

The Cochrane Library publishes new systematic review on Xpert MTB/RIF

31 January 2013

Xpert® MTB/RIF can accurately and quickly detect both TB and drug-resistant strains, according to a new study. The authors of the new systematic review assessing the diagnostic accuracy of the Xpert test published in *The Cochrane Library* say their study can provide timely advice for clinicians and policymakers in countries where TB is a major public health problem.

Xpert® MTB/RIF (Cepheid Inc, California) is a fully automated PCR test that simultaneously detects TB and resistance to rifampicin, as an indicator of multidrug resistance. Xpert is currently unique in simplifying molecular testing because sample processing and PCR amplification and detection are integrated into a single test unit, the GeneXpert cartridge. The test takes around two hours, with minimal hands-on technical time required. The World Health Organization (WHO) has previously endorsed the test.

The researchers, from the Cochrane Infectious Diseases Group, McGill University and the Foundation for Innovative New Diagnostics (FIND), analysed data from 18 studies involving a total of 7,816 people, with most studies being carried out in low- and middle-income countries. The results show that when Xpert is used to screen 1,000 people, 150 of whom have TB, it picks up 132 of the 150 cases (88%) and falsely diagnoses 17 (2%) with TB. This is in a scenario where it is being used as a replacement for smear microscopy. In a scenario where Xpert is being used as a replacement for culture-based drug susceptibility testing, it is also able to detect the equivalent of 141 out of 150 cases (94%) of rifampicin resistance. When Xpert is used as a follow-on test, after conventional smear microscopy has already produced a negative result, it picks up 101 out of 150 cases (67%).

“This study represents the most comprehensive review on the diagnostic accuracy of Xpert to date and may help countries make decisions about scaling up its use for management of TB and drug-resistant TB,” said lead researcher, Karen Steingart, of the Cochrane Infectious Diseases Group and Coordinator of the NDWG Subgroup on Evidence Synthesis and Policy.

Karin Weyer, Coordinator, Laboratories, Diagnostics and Drug Resistance at the World Health Organization (WHO) said, “This Cochrane Review provides high quality evidence that reinforces WHO’s endorsement of this test. Recent price reductions have greatly facilitated roll-out of this technology, including a new three-year initiative called the TB Xpert Project, funded by UNITAID and executed by WHO and the Stop TB Partnership. 1.4 million test cartridges and over 200 GeneXpert instruments for the rapid detection of TB and rifampicin resistance will be distributed in 21 countries with a high burden of TB.”

Lucica Ditiu, Executive Secretary of the Stop TB Partnership, said, “We welcome the Cochrane Review of Xpert, an innovation that represents a major milestone in our quest to achieve the goal of zero deaths from TB – which is curable but still takes the life of three people every minute. The Stop TB Partnership is making every effort to help countries understand how best to use this new technology. Our TB REACH initiative is deploying Xpert to numerous countries through projects that seek to increase the number of TB cases detected and treated, and these projects will deliver data that can provide an evidence base for determining how Xpert should be used for the greatest impact.”

Notes for editors

Full citation: Steingart KR, Sohn H, Schiller I, Kloda LA, Boehme CC, Pai M, Dendukuri N. Xpert® MTB/RIF assay for pulmonary tuberculosis and rifampicin resistance in adults. *Cochrane Database of Systematic Reviews* 2013, Issue 1. Art. No.: CD009593. DOI: 10.1002/14651858.CD009593.pub2.

URL upon publication: <http://doi.wiley.com/10.1002/14651858.CD009593.pub2> (The full review will be available open access upon publication)

Accompanying Podcast: <http://www.cochrane.org/podcasts/issue-1-january-2013/xpert-mtbrif-test-detection-pulmonary-tuberculosis-and-rifampicin-resi>