Rapid, low-cost test for multi-drug resistant TB gains WHO endorsement

EurekAlert

A rapid, low cost test for diagnosing tuberculosis (TB) including multi-drug resistance has been endorsed by the World Health Organisation (WHO) for use in resource-poor settings.

The microscopic observation drug susceptibility (MODS) test has been developed and evaluated by a team of researchers led by Dr David Moore from the London School of Hygiene and Tropical Medicine with Professor Jon Friedland of Imperial College London, with support from the Wellcome Trust.

The endorsement from the WHO was issued in a policy statement* in July this year on non-commercial methods for culture and drug susceptibility testing, which endorsed the use of MODS as well as nitrate reductase and specific colorimetric assays.

MODS delivers positive culture and drug resistance results within two weeks for less than $3 per test, unrivalled by any commercially available tests. If implemented, the test should ensure that people with TB and drug-resistant forms of the disease are identified and treated appropriately earlier than is currently the case, reducing both the severity of their disease and their chances of infecting others.

"The WHO approval is essential for providing health officials and laboratories world wide with the confidence that MODS is a highly reliable means of testing for TB and drug resistance," says Dr Moore. "The MODS test is low tech, low cost and rapid, which is essential in resource poor settings where the burden of TB is greatest. TB is one of the world's major killers and we need reliable, effective and financially accessible tools if we are to fight it."

WHO still recommends 'sputum smear microscopy' as the cornerstone of TB diagnosis because it is inexpensive, identifies the most infectious patients and can be performed in the most basic laboratories in peripheral health centres. However this method has low sensitivity and provides no information about drug susceptibility. Conventional culture takes at least three to six weeks, with an additional three to six weeks for drug susceptibility testing, during which time the patient may have become very sick or have transmitted the infection to others.

In 2007 WHO endorsed an enhanced approach to TB diagnosis with wider use of liquid culture and drug susceptibility testing, without specifically recommending any particular methodology.

Using MODS, *Mycobacterium tuberculosis* the organism which causes TB is cultured in liquid media, where it grows in characteristic tangles or coils readily recognisable

under a microscope. The bacteria grow more rapidly in liquid culture than in conventional solid culture and the use of a microscope allows earlier detection than inspection of solid media with the naked eye. In addition, the liquid media means that TB drugs can be more easily administered for testing: if the bacteria grow in the presence of these drugs, this indicates resistance.

The test was developed and evaluated at Cayetano Heredia University in Peru, and it is now in routine use in four regional government laboratories, including a specially designed portable MODS laboratory in a shipping container conversion in the earthquake-affected city of Ica. Since October 2008, more than 8,500 patients in the country have benefited from MODS testing and more than 500 have been diagnosed with multi-drug resistant TB (MDRTB). The test is also in use in a diverse range of countries including Ethiopia, Pakistan, Vietnam, India, Ecuador and South Africa.

In 2005 the assay won best innovation for global health at the Medical Futures Innovation Awards.

Sir Mark Walport, Director of the Wellcome Trust, says: "David Moore and his colleagues have developed an essential test to help clinicians and scientists identify and fight the emergence of multi-drug resistant forms of TB. Their perseverance has been rewarded by official recognition of the MODS test by the WHO. The test has already saved lives in Peru and other low income countries and we hope that the WHO endorsement will encourage its use more widely."

TB is one of the world's most deadly diseases. One third of the world's population are believed to be infected with *M. tuberculosis*, which in many cases remains latent. Each year, at least nine million people are in need of treatment for TB, and more than two million people die from the disease. There are an estimated 500,000 cases of MDRTB, the vast majority of which are undiagnosed.

SOURCE [1]

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