

Rapid tests for drug-resistant TB to be available in developing countries

Medicine

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Geneva -- People in low-resource countries who are ill with multidrug-resistant TB (MDR-TB) will get a faster diagnosis -- in two days, not the standard two to three months -- and appropriate treatment thanks to two new initiatives unveiled today by the World Health Organization (WHO), the Stop TB Partnership, UNITAID and the Foundation for Innovative New Diagnostics (FIND).

MDR-TB is a form of TB that responds poorly to standard treatment because of resistance to the first-line drugs isoniazid and rifampicin. At present it is estimated that only 2% of MDR-TB cases worldwide are being diagnosed and treated appropriately, mainly because of inadequate laboratory services. The initiatives announced today should increase that proportion at least seven-fold over the next four years, to 15% or more.

"I am delighted that this initiative will improve both the technology needed to diagnose TB quickly, and increase the availability of drugs to treat highly resistant TB," said British Prime Minister Gordon Brown, who helped launch the Stop TB Partnership's Global Plan to Stop TB in 2006 and whose government is a founding member of UNITAID. "The UK is committed to stopping TB around the world, from our funding of TB prevention programmes in poor countries, to our support of cutting edge research to develop new drugs."

In developing countries most TB patients are tested for MDR-TB only after they fail to respond to a standard treatments. Even then, it takes two months or more to confirm the diagnosis. Patients have to wait for the test results before they can receive life-saving second-line drugs. During this period, they can spread the multidrug-resistant disease to others. Often the patients die before results are known, especially if they are HIV-infected in addition to having MDR-TB.

The initiative comes just one week after WHO recommended "line probe assays" for rapid MDR-TB diagnosis worldwide. This policy change was driven by data from recent studies, including a large field trial--conducted by FIND together with South Africa's Medical Research Council and National Health Laboratory Services--which produced evidence for the reliability and feasibility of using line probe assays under routine conditions.

"Five months ago, WHO renewed its call to make MDR-TB an urgent public health priority," said WHO Director-General Dr Margaret Chan, "and today we have evidence to guide our response. Based on that evidence, we are launching these promising initiatives."

The new initiative consists of two projects. The first, made possible through \$26.1 million in funding from UNITAID*, will introduce a molecular method to diagnose MDR-TB that until now was used

exclusively in research settings. These rapid, new molecular tests, known as line probe assays, produce an answer in less than two days.

Over the next four years -- as lab staff are trained, lab facilities enhanced and new equipment delivered -- 16 countries** will begin using rapid methods to diagnose MDR-TB, including the molecular tests. The countries will receive the tests through the Stop TB Partnership's Global Drug Facility, which provides countries with both drugs and diagnostic supplies.

As part of the project, WHO's Global Laboratory Initiative and FIND will help countries prepare for installation and use of the new rapid diagnostic tests, ensuring necessary technical standards for biosafety and the capacity to accurately perform DNA-based tests. One country, Lesotho, is already equipped to start using these tests; Ethiopia is expected to be ready by the end of 2008. The tests will be phased in from 2009-2011 in the remaining 14 countries.

Under a second, complementary agreement with UNITAID for US\$ 33.7 million, the Global Drug Facility will boost the supply of drugs needed to treat MDR-TB in 54 countries, including those receiving the new diagnostic tests. This project is also expected to achieve price reductions of up to 20% for second-line anti-TB drugs by 2010. All the countries receiving this assistance have met WHO's technical standards for managing MDR-TB and already have treatment programmes in place. Some will use grants from the Global Fund against AIDS, Tuberculosis and Malaria to purchase the drugs.

"Through the US\$ 60 million support provided by UNITAID, these projects are expected to produce significant results in diagnosing and treating patients as well as reducing drug prices and the costs of diagnosis. These efforts illustrate the way in which innovative financing can be deployed for health and development," said Philippe Douste-Blazy, Chairman of UNITAID's Executive Board.