CORRESPONDENCE

India's new TB diagnostic algorithm – far from reality?

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Tuberculosis (TB) remains a major public health problem in India despite the massive efforts of the Revised National Tuberculosis Control Programme (RNTCP) since 1997.¹ The RNTCP has consistently advocated the implementation of its guidelines for the diagnosis and treatment of TB in both the public and private sectors. According to these guidelines, presumptive TB cases are evaluated on the basis of a diagnostic algorithm that involves the following: 1) the presumptive TB case undergoes sputum smear examination; 2) if smear-negative, initiate on general antibiotics; 3) if symptoms persist, conduct repeat smear examination; 4) if negative on repeat examination, conduct chest X-ray (CXR); 5) if negative on CXR, further work-up is suggested.

However, adherence to the TB diagnostic algorithm, i.e., initiating smear-negative presumptive TB cases on general antibiotics for 7 days and conducting repeat sputum examination, is minimal.² In routine practice, the majority of health care practitioners recommend CXR upfront, at the same time as sputum smear examination. This non-compliance with the diagnostic algorithm and the availability of newer rapid diagnostic tests endorsed by the World Health Organization (WHO) have prompted the RNTCP to introduce a new diagnostic algorithm.^{3,4} We discuss the newer diagnostic algorithm critically, with a focus on feasibility for implementation in resource-limited settings such as India.

In the more recent diagnostic approach it is recommended that presumptive TB cases should be subjected to both sputum smear examination and CXR as the first line of investigation.⁵ Then, if the smear is negative and CXR is suggestive of TB, or CXR is not suggestive of TB but clinical suspicion remains, the patient should undergo testing via the cartridge-based nucleic acid amplification assay Xpert® MTB/RIF (Cepheid Inc, Sunnyvale, CA, USA).⁵

This approach does not, however, correspond to the Indian health programme's current context, for the following reasons. First, of the nearly 13 000 designated microscopy centres (DMCs) at different levels of the public health sector, the majority are not equipped with CXR facilities, and there is a lack of skilled personnel to read and interpret CXRs at the health facilities. Furthermore, very few GeneXpert machines are available at district level. Hence, there exists a gross

logistic disparity in the tools required to implement the proposed recommendation. Second, the positioning of Xpert is a cause for concern: the WHO's recommendation for using Xpert as a follow-on test for those groups with less likelihood of multidrug-resistant TB or human immunodeficiency virus related TB was conditional, particularly for countries with limited resources,⁶ and the RNTCP faced financial difficulties in allocating the budget required. Third, the RNTCP does not have enough evidence in terms of field-testing the diagnostic algorithm in the different health care settings or cost-effectiveness studies. The newer diagnostic algorithm should have been piloted and feasibility studies conducted before the decision was taken to adopt its implementation as national policy. Programme managers trained in the new RNTCP technical operational guidelines are in a dilemma about further implementation at field level and the RNTCP needs to plan training to grass roots level for it to be effective.

It would be worthwhile for the RNTCP to conduct several operational research studies to devise a newer diagnostic algorithm which is evidence based, cost-effective and feasible for implementation in the field, before undertaking the massive training exercises which are time, cost and resource intensive.

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