MedicalXpress

Serological antibody tests to detect active tuberculosis are inaccurate and not cost-effective

August 9 2011

Despite being widely available for sale in low-and-middle income countries, commercial serological tests used to detect active tuberculosis (by identifying antibodies to the tuberculosis-causing bacterium in a blood sample) do not accurately diagnose TB and, furthermore, often test positive when the patient does not have TB (false positive) and test negative when the patient actually has TB (false negative). In addition, as shown in India, the use of such tests is not cost effective as compared to other tests available for TB.

These findings from two studies led by Madhukar Pai from McGill University and Montreal Chest Institute in Montreal, Canada, and published in this week's PLoS Medicine, formed the basis of a policy issued by the World Health Organization (WHO) on 20 July 2011 advising against the use of currently available serological tests for the diagnosis of tuberculosis. WHO recommended: "These tests should not be used in individuals suspected of active pulmonary or extra-pulmonary TB, irrespective of their HIV status." The WHO policy strongly encourages further targeted research to identify new tests for TB diagnosis and alternative serological tests which would need to have much improved accuracy.

In the first article with Karen Steingart of the University of Washington, Seattle, USA as first author, the authors report searching the literature for relevant studies evaluating the accuracy of commercial serological

tests. In their systematic review, they report that the sensitivity of serological tests (the proportion of patients with confirmed TB with a positive serological test), ranged from 0% to 100% and their specificities (the proportion of patients who did not have confirmed TB with a negative serological test) ranged from 31% to 100%. For extrapulmonary tuberculosis (TB infection affecting parts of the body other than the lungs), sensitivities and specificities for each test also varied greatly, ranging from 0% to 100% and 59% to 100%, respectively. The authors found that, overall, the quality of evidence regarding diagnostic accuracy of serological tests was very low for both pulmonary and extrapulmonary tuberculosis.

The authors conclude: "Despite expansion of the literature since 2006, commercial serological tests continue to produce inconsistent and imprecise estimates of sensitivity and specificity."

In an associated study with David Dowdy of Johns Hopkins University, Baltimore, USA as first author, the authors analyzed the cost-effectiveness of TB serological tests from the perspective of tuberculosis control in India, compared to other diagnostic tests. They found that if used as an initial test for tuberculosis in India, serology would result in more DALYs (years of healthy life lost because of premature death or disability), more secondary infections, and more false-positive diagnoses than sputum smear microscopy while increasing costs per patient to the Indian tuberculosis control sector.

The authors conclude: "In India, sputum smear microscopy remains the most cost-effective diagnostic test available for active TB; efforts to increase access to quality-assured microscopy should take priority." Where quality microscopy is available, WHO-endorsed tests such as liquid cultures should be introduced to improve TB diagnosis.

More information: www.who.int/tb/features_archiv …