Report of TB/HIV Diagnostics Task Force

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NIAID, NIH
TB/HIV Diagnostics Task Force

• STOP – TB WG on New Diagnostics reorganized with liaisons from other WG
• A statement of needs requested from the TB/HIV group
• Task force formed to discuss, establish communications with NDWG and FIND, and report back on the latest information on availability of improved diagnostics for TB/HIV co-infected.
**FIND** is a public/private partnership established in 2003 as a Geneva based non-profit foundation and Chair of the NEW DIAGNOSTICS WG.

The New Diagnostics WG was established in 2001 to promote the development and adoption of new and modified diagnostic products. The Chair of the WG is the Chief Executive Officer of the Foundation for Innovative New Diagnostics (FIND) and the secretariat is provided by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR).
New Diagnostics Working Group

Chair
Giorgio Roscigno
Andrew Ramsay

Secretary

Core Group

Optimizing TB smear microscopy
Culture-based diagnostics and resistance
Nucleic-acid amplification
Diagnostics for Latent TB infection
Point-of Care diagnostics for TB
Evidence Synthesis for TB diagnostics
TB Diagnostics and Poverty
TB Diagnostics and HIV

Jean-Francois de Lavison
Arend Kolk
Vaira Leimane
Savita Luka
Carol Nyirenda
Mark Perkins
John Ridderhof
Felix Salaniponi
Francis Varaine
TB/HIV Diagnostics Task Force

- Formed in October 2007
- Series of conference calls inviting FIND staff and others with expertise
- Statement of needs drafted (see report)
- FIND presented at the RTTF meeting Geneva 16 January and in Washington 22 January 2008
Progress and retooling needs as perceived by developers

Retooling Task Force work planning meeting
15-16 January 2008

Dr Giorgio Roscigno
CEO – FIND
FIND’s perspective:

FIND has a rich set of products in the pipeline intended for the different levels of the health system which are developed and evaluated following a well-defined process from feasibility onwards…

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<th>Level</th>
<th>Projects</th>
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Project phases and milestones

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<th>PHASES</th>
<th>Feasibility</th>
<th>Contract phase</th>
<th>Development phase</th>
<th>Evaluation Phase</th>
<th>Demonstration phase</th>
<th>Global Policy</th>
<th>National Practice</th>
<th>Access</th>
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1. Early diagnosis of active tuberculosis in people living with HIV is critical - TB with HIV infection can be rapidly fatal.

   a. Point-of-service diagnosis is needed as HIV+ individuals may seek care at sites beyond traditional TB program facilitates. Laboratories may not be equipped with TB-trained personnel and referral can be inefficient and unreliable.

   b. The costs of special TB tests (chest x-ray, microscopy, culture, etc.) at HIV clinics may be charged directly to the patients creating financial barriers for individuals.

   c. Some HIV+ individuals may present with pauci-bacillary or negative sputum. Immediate improvements in the overall quality control of smear laboratories using existing technology could greatly improve smear sensitivity and care. More sensitive fluorescence equipment may be needed.
1. Early diagnosis of active tuberculosis (continued).

   d. Some HIV+ individuals may present with extrapulmonary TB requiring early clinical suspicion and special sampling methods - aspiration, tissue samples. Appropriate laboratory processing may not be timely or available at point-of-service.

   e. Availability of rapid culture services cannot be delayed by transfer to a central laboratory. Peripheral laboratories need increased sensitivity for detection in TB/HIV patients.
2. Early detection of XDR (MDR) - TB for initiation of appropriate therapy needs to occur simultaneously with TB diagnosis.

   a. Availability of culture to support drug susceptibility testing cannot be delayed in rapidly progressing TB.

   b. Manual MGIT or agar plating or MODS systems could be implemented at point-of-service HIV sites.

   c. Existing line probe assays to detect TB and RIF drug resistance in sputum should be systematically evaluated in TB/HIV settings.
3. New diagnostic tests appropriate for TB/HIV co-infection will be needed to address these issues. Test formats recommended include:

a. Lateral flow tests or dip sticks using easily accessible specimens such as urine, saliva, or blood.

b. Line probe assays or other nucleic acid amplification assays that can integrate into laboratories already using PCR for HIV RNA copy numbers.

c. Combined HIV and MTB testing in one product.

d. Self-contained PCR test devices returning screening results during a clinical visit.
Conclusions

• Improved TB diagnosis (including MDR and XDR) for PLHIV is topmost priority for TB/HIV WG.

• The development of new tools effective for PLHIV is long overdue and should be addressed as a matter of urgency.
TB/HIV Diagnostics Task Force
Action Items

- Finalize a statement from TB/HIV WG chair regarding new diagnostics needs
- Continue to engage the New Diagnostics Working Group, especially in Geneva
- Request a focused meeting with FIND (Cairo, ASM, Geneva)
- Organize a workshop in the U.S. with technical researchers, chemists, Aby producers co-sponsored by TB/HIV, FIND, TAG, NIAID.