CORRESPONDENCE

Newer rapid TB diagnostic tests: why the uptake is low in India's private sector

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In India, tuberculosis (TB) remains a major public health problem, accounting for 25% of the global TB burden. The situation is being worsened by the emergence of drug-resistant TB.¹ India's Revised National Tuberculosis Control Programme (RNTCP) emphasises sputum smear microscopy and culture (liquid or solid)/line probe assay (LPA) as the primary tools for the diagnosis of TB and multidrug-resistant TB (MDR-TB).

The global scenario changed on 8 December 2010, when the World Health Organization (WHO) endorsed the new cartridge-based nucleic acid amplification test, Xpert® MTB/RIF (Cepheid Inc, Sunnyvale, CA, USA) for the rapid diagnosis of TB and rifampicin resistance.^{2,3} The TB community across the world was given renewed hope, expecting a drastic change in the way TB cases are diagnosed and its impact on the trends of incidence and prevalence.

In 2011, the RNTCP began a multicentric feasibility study to look into operational issues for rolling out the test under the programme. The private sector, however, which manages the majority of India's presumptive TB cases, had fewer than 10 Xpert machines in a few major cities in 2011 and 2012. Although the numbers increased in 2013, there was a huge gap in terms of demand and availability of this diagnostic facility. We describe the various setbacks encountered by the private sector in the uptake of the Xpert assay.

In the highly unstructured private sector, the mainstay for diagnosing TB is clinical findings, supplemented by chest X-ray and non-specific blood parameters. If these features are present, the patients may be subjected to smear microscopy and various confirmatory tests depending on their availability and the 'dynamics of market forces'.⁴ Along with the patient profile, additional commercial interests drive practitioners along different diagnostic pathways. For diagnosis, practitioners prefer the widely available in-house poly-

merase chain reaction (PCR) tests, which work on a similar principle to that of Xpert, and have the additional advantage of being lucrative. There has been no vigorous marketing or promotion of Xpert in the field, which is a profound hindrance to the uptake of this test, and an information vacuum remains among private practitioners about its existence. Even if the facilities for testing are available, the cost per test is high in comparison to other laboratory investigations, and unaffordable for most patients. And, although the Government of India has banned serological tests, practitioners still tend to rely on interferon-gamma release assays (QuantiFERON-TB Gold and 'TB Platinum') for the confirmation of active TB.

In the Indian context, the introduction of newer TB diagnostic tests is timely and appropriate. However, the slow uptake of these new tests in the private sector is of concern. For most of this high TB morbidity population, the new diagnostics are unattainable, and many millions of people in the country are being deprived of the best available diagnostic services. Many lives would have been saved since the introduction of Xpert if it had been affordable, accessible and more widely utilised. A 'big push' effort from international and national stakeholders is necessary to bring newer diagnostics within reach in low- and middle-income countries.

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