

Blood tests for active TB not accurate or cost-effective

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Commercial blood serum antibody tests—widely used in India and other developing countries to diagnose active tuberculosis—are not accurate or cost-effective, according to an analysis by researchers at the Johns Hopkins Bloomberg School of Public Health, the University of Washington School of Public Health and McGill University. Use of serological tests in India resulted in more DALYs (years of healthy life lost to premature death and illness), more secondary infections, and more false-positive diagnoses of TB, compared to the use of microscopic sputum smear analysis or culture. The findings, published in the August 9, 2011 edition of *PLoS Medicine*, recently led the World Health Organization to recommend against the use of commercial serology tests in the diagnosis of active TB.

"Microscopic analysis of sputum for TB is cheap and widely available, but misses half of all TB cases," said David Dowdy, MD PhD, lead author of the study and assistant professor in the Department of Epidemiology at the Bloomberg School of Public Health. "TB culture, the current gold standard, requires training and equipment not available in most resource-limited settings. Serological tests are simpler and faster than culture, and are also commercially available in India, so they are an attractive option in theory. However, we found that they are not accurate enough to be useful—after accounting for missed and false-positive TB diagnoses, serological tests cost more and delivered less than either microscopy or culture. Quite simply, serological tests should not be used to diagnose active TB."

For the study, Dowdy and his colleagues constructed a mathematical model to analyze 1.5 million patients with suspected active TB in India—about 15% of India's annual TB burden. Their analysis concluded that use of serology would result in an estimated 14,000 more TB diagnoses than microscopy, but would also incorrectly diagnose 121,000 more patients without active TB (false-positives). Serology use would also generate 102,000 more DALYs and 32,000 more secondary TB cases compared to microscopy. The estimated total cost of serologic testing (including treatment of newly diagnosed cases) was approximately four times that of microscopy, at \$47.5 million versus \$11.9 million.

"Unfortunately, we still do not have an accurate point-of-care test for TB, as we have for infections like HIV or malaria. The WHO policy strongly encourages future research to develop novel or improved serological tests," said the study's senior author, Madhukar Pai, MD, PhD, associate professor at McGill University and the Respiratory, Epidemiology and Clinical Research Unit at the Montreal Chest Institute and the Research Institute of the McGill University Health Centre.

Provided by Johns Hopkins University Bloomberg School of Public Health

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