New Diagnostics Working Group

2009 progress report

Giorgio Roscigno & Madhukar Pai
Co-chairs

Andy Ramsay & Martine Guillerm
Secretariat

www.stoptb.org
The Vision of the NDWG

• To develop and introduce cost-effective and appropriate new diagnostic tools that will contribute towards improved control of the global TB epidemic and improve the quality of patient care
Overall Goals

• To improve **TB case detection** both through higher sensitivity/specificity and improved accessibility – simple, accurate, cost-effective, same day, near-patient products that perform equally well in HIV-infected persons and children, and improve patient important outcomes

• Rapidly and inexpensively **identify drug resistant TB** disease in all patients, including people living with HIV infection and children, enabling timely effective patient treatment to reduce both individual morbidity and continuing transmission

• Accurately and reliably **identify latent TB infection** and define the **risk of future progression** to active disease enabling rational and targeted use of preventive therapy in appropriate subjects, especially child contacts and people living with HIV/AIDS
NDWG structure

Co-Chairs & Secretariat

Core Group

Sub-groups and Co-chairs of SGs

All NDWG members
# New Diagnostic Working group

## Core Group Members

<table>
<thead>
<tr>
<th>Category</th>
<th>Name</th>
<th>Organization</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academia</td>
<td>Arend Kolk</td>
<td>University of Amsterdam</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Diagnostics manufacturer</td>
<td>Jean-Francois de Lavison</td>
<td>EDMA</td>
<td>Belgium</td>
</tr>
<tr>
<td>NGOs</td>
<td>Francis Varaine</td>
<td>MSF</td>
<td>Paris</td>
</tr>
<tr>
<td>NTP</td>
<td>Charles Sandy</td>
<td>NTP</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>National TB Reference Laboratory</td>
<td>vacant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient community</td>
<td>Savita Luka</td>
<td>New Delhi</td>
<td>India</td>
</tr>
<tr>
<td></td>
<td>Mayowa Joel</td>
<td>Lagos</td>
<td>Nigeria</td>
</tr>
<tr>
<td>WHO Stop TB Partnership</td>
<td>Christian Lienhardt</td>
<td>Stop TB Partnership</td>
<td>Geneva</td>
</tr>
<tr>
<td>Lab Capacity Strengthening Sub-Group</td>
<td>John Ridderhof</td>
<td>CDC</td>
<td>Atlanta, USA</td>
</tr>
<tr>
<td>Diagnostics developer</td>
<td>Mark Perkins</td>
<td>FIND</td>
<td>Geneva, Switzerland</td>
</tr>
<tr>
<td>Int. Union against TB and Lung disease</td>
<td>Anne Detjen</td>
<td>TREAT TB team</td>
<td>NY, USA</td>
</tr>
</tbody>
</table>
# New Diagnostics Working Group
## Sub Group Leaders

<table>
<thead>
<tr>
<th>Leader 1</th>
<th>Leader 2</th>
<th>Subgroup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rick O'Brien, FIND, Geneva, Switzerland</td>
<td>Evidence Synthesis for TB diagnostics</td>
<td>Evidence Synthesis for TB diagnostics</td>
</tr>
<tr>
<td>Karen Steingart, University of California, USA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tom Shinnick, CDC, Atlanta, USA</td>
<td>Nucleic-acid amplification techniques for TB,</td>
<td>Nucleic-acid amplification techniques</td>
</tr>
<tr>
<td>Leen Rigouts, ITM, Antwerp, Belgium</td>
<td>including detection of drug resistance</td>
<td>for TB</td>
</tr>
<tr>
<td>Bertie Squire, Liverpool School of Tropical Medicine, UK</td>
<td>TB Diagnostics and Poverty</td>
<td></td>
</tr>
<tr>
<td>Gillian Mann, Liverpool School of Tropical Medicine, UK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keertan Dheda, University of Cape Town, South Africa</td>
<td>Diagnostics for Latent TB infection</td>
<td>Diagnostics for Latent TB infection</td>
</tr>
<tr>
<td>Philip Hill, University of Otago, New Zealand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ruth McNerney, London School of Hygiene and Tropical Medicine, UK</td>
<td>Point of Care</td>
<td>Point of Care</td>
</tr>
<tr>
<td>Catharina Boehme, FIND, Geneva, Switzerland</td>
<td>Tests for TB</td>
<td>Tests for TB</td>
</tr>
<tr>
<td>David Moore, Universidad Peruana Cayetano Heredia, Lima, Peru</td>
<td>Culture-based diagnostics for TB,</td>
<td>Culture-based diagnostics for TB,</td>
</tr>
<tr>
<td>Nicolas Durier, Family Health International, Thailand</td>
<td>including drug susceptibility testing</td>
<td>including drug susceptibility testing</td>
</tr>
<tr>
<td>Luis Cuevas, Liverpool School of Tropical Medicine, UK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paul Klatser, KIT, Netherlands</td>
<td>Optimizing TB smear microscopy</td>
<td>Optimizing TB smear microscopy</td>
</tr>
<tr>
<td>Colleen Adel Daniels, WHO Stop TB Dept, Geneva, Switzerland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barbara Laughon, NIH, USA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anneke C. Hesseling, Stellenbosch University, South Africa</td>
<td>TB Diagnostics and HIV</td>
<td>TB Diagnostics and HIV</td>
</tr>
<tr>
<td>Steve Graham, The Royal Children's Hospital, Melbourne, Australia</td>
<td></td>
<td>Diagnostics and paediatric TB</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NDWG structure

- New Paediatric TB Subgroup established
- Nomination and election of four new Core Group members and four Subgroup Co-Chairs
- Total membership doubled in the last year (400+ now)
Progress in meeting Global Plan targets
### Table 6: Global Plan Milestones for New Diagnostics

<table>
<thead>
<tr>
<th>GLOBAL PLAN INDICATOR</th>
<th>TARGET</th>
<th>PROGRESS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REFERRAL LEVEL</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid culture (+DST) for M. tuberculosis and diagnosis</td>
<td>2006</td>
<td>Endorsed by WHO in 2007</td>
</tr>
<tr>
<td>of MDR-TB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid speciation test for confirming M tuberculosis</td>
<td>2008</td>
<td>Endorsed by WHO in 2007</td>
</tr>
<tr>
<td>grown in culture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual nucleic acid amplification test (NAAT) for</td>
<td>2008</td>
<td>Endorsed by WHO in 2008</td>
</tr>
<tr>
<td>detection of M tuberculosis and isoniaizid and/or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rifampicin resistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automated NAAT for detection of M tuberculosis and</td>
<td>2008</td>
<td>Expected 2010</td>
</tr>
<tr>
<td>rifampicin resistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PERIPHERAL LABORATORY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved microscopy</td>
<td>2006</td>
<td>More sensitive definition of a smear</td>
</tr>
<tr>
<td></td>
<td></td>
<td>positive case: endorsed by WHO in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduced number of smear examinations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>required: endorsed by WHO in 2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Light-emitting diode (LED) fluoresc</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ence microscopy - approval by WHO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>expected in 2009</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Front-loaded smear microscopy -</td>
</tr>
<tr>
<td></td>
<td></td>
<td>approval by WHO expected in 2009</td>
</tr>
<tr>
<td>Introduction of simplified NAAT (1)</td>
<td>2008</td>
<td>Expected 2011</td>
</tr>
</tbody>
</table>

1. [http://www.who.int/tdr/](http://www.who.int/tdr/)
However, not all targets were met; pipeline has grown and right shifted
Updating Global Plan to Stop TB

1. To review and update the goal, objectives, major activities, indicators and targets for the new drugs, new diagnostics and new vaccines components of the Global Plan to Stop TB for the period 2010–2015

2. To estimate the funding needed to implement the major components of the research agenda/workplan during the period 2010–2015, including identification of potential funding gaps
New publication

Available on NDWG website:
http://www.stoptb.org/wg/new_diagnostics/
Promoting a standardized pathway to develop TB diagnostics
30+ contributors

Contributors are listed in alphabetical order.

Catharina Boehme, FIND (Foundation for Innovative New Diagnostic), Geneva, Switzerland

Patrick Bossuyt, Clinical Epidemiology, Biostatistics and Bioinformatics Department, University of Amsterdam, The Netherlands

Antonio Campos-Neto, Department of Cytokine Biology, Forsythe Institute, Boston, USA


Russell Dacombe, Liverpool Associates in Tropical Health, Liverpool, United Kingdom

Mark Doherty, Infectious Disease Immunology, Statens Serum Institut, Copenhagen, Denmark


Christy Hansen, Office of Health, Infectious Diseases and Nutrition, U.S. Agency for International Development, Washington, USA

Carole Jefferson, Becton Dickinson Diagnostics, USA

Paul Klater, KIT Biomedical Research Department, Royal Tropical Institute, Amsterdam, The Netherlands

Arend Kolk, Polymer-Analysis Group, Van’t Hoff Institute for Molecular Sciences, University of Amsterdam, The Netherlands

Heather Alexander, FIND (Foundation for Innovative New Diagnostic), Geneva, Switzerland

Suman Laal, Manhattan Veterans Affairs Medical Center, New York University, USA

Gillian Mann, Liverpool School of Tropical Medicine, United Kingdom

Dermot Maher, Research Unit on AIDS, MRC/UVRI Uganda

Ruth McNerney, TARGETS international research consortium on communicable diseases of vulnerability and poverty, London School of Tropical Medicine, United Kingdom

Dick Menezes, Respiratory Division, McGill University Health Centre, Montreal, Canada

David Moore, Imperial College London, Universidad Peruana Cayetano Heredia (UPCH), Lima, Peru

Richard O'Brien, FIND (Foundation for Innovative New Diagnostics), Geneva, Switzerland

Madhujit Pal, McGill University, Montreal, Canada and Co-Chair, Stop TB Partnership’s New Diagnostics Working Group

Juan Carlos Palomino, Mycobacteriology Unit, Institute of Tropical Medicine, Antwerp, Belgium

Mark Perkins, FIND (Foundation for Innovative New Diagnostics), Geneva, Switzerland

Françoise Portaels, Mycobacteriology Unit, Institute of Tropical Medicine, Antwerp, Belgium

Andrew Ramsay, UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, Geneva, Switzerland and Secretary, Stop TB Partnership’s New Diagnostics Working Group

Leen Rigouts, Mycobacteriology Unit, Institute of Tropical Medicine, Antwerp, Belgium

Giorgio Rosigno, FIND (Foundation for Innovative New Diagnostics), Geneva, Switzerland and Co-Chair, Stop TB Partnership’s New Diagnostics Working Group

Max Salfinger, Bureau of Laboratories, Florida Department of Health, USA

Thomas M Shinick, Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, USA

Tido von Schoen Angerer, Access Campaign for Essential Medicines, Médecins sans Frontières, Geneva, Switzerland

Hojoon Shin, FIND (Foundation of Innovative New Diagnostics), Geneva, Switzerland

Bertio Squira, Clinical Tropical Medicine, Liverpool School of Tropical Medicine

Francis Vannine, TB Working Group, Médecins sans Frontières, Geneva, Switzerland

These experts’ contributions have undergone a thorough review at all stages, and in addition to several of the contributors themselves, the following are to be thanked for having given their time to ensure this document is an up-to-date and accurate reflection of the subject matter: Heidi Albert, Peter Anderson, Jean-François de Lavison, Peter Kaspary, Sung-Jae Kim, Gerl Michel, CN Param, Richard Urbanovicz and Véronique Vincent.

Special thanks to:
Russell Dacombe, Tony Murdoch & Martine Guillerm
UNITAID project launched in June 2009

• WHO endorsed line probe assays in 2008
• Project to provide rapid diagnostics for MDR-TB in 27 endemic countries
• Collaboration between WHO, Global Laboratory Initiative, FIND and Global Drug Facility
Rapid tests for drug-resistant TB to be available in developing countries

EXPAND-TB supplies MDR-TB diagnostics to high-burden countries. With a new grant of US$ 61 482 085, the project, led by the GLI in close collaboration with FIND and GDF, will be expanded to increase the countries covered from 16 to 27. The overall objective is to jump-start strengthening of laboratories in these countries, through collaboration between a variety of partners.


http://www.unitaid.eu
WHO policy reviews in 2009

Expert Group meetings in Sept 2009
STAG-TB review in Nov 2009 (recommendations pending)

• Microscopy
  – LED microscopy
  – Sputum processing
  – Front-loaded approaches

• Non-commercial DST and phage-based methods
  – MODS
  – TLA
  – NRA
  – CRI
  – Phage assays
Point-of-care diagnostics Sub-Group organized symposium at ESM 30th annual congress Porto

**30th Annual Congress | Porto | 5th-8th July 09**

SYMPOSIUM SPONSORED BY STOP-TB WORKING GROUP ON NEW DIAGNOSTICS, POINT OF CARE SUB GROUP
A SYMPOSIUM ON POINT-OF-CARE TESTS FOR TUBERCULOSIS

Dr. Catharina Boehme, M.D., Foundation for Innovative Diagnostics (FIND) (Geneva, Switzerland)

**What is a POC test?**
Carol Nawina Nyirenda (Zambia)

**Why do we need rapid tests: a patient's perspective?**
Prof. Rosanna Peeling, Ph.D., London School of Hygiene & Tropical Medicine (London, UK)

**Rapid tests for TB: what is wrong with them?**
Dr. Gerd Michel, Ph.D., Foundation for Innovative Diagnostics (FIND) (Geneva, Switzerland)

**Biomarker discovery: are we making progress**
Dr. Ruth McNerney, Ph.D., London School of Hygiene & Tropical Medicine (London, UK)

**Volatile markers for TB: myth or reality?**
Dr. Amy P Wong, Ph.D., X PRIZE Foundation (California, U.S.A.)

**Barriers to TB test development**

**Discussion: The way forward**
Platform and floor
Welcome to the website of the 'point of care' subgroup of the STOP TB Working Group on New Diagnostics.

This website is for sharing information and ideas about developing simple rapid tests to diagnose tuberculosis.

We also have a HOT TOPICS page for current areas of debate in TB diagnostics and a calendar of TB meetings.
ANNUAL MEETING NEW DIAGNOSTICS WORKING GROUP

The Stop TB Partnership New Diagnostics Working Group is holding its annual meeting in Cancun, Mexico, in conjunction with the 40th Union World Conference on Lung Health.

The Secretariat and Co-Chairs of the Working Group are very pleased to invite all members and non-members to attend the open session on the 3rd of December, 2009 from 13.00 to 17.00h. This meeting will be a great opportunity to obtain information on the latest topics in global TB diagnostics and to become involved in the New Diagnostics Working Group activities. Also, the Working Group will present its latest production:

**Pathways to better diagnostics for tuberculosis: A blueprint for the development of TB diagnostics.**

For more details and the agenda of the annual meeting, please click here to see the Meeting Flyer.
Evidenced-based TB Diagnosis Website:
www.tbevidence.org
43,000 page views since launch in Aug 2009
Accessed in over 160 countries
New Diagnostics Working Group Childhood TB Subgroup

WELCOME

The mission of the New Diagnostics: Child TB Subgroup

- To ensure that every child has access to effective diagnosis for TB
- To develop and implement new diagnostic tools and strategies to stop TB in children

Launch in Cancun 2009: During the annual Union meeting in Cancun during December 2009, the NDWG Childhood TB Subgroup will be officially launched during the NDWG session. Download the flyer below for more information.

Attachments:

- NDWG Annual Meeting 2009 (582 Kb)
Collaboration with

• To map the landscape and quality of TB diagnostic research
• To support the development of a Global TB Research Agenda
Acknowledgements

• Secretariat & TDR:
  – Andy Ramsay
  – Martine Guillerm
  – Sanne van Kampen

• FIND, Geneva

• We thank all Core Group and Sub-Group members for their support and contributions

• Marcos Espinal, Executive Secretary, STP