

New test seen as big advance in diagnosing TB

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This undated photo released by Cepheid, shows a Cepheid Xpert MTB/RIF cartridge. The cartridge is part of a test that is a major advance in diagnosing tuberculosis and can reveal in less than two hours, with very high accuracy, whether someone has the disease and if it's resistant to the main drug for treating it. (AP Photo/Cepheid) NO SALES

Scientists are reporting a major advance in diagnosing tuberculosis: A new test can reveal in less than two hours, with very high accuracy, whether someone has the disease and if it's resistant to the main drug for treating it.

The test could revolutionize TB care and replace the 125-year-old process used now, which is slow and misses more than half of all cases, experts say. A better test would be a powerful tool to curb TB in poor countries, where most people spread the lung disease before they are diagnosed and treated, and many don't return for follow-up doctor visits to get [test results](#).

In the United States, it could be a big help in inner city clinics, where diagnosing a drug-resistant strain on someone's first visit enables proper treatment right away.

"You can tell the patient before they leave the office if they have TB and if it's drug-resistant. It's transformational," said Dr. Peter Small, head of TB programs at the Bill & Melinda Gates Foundation, which helped fund the work, along with the U.S. government.

The World Health Organization will meet with experts over the next few days to review results and plan steps forward, says a statement from one of its TB experts, Dr. Mario Raviglione.

"These results suggest that it has the potential to revolutionize TB care, and WHO will treat it as a top priority," the statement says.

A study of the test was published online Wednesday by the *New England Journal of Medicine*.

TB kills about 1.8 million people a year and increasingly is caused by bacteria that are resistant to one or more drugs. The best test - growing the bacteria in a lab dish from a mucus sample - takes a week or more, so the most common approach is to look for bacteria in a sample under a microscope. That misses many cases, tells nothing about drug resistance, and doesn't usually give an answer before a patient leaves the clinic.

"It's antiquated," said Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases. "If you have 50 patients in a clinic and one person looking at a microscope it could take hours and hours."

The government set out to develop a better test with a host of partners: Cepheid, a California-based diagnostics company; the University of Medicine and Dentistry in New Jersey, and the Foundation for Innovative New Diagnostics, a Swiss-based nonprofit group supported by the Gates Foundation.

The test they devised is simple enough to be done with minimal training. It requires only 15 minutes of manual labor, for taking the mucus sample, mixing it with chemicals and putting it in an inkjet-like cartridge that goes into a machine. The machine amplifies the DNA in the sample and checks for bits of bacterial genes.

The whole process takes less than two hours.

The study tried it on 1,730 patients with suspected TB in Peru, Azerbaijan, South Africa and India. The test successfully identified 98 percent of all confirmed TB cases and 98 percent of ones resistant to rifampin, one of the top drugs to treat the disease.

It correctly picked out nearly three-quarters of TB cases that were mistakenly declared negative from the microscope exam. And it accurately ruled out TB in 99 percent of people who did not have it.

Besides WHO endorsement, Cepheid will seek U.S. Food and Drug Administration approval for the test, which went on sale late last year in Europe. The test costs about \$63 there, but the company has agreed to provide it for less than half that in poor countries, said John Bishop, Cepheid's chief executive officer. The machine costs around \$30,000,

but would be priced under \$20,000 in [poor countries](#), he said.

While the cost per test is higher, it doesn't take a sophisticated lab to do the test, so the overall cost may be lower, Bishop said. It also tells the diagnosis and drug resistance for that price.

The microscope-sample method costs a few dollars, plus \$15 for drug-resistance testing, said Small of the Gates Foundation. He agreed that the new test may be viewed as more cost-effective because it's more accurate, fast and gives more information.

Further study is under way to see if the test can reveal multi-drug-resistant strains. If TB is resistant to rifampin, it's often resistant to another commonly used drug, Fauci said.

Testing for TB in someone who has symptoms is not the same as the TB screening skin tests that many people get. The skin [test](#) just shows whether someone has been exposed to TB at some time, and may warrant further testing to ensure they don't have a latent case.

More information: Medical journal: www.nejm.org

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