug regimens were prescribed, and only 6 of these prescriptions were found to be appropriate (30). The study was conducted as a follow–up to a widely cited study published in 1991 in the same geographical region and with the same study question (31). Sadly, the conclusion of the study was that little had changed in the intervening two decades, and evidently, the gravity of the problem that was highlighted by the original study had not led to efforts to correct the situation commensurate with the magnitude of the problem.

B. Limited access to treatment regimens for MDR–TB and continued use of retreatment regimens which are not evidence based

In 2006, the RNTCP launched the DOTS–Plus initiative for dealing with the problem of MDR–TB, but even today, less than 1% of the estimated number of MDR–TB patients have access to adequate treatment. Furthermore, another large subgroup of patients (nearly 0.2 million per year) who receive suboptimal care are those who are treated in the RNTCP, but have failed treatment, or had relapses, or had interrupted therapy earlier. These patients have higher rates of drug resistance, including single drug resistance, poly drug resistance and MDR–TB (4), and therefore require treatment regimens that are guided by DST results.

Unfortunately, retreatment patients in India continue to receive a single standardized regime of 2HRZES/HRZE/5HRE. This leads to a situation where a patient who has failed a first line treatment with HRZE (isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E)) is given a single new drug, streptomycin (S), as part of the retreatment regime. This regime violates a basic tenet of TB chemotherapy – which is to never add a single drug to a failing regimen (32). The WHO in its TB treatment guidelines (2010) no longer recommends this regimen, and despite demands for a review of this policy (8), this suboptimal re–treatment regimen continues to be used for treatment failure patients in RNTCP (33–35). This can lead both to poor cure rates, and further amplification of the problem of drug resistance in India.

C. Lack of patient–centered approaches to enhance accessibility to and acceptability of the DOTS programme

Directly Observed Therapy (DOT) is a key component of the DOTS strategy, but excessive emphasis on DOT alone can undermine a more patient–centered approach to supporting treatment completion. “Successful treatment of TB depends on more than the science of chemotherapy. To have the highest likelihood of success, chemotherapy must be provided within a clinical and social framework, based on an individual patient’s circumstances” (36).

Improved cure rates with the DOTS strategy, seen in observational studies, were initially attributed to the DOT component. However a review showed that these DOTS programmes were using a variety of interventions in addition to DOT, such as incentives (free meal and transport coupons), defaulter actions (including court–mandated involuntary admission or incarceration), and patient-centered designs (giving patients a range of supervision options, and focusing on their convenience) (37). In this regard, the WHO acknowledges that “implementation of DOT alone with no other supportive measures is unlikely to be effective in promoting adherence” (38). These supportive measures include ‘the placing of the patient at the center of tuberculosis control activities, confidentiality and consideration of patients’ needs, organization of tuberculosis services to ensure the patient has treatment as close to home as possible, possible incentives, identification of potential difficulties in advance, accurate address records, and taking action against defaulters’(38).’

The International Standards for TB Care as well as the current WHO TB treatment guidelines emphasized that apart from DOT, other patient support services are essential for success of treatment (20, 35). A Cochrane review in 2007 of 11 randomized controlled trials, found no significant effect of DOT compared to self–administration, on cure or

treatment completion in people receiving treatment for tuberculosis (39). The Patients' Charter for TB care codifies the rights of patients to care, dignity, information, privacy, food supplements and/or other types of support and incentives if needed (40).

The model of DOT being implemented in India needs to be reconsidered to incorporate such patient–centered approaches, which enable access to treatment and maximize adherence. TB in India is a disease strongly associated with poverty and deprivation and patients with TB suffer many barriers to getting care and adhering to therapy. Patients have enormously benefited from having an uninterrupted supply of drugs in the RNTCP, and directly observed therapy has improved cure rates but the programme needs to be flexible and adaptable to the needs and concerns of patients. In fact, with a rigid model of DOT, the targets of the programme can sometimes compete with the needs of the patients. For example, in a pilot project of the RNTCP, it was found that the staff did not register nearly half of the diagnosed patients in the RNTCP, because these patients were perceived to be at higher risk of defaulting (41). The programme had itself identified in 2002, the need to "establish patient friendly services, with the patient as 'VIP' for the programme" as an important challenge, and stated, "the program's goal is that no patient should have to pay for transportation or lose wages to participate"(3). However this goal has yet to be realized.

In addition to integrating private and public healthcare systems to provide a truly universal coverage, it would be equally important to address the reasons why patients prefer private healthcare despite a highly successful DOTS programme in India.

Evidence from studies in urban Zambia and Brazil suggests that clinic based DOT programs in urban areas increased by two fold the indirect costs, and imposed a serious financial burden on the patients (42,43). Studies on patients defaulting from treatment in India have shown that inconvenience of clinic timing resulting in loss of wages, costs of travel to clinic, lack of provision for continuity of treatment in case of a family emergency which precluded a visit to the clinic, lack of respectful communication between staff and the patient, and inadequate information and poor management of adverse events and toxicity continue to result in patients defaulting on treatment (44,45). There is a need for operational research into alternative models of DOT, especially in urban areas, which do not impede access to care under the RNTCP, and which minimize the indirect costs of DOT based treatment. A flexible patient–centered approach, incorporating the entitlements of the Patients' Charter for TB Care, will substantially enhance the effect of DOT on success of treatment.

The way forward

Mismanagement of TB is a serious threat for TB control in India. Misdiagnosis and mismanagement can result in only a fraction of TB patients getting correct diagnosis, appropriate therapy, and positive outcomes (Figure 2). Therefore, to improve TB control, TB diagnosis and treatment must be improved so that transmission can be successfully reduced. In addition to addressing the technical and operational issues discussed, there is a need for closer linkages and integration of RNTCP with the general health services on the one hand and with private healthcare providers on the other.

The TB programme in context of primary health care and public health in India

In India, since the very inception of the NTP, TB treatment services do not exist as a specialized service but are integrated with the general health services. The main driver of TB mismanagement in the NTP was the low priority given to healthcare in general, especially primary health care services, and the

very low priority given to TB among various healthcare programs.

In 1982, the total budget of the NTP was less than $0.5 million (Rupees 20 million) for an estimated burden of 2 million patients per year (46). The network of general health services did not keep pace with the growing population and their credibility with people suffered due to lack of staff, infrastructure and consumables such as medicines, which affected all aspects of the NTP, designed as it was *"to sink or sail with the general health services"* (47). This constellation of factors is probably what forced people in both rural and urban areas to seek treatment from private healthcare providers, for many health problems including TB.

The current RNTCP has been better funded and better managed, although substantial budget increases will be needed to tackle MDR–TB and to achieve universal case detection and management. A key limiting factor in the achievements of RNTCP goals will again be the ability of the general health services to detect a large enough number of cases and cure them. A revitalization of the primary health services in both urban and rural areas, by according them higher priority and improving their funding and management, will help in the realization of the tremendous potential that the RNTCP has for the control of TB in India.

A beginning has been made in this direction with the National Rural Health Mission (NRHM), launched by the Government of India in 2005, and with the newly proposed National Urban Health Mission. The result of the renewed focus on TB as well as on the functioning of health services can yield enormous dividends. A recent study from south India indicated preferential utilization in favor of government facilities for TB diagnosis and treatment, which is a hopeful sign (48). The success of both the general health services and the TB programme are dependent on one another and with a renewed focus on both, a truly win-win situation for both TB control and public health is possible.

The need for linkage and integration of the private sector in TB control

While the RNTCP focused its resources and strategies for TB control in the public sector, and consistently reported notable successes in these strategies, a blind spot that seems to be overlooked is the management of TB in the private sector. Various studies in the 1990's had indicated that there was an urgent need to address this component, not only because 50–80 percent of all TB patients in the country were treated in the private sector (49, 50), but also because audits had shown diagnostic and treatment practices in the private sector to be suboptimal and of a standard not in compliance with international guidelines for TB care (31). Indeed, the International Standards for TB Care were created to explicitly address this problem (20).

Figure 3 | Dozens of serological antibody tests for TB are available on the Indian market, although no international guideline recommends their use. The World Health Organization has recently published a policy recommending against their use.

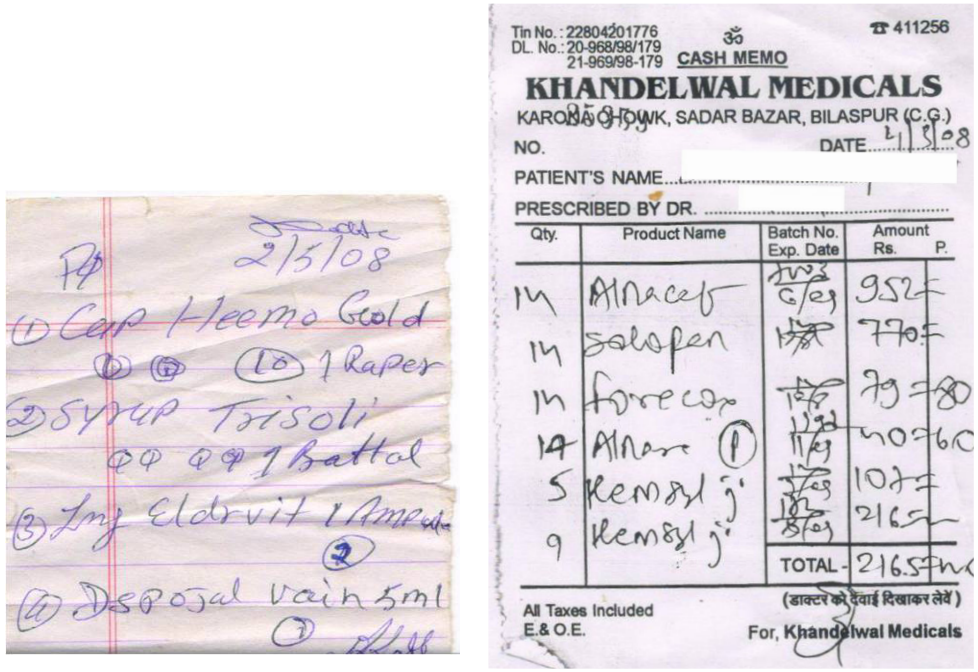


Figure 4 | The Indian TB drug market is largely unregulated. Even unqualified practitioners manage TB; an unqualified practitioner's prescription (on the left) for a TB patient includes only vitamins and a cough syrup. Poor patients spend a lot of money, out of pocket, for drug prescriptions in the private market; a rickshaw-puller pays more than his monthly income for a week of medicines for TB, prescribed by a private practitioner (on the right). Unnecessary drugs, including broad-spectrum antibiotics dominate the prescription, while the cost of TB drugs make up only 3% of the total cost of the prescription.

Despite these indicators, initiatives to involve the private sector in the national TB programme were not taken until about a decade later, and the latest reports still paint a dismal picture. Pilot public–private mix (PPM) projects that were initiated in response to the urgent need to involve the private sector were found to be both successful at increasing case detection and cure (51), and also cost-effective (52). Despite the promise shown by the model, PPM strategies have not been aggressively pursued and scaled–up. A report published in January 2010 found only 19,000 private providers in the entire country working with the RNTCP, and only 2%–3% of RNTCP case findings and less than 1% of case management being reported through PPM projects (53). This inadequate approach to private sector engagement poses a major challenge that must be addressed in the next phase of the RTNCP.

In addition to integrating private and public healthcare systems to provide a truly universal coverage, it would be equally important to address the reasons why patients prefer private healthcare despite a highly successful DOTS programme in India. A study conducted among TB patients seeking care in the private sector in Mumbai found a significant lack of awareness of the DOTS programme (54). On being explained the tenets of the programme, there was a significant resistance to the DOT (Directly Observed Treatment) component as it was considered an invasion of privacy and patients reported that they would be embarrassed to be observed while swallowing TB drugs. A generalized mistrust of government services and reluctance to receive drugs from government services owing to a lack of faith in the quality of such drugs also seemed to be a recurring theme.

Improving regulation and quality of medical care in India

Better regulation of the private medical sector in India is another key area for improvement (55–57). India has the largest private health sector in the world, with a health care market that is worth billions of rupees. Despite its

enormous size and importance, this sector is largely unregulated, although the Clinical Establishment Act of 2010 attempts to address this tricky and controversial issue. Weak regulation of health products is another area of concern (55–57). Unlike drugs, the regulation of in–vitro diagnostics is weak in India, and this allows for bad diagnostics to enter the market despite lack of evidence or policies to support their use. Unlike tests used for blood safety (e.g. HIV, hepatitis B and C), TB tests are not classified as "critical tests" by the Drug Controller General of India (DCGI), and this allows for entry and sale of suboptimal diagnostics with very little independent validation (Figure 3). Once on the market, financial gains by various stakeholders keep such products profitable. If diagnostic companies (domestic as well as foreign), local distributors, laboratories and doctors earn money from suboptimal tests, then market logic dictates that irrational practices will continue to flourish (55–57). It is important that diagnostics for an important public health problem like TB should be better regulated by the DCGI and the current use of misleading serological tests prevented.

If any solution can work in India, it must account for these market–based ground realities and address the underlying economic issues that may perpetuate irrational practices (57). In fact, this is true not just for TB care, but for all aspects of medicine in India, whether it is unnecessary surgical interventions (e.g caesarean sections and hysterectomies), widespread antibiotic abuse, kickbacks associated with diagnostic imaging services, linkage of physician incomes to procedures/tests performed, or the widely acknowledged nexus between doctors and the pharmaceutical industry (57). As pointed out by Das and colleagues, healthcare markets in countries such as India are complex, involving a wide spectrum of healthcare providers, from unqualified practitioners ("quack doctors") to highly trained specialists, with wide variation in quality of medical care, in both public and private sectors (58). Much more research is needed to understand provider behavior, variations in practice quality, market dynamics, and incentives that promote mismanagement (58). A recent analysis of the global private TB drug market estimated that the volume of first line anti-TB drug sold in India was sufficient to provide a full course of treatment to 117% of the estimated incident cases in India (59), underscoring the importance of the private sector in TB management, and the need for greater regulation of TB drugs, and expansion of PPM approaches (Figure 4).

Towards universal access to quality diagnosis and treatment

The next phase of the RNTCP aims for the provision of universal access to quality diagnosis and treatment for the entire population, and for the detection of at least 90 percent of all TB patients in the community. It would be fallacious to believe that the RNTCP alone can achieve this without scaling up further, and the active engagement of the private sector and other providers such as the non-profit sector, in the delivery of TB services. Small–scale pilot PPM projects will no longer be sufficient — the Indian private sector must be incentivised and engaged on a scale commensurate with its significant role. This will require socially–oriented, but economically viable business models. It is important to emphasize that PPM initiatives should not be used as an excuse for the government to scale back on its TB control investments, or seen as a way of promoting the private sector without adequately regulating it.

The past decade has revealed how despite "100 percent coverage" and impressive case detection and cure rates, TB still continues to be an epidemic of enormous magnitude in India. If this massive epidemic can be controlled, both public and private sectors must work together. And the next phase of RNTCP must be supported with substantially increased budgets, to ensure that it continues to succeed and meet its ambitious new goal of universal access. The lessons from the failure of the original NTP must not be forgotten. H

Competing interests

Authors declare no competing interest.

Authors' contributions

All authors contributed to the conception of the article. AB and LP wrote the initial draft of the manuscript. MP revised the manuscript. All authors read and approved the final draft of the manuscript.

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