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WHO warns against the use of inaccurate blood tests for active tuberculosis

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A substandard test with unreliable results

News release

20 JULY 2011 | GENEVA - The use of currently available commercial blood (serological) tests to diagnose active tuberculosis (TB) often leads to misdiagnosis, mistreatment and potential harm to public health, says WHO in a policy recommendation issued today. WHO is urging countries to ban the inaccurate and unapproved blood tests and instead rely on accurate microbiological or molecular tests, as recommended by WHO.

TB can be wrongly diagnosed

Testing for active TB disease through antibodies or antigens found in the blood is extremely difficult. Patients can have different antibody responses suggesting that they have active TB even when they do not. Antibodies may also develop against other organisms which again could wrongly indicate they have active TB. In addition, different organisms share the same antigens, making tests results unreliable. These factors can result in TB disease not being identified or wrongly diagnosed.

A blood test for diagnosing active TB disease is bad practice

"In the best interests of patients and caregivers in the private and public health sectors, WHO is calling for an end to the use of these serological tests to diagnose tuberculosis," said Dr Mario Raviglione, Director of WHO Stop TB Department. "A blood test for diagnosing active TB disease is bad practice. Test results are inconsistent, imprecise and put patients' lives in danger."

Today's policy recommendation applies to blood tests for active TB. Blood tests for inactive TB infection (also known as dormant or latent TB) are currently under review by WHO.

New recommendation after 12 months of rigorous analysis

The new recommendation comes after 12 months of rigorous analysis of evidence by WHO and global experts. Ninety-four studies were evaluated - 67 for pulmonary tuberculosis (TB in the lungs) and 27 for extrapulmonary tuberculosis (TB elsewhere in other organs). Overwhelming evidence showed that the blood tests produced an unacceptable level of wrong results - false-positives or false-negatives - relative to tests endorsed by

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[Commercial Serodiagnostic Tests for Diagnosis of Tuberculosis - Policy Statement pdf, 809kb](#)

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WHO.

Problems of misdiagnosis

The research revealed "low sensitivity" in commercial blood tests which leads to an unacceptably high number of patients wrongly being given the 'all clear' (i.e. a false-negative when in reality they have active TB). This can result in the transmission of the disease to others or even death from untreated tuberculosis. It also revealed "low specificity", which leads to an unacceptably high number of patients being wrongly diagnosed with TB (i.e. a false-positive when in reality they do not have active TB). Those patients may then undergo unnecessary treatment, while the real cause of their illness remains undiagnosed, which may then also result in premature death.

The inaccurate blood tests are costly

More than a million of these inaccurate blood tests are carried out annually to diagnose active TB, often at great financial cost to patients. Many patients pay up to US\$ 30 per test. There are at least 18 of these blood tests available on the market. Most of these tests are manufactured in Europe and North America, even though the blood tests are not approved by any recognized regulatory body.

Selling substandard tests with unreliable results

"Blood tests for TB are often targeted at countries with weak regulatory mechanisms for diagnostics, where questionable marketing incentives can override the welfare of patients," said Dr Karin Weyer, Coordinator of TB Diagnostics and Laboratory Strengthening for the WHO Stop TB Department. "It's a multi-million dollar business centred on selling substandard tests with unreliable results."

This is the first time WHO has issued an explicit "negative" policy recommendation against a practice that is widely used in tuberculosis care. It underscores the Organization's determination to translate strong evidence into clear policy advice to governments.

Tuberculosis kills 1.7 million people every year, and is the major killer of people living with HIV. Improving the early and effective diagnosis of TB to ensure more lives are saved is a priority action for WHO and the international TB community. TB research is currently underway to bring better and more rapid tests that are easy to administer, effective and accurate.

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