Editorial

Management of Tuberculosis in India: Time for a deeper dive into quality

The diagnosis and treatment of tuberculosis (TB) remains a persistent challenge for health services in India. While the Revised National TB Control Programme (RNTCP) has announced 'universal access to quality TB diagnosis and treatment for all TB patients in the community' as its new goal in the new National Strategic Plan (2012–17),[1] there seems to be no clear strategy to systematically measure and document the quality of TB care, in both public and private sectors. The continuing lack of such a strategy goes hand-in-hand with a narrative of 'blame', where every new TB crisis is predictably assigned to the actions of the private sector in India. It is time to move beyond assigning blame to systematically understanding the practices of diagnosis and treatment of TB among multiple healthcare providers in multiple settings.

For instance, it is widely believed that how an average patient with TB gets diagnosed and treated in India depends entirely on where they seek care. If they go to the public sector, they will likely be diagnosed using sputum smears (which are known to have low sensitivity and cannot detect drug-resistance) and treated with a thrice-weekly, intermittent short-course regimen, and will likely have treatment supervision support. Their diagnosis and treatment will be free, but not necessarily convenient or accessible to all patients.

Similarly, it is also believed that if patients go to the private sector, they will likely be diagnosed with just chest X-rays, or a combination of chest X-rays and a blood test (either an antibody serological test, or an interferon-γ release assay such as QuantiFERON-TB Gold; marketed in India as 'TB Gold').[2,3] These patients will then be started on a variety of daily drug regimens with little or no supervision.[4,5] For them, diagnosis and treatment will not be free and most patients will pay out-of-pocket, regardless of how poor they are.[6]

Of particular concern has been the overuse of blood-based tests for TB in the private health sector.[2,3] Sputum is the most important sample for diagnosis of pulmonary TB and every guideline recommends the use of sputum-based tests such as smears, culture and nucleic acid amplification tests. But, for several reasons, including poor regulation and financial incentives, blood is the most popular sample in the Indian private sector.[3] Blood-based antibody tests (e.g. IgG/IgM ELISA or rapid tests) and interferon-γ release assays (e.g. TB Gold) are inaccurate[7,8] and not recommended for the diagnosis of pulmonary TB.[9,10] In fact, in 2012, the Government of India banned the use of serodiagnostic tests for TB (Fig. 1), and has discouraged the use of tests such as TB Gold. Despite this ban, blood tests continue to be widely used in the private sector.[11]

Although at first glance, this narrative paints a very believable picture, it is based on a set of studies that were important, but ultimately limited in their ability to parse out the deeper determinants of care. Based on recent research, we believe that there are at least three ways in which this narrative should be further elaborated.

First, an average TB patient in India may end up experiencing both private and public sector approaches to management.[12] Patients with TB may begin in the informal private sector (chemists and unqualified practitioners), then seek care from qualified

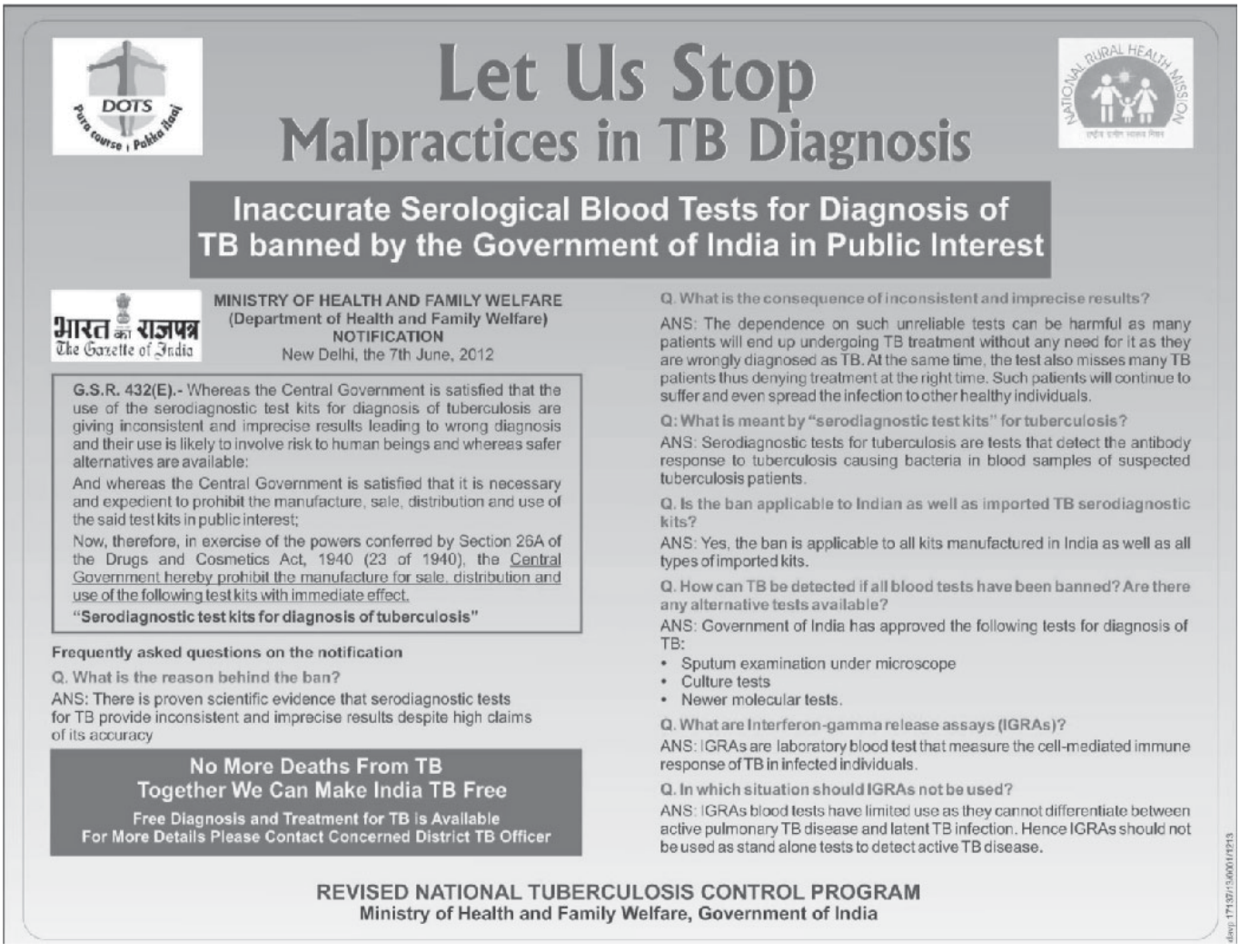

FIG 1. Leading Indian newspapers carried this advertisement on TB blood tests in December 2012 (reproduced with permission from the Central TB Division, Ministry of Health and Family Welfare, Government of India, New Delhi)

practitioners, and eventually end up in the RNTCP for free treatment.[13] Studies have shown considerable delays in the diagnosis of TB, and patients often move from one healthcare provider to another, and between private and public sectors, before they are finally diagnosed and put on treatment for TB.[6,13] And while they do this, they continue to transmit the infection to those in their communities. By the time patients are diagnosed, many have advanced, cavitary disease. Thus, poorly managed TB is a major driver of the epidemic, and a critical risk factor for mortality and drug-resistance.[14] Understanding case-detection rates for different presentations of TB in the private and public sector and the reasons for transitions between these two sectors is therefore a priority. Equally important is research on the eventual outcomes of patients who move from the public to the private sector and those who are treated entirely in the private sector.

Second, the private health sector is not a homogeneous entity—it has some of the world's best and highly trained doctors as well as a large number of untrained providers practising in rural areas and urban slums. This heterogeneity in healthcare providers matters. Our current research using medical vignettes in Delhi (unblinded tests of knowledge with standardized case presentations) shows that at high levels of competence, there is no difference in the tests that are asked for in the public and private sectors for patients with textbook presentations of pulmonary TB: 80% order blood tests, 80% order sputum tests and 90% order chest X-rays. However, at the

lowest levels of competence, the public health sector is far less likely to order blood tests and chest X-rays and much more likely to order sputum tests (Das J *et al*., unpublished data). Consequently, if these initial findings are confirmed, the 'difference' between the public and private sector in their propensity to order different types of tests may depend critically on the overall competence of the doctor.

Third, there is a large difference between the knowledge that doctors have and the way they put this knowledge to use in their clinical practice. Previous work from Delhi shows that although healthcare providers in the public sector are more knowledgeable, their lower effort leads to worse quality of care than their knowledge alone would predict.[15] Therefore, tests of knowledge and attitudes alone, which represent the bulk of the published research on TB practices,[4,5,16] may be less than informative when it comes to understanding actual clinical practice.

Unfortunately, poor quality of care is a bigger problem than just TB care.[17] Recently, standardized patients (mystery clients) were used in India to examine the quality of care for angina, asthma and dysentery.[18] The study found low levels of medical training and confirmed previous observations that many practitioners in India lack medical qualifications and often practise in large numbers in poor areas of rural and urban India. In this study, correct diagnoses were rare, and incorrect treatments were widely prescribed, in both public and private sectors.[18] Unlike prescription audits and hypothetical vignettes, which measure clinical knowledge and competence, the mystery client approach has been shown to accurately assess the practice of a healthcare provider, but has never been used to study TB care—this is important given previous research documenting dramatic differences between competence and clinical practice.

We believe that all patients with TB should receive the same quality of care, based on the best evidence we have about interventions that work or not. Indeed, best practices for TB are enshrined in the International Standards of TB Care (ISTC)[19] and numerous WHO guidelines.[20] It is a sad reality that quality of TB care in India is variable and often not aligned with international standards.

The RNTCP has recently taken several steps towards improving the situation. The National Strategic Plan (2012–17) will seek to engage the private health sector in a big way, and efforts are already under way to develop an 'Indian Standards of TB Care' to harmonize TB diagnostic and treatment practices across public and private health sectors.[1] In 2012, the RNTCP made it mandatory for all TB patients to be notified to local health authorities, and also banned the use of inaccurate serodiagnostic tests. These welcome initiatives will need to be supplemented with a clear strategy for continuous measurement and improvement of quality in diagnosis and treatment of TB. Such a strategy would provide a positive feedback loop from new initiatives to outcomes, allowing policy-makers to understand what works and what does not in the fight against TB.

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REFERENCES

1 Sachdeva KS, Kumar A, Dewan P, Kumar A, Satyanarayana S. New vision for Revised National Tuberculosis Control Programme (RNTCP): Universal access—'Reaching the un-reached'. *Indian J Med Res* 2012;**135:**690–4.
2 Grenier J, Pinto L, Nair D, Steingart K, Dowdy D, Ramsay A, *et al*. Widespread use of serological tests for tuberculosis: Data from 22 high-burden countries. *Eur Respir J* 2012;**39:**502–5.
3 Jaroslawski S, Pai M. Why are inaccurate tuberculosis serological tests widely used in the Indian private healthcare sector? A root-cause analysis. *J Epidemiol Global Health* 2012;**2:**39–50.
4 Uplekar MW, Shepard DS. Treatment of tuberculosis by private general practitioners in India. *Tubercle* 1991;**72:** 284–90.
5 Udwadia ZF, Pinto LM, Uplekar MW. Tuberculosis management by private practitioners in Mumbai, India: Has anything changed in two decades? *PLoS One* 2010;**5:**e12023.
6 Pantoja A, Floyd K, Unnikrishnan KP, Jitendra R, Padma MR, Lal SS, *et al.* Economic evaluation of public–private mix for tuberculosis care and control, India. Part I. Socio-economic profile and costs among tuberculosis patients. *Int J Tuberc Lung Dis* 2009;**13:**698–704.
7 Steingart KR, Flores LL, Dendukuri N, Schiller I, Laal S, Ramsay A, *et al.* Commercial serological tests for the diagnosis of active pulmonary and extrapulmonary tuberculosis: An updated systematic review and meta-analysis. *PLoS Med* 2011;**8:**e1001062.
8 Metcalfe JZ, Everett CK, Steingart KR, Cattamanchi A, Huang L, Hopewell PC, *et al.* Interferon-gamma release assays for active pulmonary tuberculosis diagnosis in adults in low- and middle-income countries: Systematic review and meta-analysis. *J Infect Dis* 2011;**204** (Suppl 4):S1120–S1129.

9 World Health Organization. *Policy statement: Commercial serodiagnostic tests for diagnosis of tuberculosis.* Geneva:WHO; 2011.
10 World Health Organization. *Policy statement: Use of tuberculosis interferon-gamma release assays (IGRAs) in low- and middle-income countries.* Geneva:WHO; 2011.
11 Express News Service. Doctors fail TB test. *The New Indian Express* 2012 Dec 6. Available at *http://newindianexpress.com/cities/hyderabad/article1368075.ece* (accessed on 6 Dec 2012).
12 Pai M. As India grows, tuberculosis control must not be left behind. *Lancet Infect Dis* 2012;**12:**263–5.
13 Kapoor SK, Raman AV, Sachdeva KS, Satyanarayana S. How did the TB patients reach DOTS services in Delhi? A study of patient treatment seeking behavior. *PLoS One* 2012;**7:**e42458.
14 Bhargava A, Pinto LM, Pai M. Mismanagement of tuberculosis in India: Causes, consequences, and the way forward. *Hypothesis* 2011;**9:**1–13.
15 Das J, Hammer J. Which doctor? Combining vignettes and item response to measure clinical competence. *J Development Economics* 2005;**78:**348–83.
16 Prasad R, Nautiyal RG, Mukherji PK, Jain A, Singh K, Ahuja RC. Treatment of new pulmonary tuberculosis patients: What do allopathic doctors do in India? *Int J Tuberc Lung Dis* 2002;**6:**895–902.
17 Das J. The quality of medical care in low-income countries: From providers to markets. *PLoS Med* 2011;**8:**e1000432.
18 Das J, Holla A, Das V, Mohanan M, Tabak D, Chan B. In urban and rural India, a standardized patient study showed low levels of provider training and huge quality gaps. *Health Aff (Millwood)* 2012;**31:**2774–84.
19 Hopewell PC, Pai M, Maher D, Uplekar M, Raviglione MC. International standards for tuberculosis care. *Lancet Infect Dis* 2006;**6:**710–25.
20 World Health Organization. *Treatment of tuberculosis.* 4th ed. Geneva:WHO; 2009.

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