

<b>SUMMARY SHEET</b>		
AGENDA NR. 1.10- 6.0	SUBJECT	<b>ADVANCING THE AGENDA OF DIAGNOSTICS</b>
FOR INFORMATION <input type="checkbox"/>	FOR DISCUSSION <input checked="" type="checkbox"/>	FOR DECISION <input type="checkbox"/>
<p><b>RATIONALE:</b> The number of WHO-endorsed diagnostic tools for tuberculosis has expanded greatly in the last three years: from two (Ziehl-Neelsen smear microscopy and solid egg-based culture) in early 2007 to over ten in 2010. These include tools that can make the diagnostic process easier for poor patients, tools that improve diagnosis in HIV-positive patients, and tools to detect MDR-TB.</p> <p>A point-of-care (POC) test for TB still eludes us, and may still be some years away. However, determined efforts are on-going and reflected in the New Diagnostics Working Group (NDWG) document, "Pathways to Better Diagnostics for TB: A Blue-Print for the Development of TB Diagnostics"</p> <p>While there are increased efforts and promise in developing POC tests there is a parallel and synergistic initiative through the Global Laboratory Initiative (GLI) to strengthen the laboratory system to accelerate implementation of new tools and prepare countries to adopt multiple diagnostics that can be used in effective algorithms for diagnosis and monitoring.</p> <p><b>SUMMARY:</b></p> <p>Major gains have been made in TB diagnostics development, evaluation, evidence review and tool endorsement. The new tools that are currently in the WHO-endorsed toolbox include: two specimen same-day strategies for microscopy, a revised and more sensitive case definition for smear-positive TB, LED-based fluorescence microscopy, liquid culture, rapid <i>M. tuberculosis</i> identification tests, molecular line probe assays, and selected non-commercial culture and drug-susceptibility methods (MODS, the nitrate reductase test, colorimetric redox indicator methods). The evidence for the performance of immunodiagnostic tests for TB will be reviewed by a WHO Expert Group Meeting in 2010, as will the evidence for the Cepheid-FIND GeneXpert technology. The latter has been designed to diagnose TB and identify rifampicin resistance within 90 minutes. Early results are encouraging in both smear-positive and smear-negative cases.</p> <p>The design of test evaluations and methods for collecting evidence on the performance of new TB tests has been greatly facilitated by the production of a "scientific blueprint" developed by the New Diagnostics Working Group. The processes for evidence synthesis and review and for WHO guideline formulation have evolved rapidly in the past few years, resulting in a well-defined systematic process that includes application of the GRADE approach to evidence quality and strength of recommendations.</p> <p>Countries and technical partners are now guided by strong WHO policy and the availability of several recommended diagnostics; however, implementation at country level requires increased efforts to strengthen laboratory infrastructure, training and human resource development, facility design, biosafety measures and quality management systems. The GLI Working Group is working with NDWG and others to assure that system improvements, training tools and quality assurance are available; this is important in order to assist laboratories with the choices and changes involved in adopting effective algorithms that consist of several diagnostic methods (e.g. smear, culture, line probe, DST). These activities include the availability of a comprehensive laboratory tools set, developed under the TBCAP initiative.</p>		



# Stop TB Partnership

Despite acceleration in policy changes and significant growth in the TB diagnostic pipeline, the need remains for a robust point-of-care test and/or less complex diagnostics methods, largely due to weak infrastructure in many HBC laboratory systems. Culture, drug susceptibility testing and current molecular methods require special considerations and specific guidance for biosafety to address hazards when manipulating specimens and cultures from suspect MDR-TB patients. GLI and partners are therefore in the process of completing comprehensive biosafety guidance that includes practical and effective facility and engineering design for resource-limited settings.

Given the availability of several tools, there is an imperative now to implement these under international norms and standards and to rapidly move contemporary diagnostics into countries in quality-assured laboratory systems. A flagship project funded by UNITAID and coordinated by WHO, GLI and FIND (the EXPAND-TB) aims to accelerate and expand access to MDR-TB diagnosis in 27 priority countries. At least 12 countries will be ready during 2010 to routinely diagnose MDR-TB using rapid diagnostics in state-of-the-art laboratories; paving the way for accelerated case finding and a move to routine surveillance of MDR-TB in high-risk groups. EXPAND-TB has also successfully established and operationalised fully integrated molecular laboratory capacity in several African countries, enabling these laboratories to simultaneously detect MDR-TB and perform PCR-based HIV diagnosis while ensuring a systems approach to laboratory strengthening. Efforts are underway to expand the integrated approach to other settings.

## **DECISIONS REQUESTED (FROM STOP TB COORDINATING BOARD):**

- Broad support for the achievements and results produced thus far by the New Diagnostics Working Group and the Global Laboratory Initiative
- Urge partners to further disseminate information related to rapid progresses achieved, with particular reference to resource mobilization needed for the POC development and for NDWG, including for its subgroups and Secretariat.

## **IMPLICATIONS (POLITICAL / FINANCIAL / STAFFING, ETC)**

To be determined

## **Next Steps**

**ACTION REQUIRED:** Follow up as needed

**FOCAL POINT:** Andy Ramsay/Karin Weyer

**TIMEFRAME:** Now going forward