Use of commercial serological tests for the diagnosis of TB

- EXPERT GROUP MEETING -

Date and time: 22 July 2010, 09:00 – 1600
Venue: Salle B, WHO-HQ Main Building, Geneva, Switzerland

BACKGROUND

Commercial serological tests for diagnosis of TB have been used for many years, especially in the private health sector. In 2008, a head-to-head comparison by TDR of 19 commercial tests showed clear deficiencies in the performance characteristics of these tests, particularly in specimens from patients co-infected by HIV, where the sensitivity was greatly affected[1]. It was concluded that none of the tested assays performed well enough to replace conventional microbiological tests for TB. Nevertheless, aggressive marketing of serodiagnostics continues in many parts of the world, with claims about accuracy often based on poor quality and grossly insufficient data. WHO has therefore called for an update on the current evidence base for commercial serodiagnostic tests, with the aim of developing global policy guidance on their relevance in TB diagnosis.

WORLD HEALTH ORGANIZATION: EVIDENCE-BASED PROCESS FOR POLICY GUIDANCE

In order to facilitate rapid policy guidance on the use of new diagnostic tools, new methods, and/or novel approaches using existing tools, WHO has developed a systematic, structured, evidence-based process. The first step involves a systematic review and meta-analysis of available data, using standard methods appropriate for diagnostic accuracy studies. The second step involves the convening of an Expert Group to evaluate the strength of the evidence base and recommend operational and logistical considerations for mainstreaming such tools/approaches into national TB control programmes, and/or identify gaps to be addressed in future research. The third and final step involves WHO policy guidance on the use of these tools/approaches, presented to the WHO Strategic and Technical Advisory Group for TB (STAG-TB) for endorsement and subsequent dissemination to member states for implementation.

[1] Laboratory-based evaluation of 19 commercially available rapid diagnostic tests for tuberculosis. Diagnostics Evaluation Series No. 2 - WHO/TDR, 10 October 2008

MEETING OBJECTIVE

- To review the evidence base and evaluate data from systematic reviews on the performance characteristics of commercial serological diagnostic tests for the diagnosis of tuberculosis.

EXPECTED OUTCOME

- Evidence-based recommendations on the use of commercial serological diagnostic tests for the diagnosis of pulmonary and extra-pulmonary tuberculosis.

PROVISIONAL AGENDA

Chair and co-chair: H. Schünemann and K. Weyer
Rapporteur: To be confirmed

09:00 - 09:10	Welcome	M. Raviglione, WHO R. Ridley, TDR
09:10 - 09:20	Meeting scope and objectives	K. Weyer
09:20 - 09:30	Declaration of Interest by Expert Group members	C. Lienhardt
09:30 - 10:15	*Systematic review and meta-analysis:* Commercial serological antibody detection tests for the diagnosis of TB	K. Steingart
10:15 - 10:45	Discussion	All
10:45 - 11:15	**BREAK**	
11:15 - 11:45	TB serological testing in India: an economic-epidemiological model	D. Dowdy & M. Pai
11:45 - 12:00	Discussion	All
12:00 - 13:00	**LUNCH**	
13:00 - 14:00	Draft recommendations: Use of commercial serological antibody detection tests for the diagnosis of TB	All
14:00 - 14:30	GRADE summary	K. Weyer
14:30 - 14:45	Next steps	K. Weyer
14:45 - 15:00	Closing	M. Raviglione
15:00 - 15:30	**BREAK**	