

New TB drug-resistance test shows promise but needs investment for those diagnosed to be cured

July 26 2011

Two research studies in this week's *PLoS Medicine* suggest that a new automated DNA test for tuberculosis (Xpert MTB/RIF), which can detect TB within 2 hours and has been endorsed by the World Health Organization, can significantly increase TB detection rate compared to other tests, particularly in HIV positive patients who have a high risk of being infected with TB, including multidrug resistant TB. An accompanying Essay and Perspective highlight the economic challenges and implications of such diagnostic tests.

In the first study, led by Stephen Lawn from the Desmond Tutu HIV Centre at the University of Cape Town in South Africa, the authors collected sputum from HIV-infected adults with no current TB diagnosis who were enrolling at an [HIV treatment](#) clinic in a South African township. The authors then compared the [diagnostic accuracy](#) of Xpert MTB/RIF with several other tests, including liquid culture (the reference test).

Nearly a fifth of the patients had culture-positive TB and Xpert MTB/RIF identified three-quarters of these patients. Furthermore, the [new test](#) had a low false-positive rate and was able to detect all cases of smear-positive, culture-positive TB but only 43.4% of smear-negative, culture-positive cases from a single sputum sample. The new test also correctly identified rifampicin resistance, a marker for multidrug resistant TB, in all four patients who had this form of TB, but incorrectly

identified resistance in three patients with drug-sensitive TB.

The authors say: "In this population of individuals at [high risk](#) of TB, intensive screening using the Xpert MTB/RIF assay increased case detection by 45% compared with smear [microscopy](#), strongly supporting replacement of microscopy for this indication. " They continue: "However, despite the ability of the assay to rapidly detect rifampicin-resistant disease, the specificity for [drug resistant TB](#) was sub-optimal."

In a smaller study led by Lesley Scott from the University of the Witwatersrand in Johannesburg, South Africa, the authors compared the performance of Xpert MTB/RIF on a single sputum sample with that of smear microscopy, liquid culture and two other nucleic acid amplification tests (MTBDRplus and LightCycler MTB) in 311 adults suspected to have TB in Johannesburg, South Africa, a region where many adults are HIV-positive. Although these findings are likely to be affected by the study's small size, the results suggest that Xpert MTB/RIF may provide a more accurate rapid diagnosis of TB than smear microscopy and other currently available tests in regions where HIV and TB are endemic.

The authors conclude: "The Xpert MTB/RIF test has superior performance for rapid diagnosis of Mycobacterium tuberculosis over existing ... smear microscopy and other molecular methodologies in an HIV- and TB-endemic region. Its place in the clinical diagnostic algorithm in national health programs needs exploration."

In an Essay in the same issue, David Dowdy from the University of California in San Francisco, and colleagues discuss the challenges of economic analysis of [diagnostic tests](#) for tuberculosis, and argue that standard cost-effectiveness analyses may give misleading results when blindly applied to the scale-up of TB diagnostics.

To be useful to both policy-makers and decision-makers, the authors suggest that such analyses should establish society's valuation of false-positive tests relative to false-negative tests; evaluate the consequences of false-negative and false-positive diagnoses when new diagnostics are implemented in field settings; and set local cost-effectiveness thresholds for disease-specific interventions.

Furthermore, a Perspective by Carlton Evans from the Universidad Peruana Cayetano Heredia in Lima, Peru (not involved in any of the research studies here) stresses that although the new MTB/RIF-test has the capacity to be a "game-changer" in TB diagnosis, the new research in this week's [PLoS Medicine](#) raises important points of concern as the field progresses to implementation of this innovative technology. He emphasizes the shameful context that almost 2 million people die each year from TB, and very few of them would have been saved by any diagnostic test.

Evans says; "Specifically, these deaths occur in mainly HIV-negative people, almost all of whom die from drug-susceptible TB, principally because of the inadequacy of basic, inexpensive health care provision for this curable infectious disease."

More information: Lawn SD, Brooks SV, Kranzer K, Nicol MP, Whitelaw A, et al. (2011) Screening for HIV-Associated Tuberculosis and Rifampicin Resistance before Antiretroviral Therapy Using the Xpert MTB/RIF Assay: A Prospective Study. *PLoS Med* 8(7): e1001067. [doi:10.1371/journal.pmed.1001067](https://doi.org/10.1371/journal.pmed.1001067)

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be cured (2011, July 26) retrieved 5 May 2024 from <https://medicalxpress.com/news/2011-07-tb-drug-resistance-investment.html>

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