

Rapid test allows for earlier diagnosis of tuberculosis in children

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A new test for diagnosing tuberculosis (TB) in children detects roughly two-thirds of cases identified by the current culture test, but in a fraction of the time, according to the results of a study in South Africa supported by the National Institutes of Health.

The test, known as Xpert MTB/RIF, also detected five times the number of cases identified by examining [specimens](#) under the microscope, a preliminary method for diagnosis that is often performed as an initial test, but which must be verified by the culture test.

Xpert MTB/RIF results from respiratory secretions were ready in 24 hours, on average, compared with an average of more than two weeks for the culture test used in the study, the researchers found. Previous studies have shown that Xpert MTB/RIF is effective for diagnosing TB in adults and in children with pronounced symptoms of TB who have been admitted to a hospital. Diagnosing TB in children is more difficult than diagnosing it in adults, because children tend to have much lower levels of the TB bacteria than do adults.

The results of the current study indicated that the ease and speed of diagnosis would be useful for children seen in clinics in resource-limited countries, which often lack the resources for traditional testing that are available in hospitals. The test also was able to identify children with drug resistant TB. In addition, the researchers found that Xpert can readily determine when treatment for [tuberculosis](#) is not appropriate. Among children who did not in fact have TB, the results of the Xpert test came back negative for TB with 99 percent accuracy.

Xpert MTB/RIF was developed with funding from the NIH's National Institute of Allergy and Infectious Diseases NIH's National Institute of Allergy and Infectious Diseases. Testing of Xpert MTB/RIF in children was funded by NICHD.

Preliminary diagnosis of TB is often made by collecting a sample of lung secretions and examining the sample under a microscope to see if it contains the bacteria that cause TB. A sample is also sent to a laboratory so the bacteria can be cultured and identified. It may take as long as six weeks for the culture test to show a positive result. Because, children have lower levels of infectious bacteria than do adults, it is more difficult to detect the bacteria under a microscope and to grow it in a culture. For this reason, accurately diagnosing TB in children has been difficult.

"The availability of this test in primary care settings can help children get appropriate treatment faster," said Lynne M. Mofenson, M.D., of the Maternal and Pediatric Infectious Disease Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the NIH institute that funded the study. "Looking at a specimen under the microscope, often used for initial diagnosis of TB in adults, is very inaccurate in children."

The Xpert MTB/RIF test also detects TB strains that are resistant to the drug rifampicin, allowing physicians to more accurately prescribe an appropriate treatment, said Carol Worrell, M.D., also of the NICHD's MPIDB. This is particularly important in areas where drug-resistant TB is common, such as South Africa.

The World Health Organization estimated that in 2011 there were 500,000 TB cases and 64,000 deaths among those younger than 15 years.

The study was led by first author Heather J. Zar, M.D., Ph.D., of the University of Cape Town and Red Cross War Memorial Children's Hospital, also in Cape Town, South Africa; and Mark P. Nicol, Ph.D., also of the University of Cape Town and the South African National Health Laboratory Service at Groote Schuur Hospital, Cape Town.

The findings appear in *The Lancet* Global Health.

"There has been a perception amongst health care workers that rapid diagnosis of TB in children wouldn't be possible in primary care, but this study disproves that view, Dr. Zar said. "Given our results, widespread adoption of rapid testing for TB and drug resistance in children may substantially improve public health without greatly increasing costs."

Dr. Zar and her colleagues collected almost 1500 samples from nearly 400 children who went to a primary care clinic with symptoms of TB. Collecting the samples—secretions from the lungs, the nasal passages or both—requires special equipment and trained clinical staff. The researchers compared the results from the Xpert MTB/RIF test, examination of samples under a microscope, and from growing the tuberculosis bacteria in laboratory cultures. Bacterial culture is the most accurate method for diagnosing TB.

Of the 30 TB cases detected by culture, 19 (63 percent) were positive by the Xpert MTB/RIF test on lung or nasal samples, while examining the samples under the [microscope](#) turned up only four cases (13 percent). Adding a second test (of a second lung or nasal passage sample) improved the detection rate for both culture and Xpert MTB/RIF

In some cases, researchers started TB treatment for children they suspected had TB based on their symptoms. Xpert MTB/RIF identified seven children who had clinical symptoms of tuberculosis and responded well to treatment for tuberculosis, but whose tuberculosis had not been detected by the tuberculosis culture test. This might occur when a child is sick with TB, but the bacteria are at especially low levels, or because a sample did not contain enough of the bacteria present in the child's body to appear when cultured, Dr. Mofenson explained. The total number of cases detected by culture (30 cases) and by XpertMTB/RIF (26 cases) was similar.

"Because of the global burden of this disease among children, it's vital to make rapid, accurate diagnostic tests available in [primary care](#) settings in

order to identify the disease and start treatment before children end up in the hospital," said Dr. Worrell. "NICHD recognizes the value of supporting research to improve the accuracy of TB diagnosis in children, reduce the number of samples required, and make diagnostic tools widely accessible."

More information: www.who.int/tb/publications/gl..._executivesummary.pdf

Provided by National Institutes of Health

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