

## New Diagnostics Working Group

2009 progress report

Giorgio Roscigno & Madhukar Pai  
Co-chairs

Andy Ramsay & Martine Guillerm  
Secretariat



# 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

Academia

*Arend Kolk, University of Amsterdam, Netherlands*

Diagnostics manufacturer

*Jean-Francois de Lavison, EDMA, Belgium*

NGOs

*Francis Varaine, MSF, Paris*

NTP

*Charles Sandy, NTP, Zimbabwe*

National TB Reference Laboratory

*vacant*

Patient community

*Savita Luka, New Delhi, India*  
*Mayowa Joel, Lagos, Nigeria*

WHO Stop TB Partnership

*Christian Lienhardt, Stop TB Partnership, Geneva*

Lab Capacity Strengthening Sub-Group

*John Ridderhof, CDC, Atlanta, USA*

Diagnostics developer

*Mark Perkins, FIND, Geneva, Switzerland*

Int. Union against TB and Lung disease

*Anne Detjen, TREAT TB team, NY, USA*

# New Diagnostics Working Group

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Africa  
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Melbourne, Australia

Evidence Synthesis for TB  
diagnostics

Nucleic-acid amplification techniques for TB,  
including detection of drug resistance

TB Diagnostics and Poverty

Diagnostics for  
Latent TB infection

Point of Care  
Tests for TB

Culture-based diagnostics for TB,  
including drug susceptibility testing

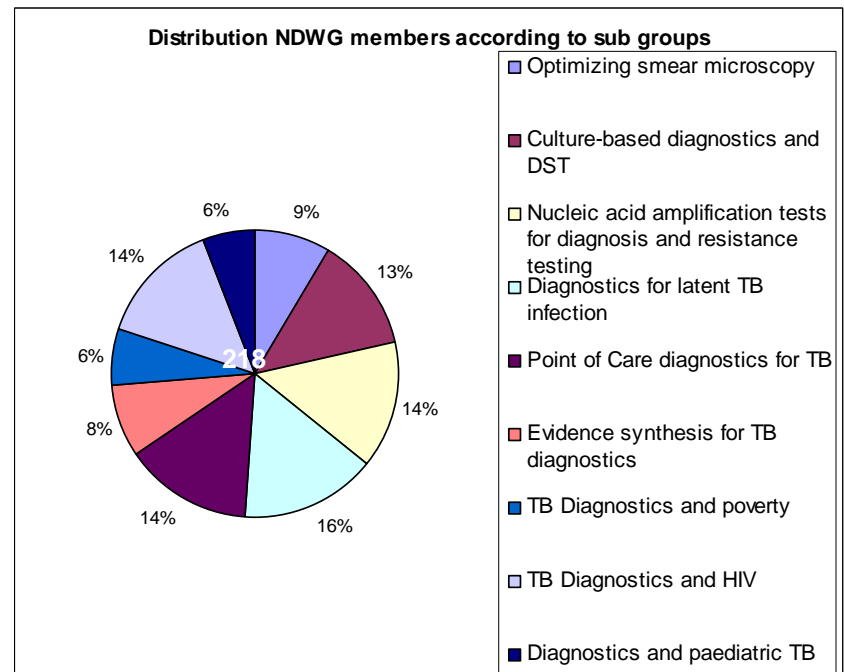
Optimizing TB smear  
microscopy

TB Diagnostics and HIV

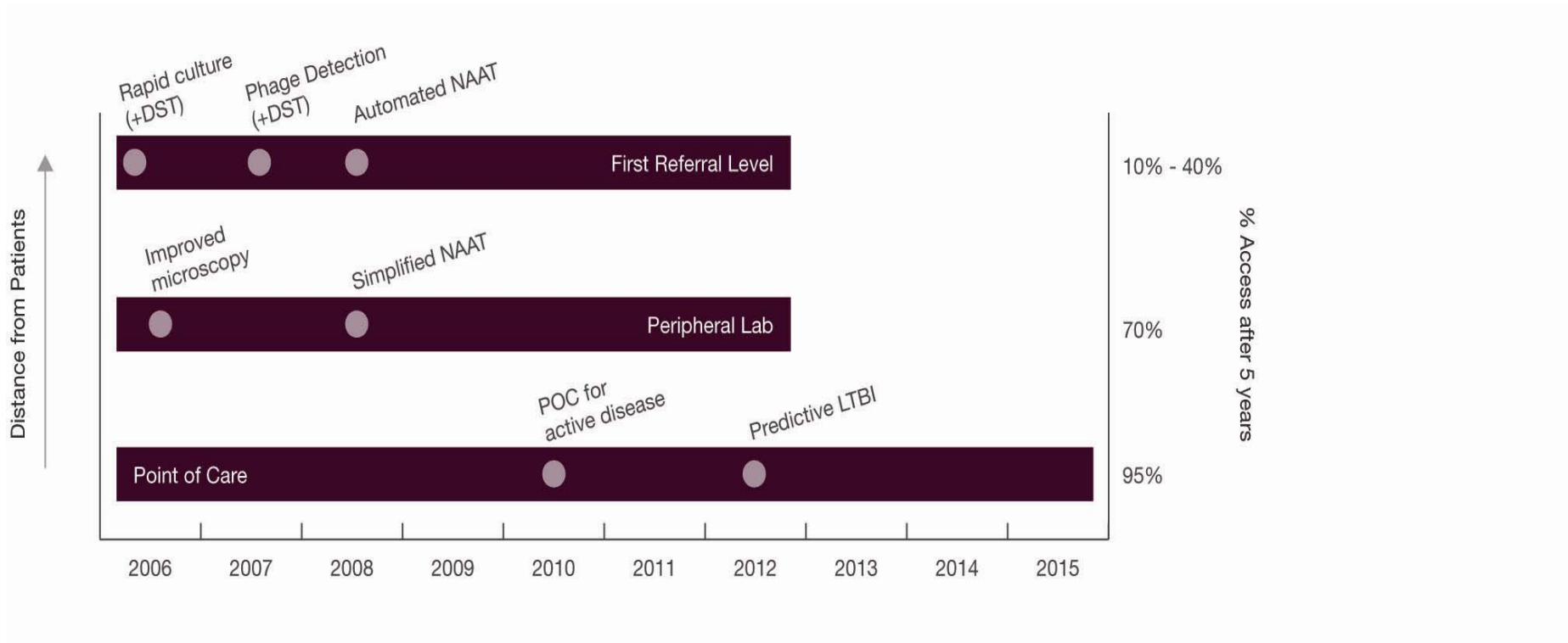
Diagnostics and paediatric  
TB

# 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





# Global Plan: Progress Report 2006 – 2008

Published: November 2009

Table 6: Global Plan Milestones for New Diagnostics

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

<sup>1</sup> <http://www.who.int/tdr/>

<sup>2</sup> <http://www.stoptb.org/retooling/>

<sup>3</sup> New laboratory diagnostic tools for tuberculosis control (ISBN 978 92 4 159748), World Health Organization, 2008.

# However, not all targets were met; pipeline has grown and right shifted

Summary of technologies			Estimated costs			
Technology	Description	Product	Training <sup>1</sup>	Infrastructure <sup>2</sup>	Equip. <sup>3</sup>	Consumables
<b>WHO-endorsed tools (2006-2008)</b>						
Liquid culture	Commercial broth-based culture systems detect TB bacteria (manual and automated systems are available); can be configured for DST.	BacT/ALERT 3D; MGIT	Extensive (3 weeks)	■■■	High	High
Molecular line probe assay	Strip test simultaneously detects TB bacteria and genetic mutations that indicate isoniazid and/or rifampicin resistance.	GenoType® MTBDR and MTBDRplus; INNO-LiPA Rif.TB	Moderate (3 days)	■■ to ■■■	High	High
Strip speciation	Strip speciation test detects a TB-specific antigen from positive liquid or solid cultures to confirm the presence of TB bacteria in culture samples.	Capilia TB Rapid Diagnostic Test	Minimal (1 day)	■■■	Low	Medium
<b>Tools in late-stage development/evaluation</b>						
Automated detection and MDR screening	Device allows automated sample processing, DNA amplification and detection of <i>M. tuberculosis</i> and screening for rifampicin resistance.	Cepheid GeneXpert device and Xpert MTB cartridge	Minimal	■	High	High
Colorimetric redox indicators	Technique detects isoniazid and rifampicin resistance in culture samples after incubation with redox dyes.	Non-commercial method (Resazurin)	Extensive	■■■	Low	Medium
Front-loaded smear microscopy	Based on 2 or 3 specimens but aims to examine specimens on the day that patient presents to the health service (thus identifying 95% of TB cases).	n/a	Minimal	■	Low	Low
Interferon gamma release assay	Blood test detects specific cellular immune responses indicating TB infection.	QuantiFERON®-TB Gold In Tube; T-SPOT.TB®	Moderate	■	Low	High
LED fluorescence microscopy	Robust fluorescence microscopy (FM) systems based on light-emitting diodes (LEDs) that could allow the advantages of FM at levels of the health system where conventional FM would be impractical.	Fraen	Moderate	■	Medium	Low
		LW Scientific	Moderate	■	Medium	Low
		Zeiss	Moderate	■	Medium	Low
Microscopic Observation Drug Susceptibility (MODS)	Manual liquid culture technique uses basic laboratory equipment (incl. an inverted light microscope) and microscopy skills to detect TB bacteria.	Non-commercial method	Extensive	■■ to ■■■	Medium	Medium
New solid culture methods	Solid culture technique measures nitrate reduction to indicate isoniazid and rifampicin resistance. Solid culture technique simultaneously detects TB bacteria and indicate isoniazid and rifampicin resistance.	Non-commercial method (Nitrate reductase assay)	Moderate	■■ to ■■■	Low	Medium
		Non-commercial method (Thin layer agar culture)	Extensive	■■ to ■■■	Low	Medium
<b>Tools in early phase of development</b>						
Tool	Level of health system	Tool	Level of health system			
Breathalyser screening test	Community or point-of-care	Sodium hypochlorite (bleach) microscopy	Peripheral laboratory			
First-generation loop-mediated isothermal amplification technology platform (LAMP)	Peripheral laboratory	Sputum filtration	Peripheral laboratory			
Lipoarabinomannan (LAM) detection in urine	Peripheral laboratory	TB Patch Test	Health post			
Phage-based tests	Reference laboratory	Vital fluorescent staining of sputum smears	Peripheral laboratory			
<sup>2</sup> Key	Description					
■	Basic laboratory <sup>4</sup> ; no specialized biosafety equipment.					
■■	Biosafety level 2. Specialized biosafety equipment required, such as biosafety cabinet.					
■■■	Biosafety level 3. Biosafety cabinet and other primary safety equipment required. Controlled ventilation system that maintains a directional airflow into the laboratory required.					
<b>8</b>	<sup>1</sup> Estimates assume that technicians are already trained in existing TB diagnostic techniques (such as smear microscopy and culturing) and the necessary laboratory safety precautions. <sup>2</sup> Product prices may vary depending on geographical location and terms of supply. Ranges are indicative only: Low (minimum-2000 US\$); Medium (2001-7000 US\$); high (7001+ US\$). <sup>3</sup> Detailed information available in the WHO Laboratory Biosafety Manual: <a href="http://www.who.int/csr/delibepidemics/WHO_CDS_CSR_LYO_2004_11/en/">http://www.who.int/csr/delibepidemics/WHO_CDS_CSR_LYO_2004_11/en/</a> .					

# Updating Global Plan to Stop TB

**Updating the Research and Development component of the  
Stop TB Partnership's Global Plan to Stop TB, 2006-2015**

**A Workshop held in Geneva on 24-25 September 2009**

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/](http://www.stoptb.org/wg/new_diagnostics/)

## **Pathways** to better diagnostics for **tuberculosis**

**A blueprint for the development of TB diagnostics**

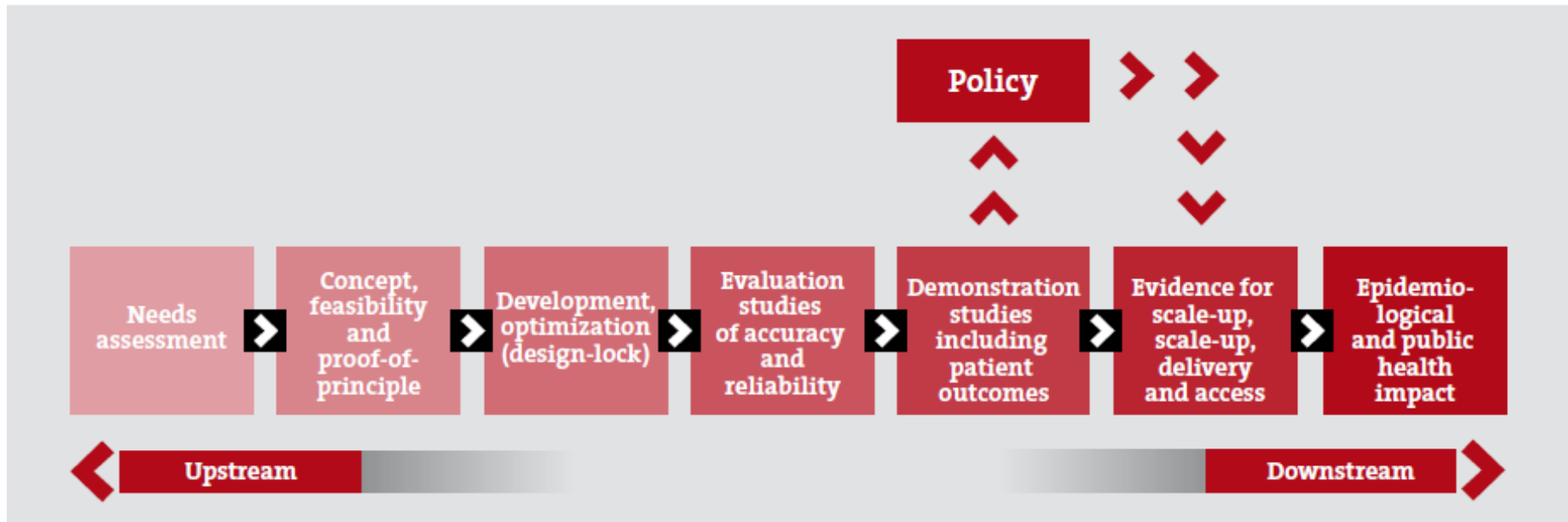
By the New Diagnostics Working Group of the Stop TB Partnership



**Stop TB Partnership**



# Promoting a standardized pathway to develop TB diagnostics



Contributors	2
Glossary	4
Executive summary	6
Introduction: delivering diagnostics, from concept to delivery	11
1. The search for <i>tubercle bacilli</i>	18
2. TB diagnosis today: the search for improved diagnostics continues	22
3. The current TB epidemic	26
4. The rationale for the diagnostic pipeline	30
5. Assessing the needs	32
6. Aiming for the right targets	38
7. Feasibility – A guarantee of strong foundations	46
8. Development and optimization: additional hurdles	50
9. Evaluation, putting it through its paces: does the test work?	54
10. Demonstration, putting the test to the test: is it worth it?	60
11. Measuring impact	70
12. Access: the final test of success	78
13. Barriers and challenges	84
14. References	88

⊙ ANNEXES - see CD in back cover

### *The principles of current TB diagnostic tools*

1. Optimizing TB smear microscopy
2. Rapid solid and liquid culture
3. Antigen detection tests for diagnosis of active TB
4. Antibody detection
5. T-cell-based interferon-gamma release assays
6. Nucleic acid amplification tests
7. Molecular drug resistance testing
8. Phage-based tests
9. Nose technologies
10. References and glossary



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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



TOGETHER TO HEAL



# POLICY



# ACTION



**World Health Organization**

Home **Tuberculosis (TB)**

WHO > Programmes and projects > Tuberculosis (TB) > TB news - past home page features

printable version

### Rapid tests for drug-resistant TB to be available in developing countries

30 JUNE 2008 | GENEVA -- People in low-resource countries who are ill with multidrug-resistant TB (MDR-TB) will get a faster diagnosis -- in two days, not the standard two to three months -- and appropriate treatment thanks to two new initiatives unveiled today by WHO, the Stop TB Partnership, UNITAID and the Foundation for Innovative New Diagnostics (FIND).

WHO/G. Thomas MDR-TB is a form of TB that responds poorly to standard treatment because of resistance to the first-line drugs isoniazid and rifampicin. At present it is estimated that only 2% of MDR-TB cases worldwide are being diagnosed and treated appropriately, mainly because of inadequate laboratory services. The initiatives announced today should increase that proportion at least seven-fold over the next four years, to 15% or more.

"I am delighted that this initiative will improve both the technology needed to diagnose TB quickly, and increase the availability of drugs to treat highly resistant TB," said British Prime Minister Gordon Brown, who helped launch the Stop TB Partnership's Global Plan to Stop TB in 2006 and whose government is a founding member of UNITAID. "The UK is committed to stopping TB around the world, from our funding of TB prevention programmes in poor countries, to our support of cutting edge research to develop new drugs."

In developing countries most TB patients are tested for MDR-TB only after they fail to respond to standard treatments. Even then, it takes two months or more to confirm the diagnosis. Patients have to wait for the test results before they can receive life-saving second-line drugs. During this period, they can spread the multidrug-resistant disease to others. Often the patients die before results are known, especially if they are HIV-infected in addition to having MDR-TB.

**RELATED DOCUMENTS**

- WHO policy statement [pdf 78kb]
- Expert group report - Molecular line probe assays for rapid screening of patients at risk of MDR-TB [pdf 892kb]
- Further information on the UNITAID MDR-TB diagnostic initiative [pdf 652kb]
- Feasibility study - Am J Respir Crit Care Med, Vol 177, pp 787-792, 2008 (American Thoracic Society - official journal). Rapid molecular screening for multidrug-resistant tuberculosis in a high-volume public health laboratory in South Africa [pdf 402kb]
- Turning evidence into policy and policy into practice - the steps to building Lesotho's modern TB central laboratory [pdf 2.71Mb]
- GenoType MTBDR assays for the diagnosis of multidrug-resistant tuberculosis: a meta-analysis. Eur Resp J 2008
- A commercial line probe assay for the rapid detection of rifampicin resistance in Mycobacterium tuberculosis: a

[http://www.who.int/tb/features\\_archive/mdrtb\\_rapid\\_tests/en/index.html](http://www.who.int/tb/features_archive/mdrtb_rapid_tests/en/index.html)



TOGETHER TO HEAL

ABOUT

PROJECTS

RESOURCES

GOVERNANCE

## Expanding and accelerating access to diagnostics for patients at risk of MDR-TB

[Print](#)  
[E-mail](#)

### Description of the project

- A. Project title:** Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB)
- B. Timeframe:** Project duration: 2009-2011, starting on the date of the final signature of the Memorandum of Agreement.
- C. Amount committed by UNITAID:** US\$ 26 129 897
- D. Lead partner:** Global Laboratory Initiative (GLI), Stop TB Department, World Health Organization
- E. Other partner(s):**
  - Global Drug Facility (GDF), Stop TB Partnership, World Health Organization
  - Foundation for Innovative New Diagnostics (FIND)

<http://www.unitaid.eu>

EXPERT  
REVIEWS

## Rapid diagnosis of drug-resistant TB using line probe assays: from evidence to policy

Expert Rev. Resp. Med. 2(5), 583-588 (2008)

Daphne I Ling,  
Alice A Zwerling and  
Madhukar Pai\*

Growing concerns about the spread of multidrug-resistant tuberculosis (MDR-TB) and the emergence of extensively drug-resistant TB have triggered substantial interest in the development and application of rapid tests for the detection of drug-resistant TB. Molecular assays to detect

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.

# WHO policy reviews in 2009

Expert Group meetings in Sept 2009

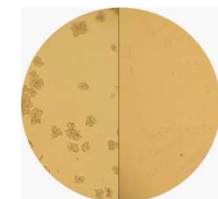
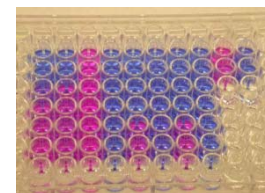
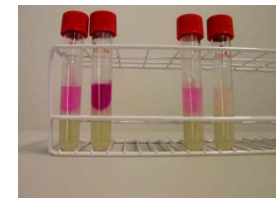
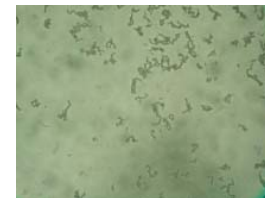
STAG-TB review in Nov 2009 (recommendations pending)

- **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



**30<sup>th</sup> Annual Congress** | **Porto** | **5<sup>th</sup>-8<sup>th</sup> July 09**  
Portugal

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)

#### **Blomarker 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?**

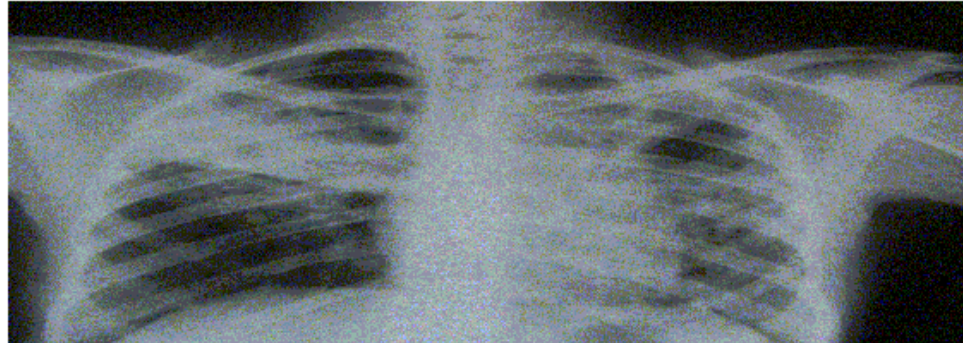
Dr. Amy P Wong, Ph.D., X PRIZE Foundation (California, U.S.A.)

#### **Barriers to TB test development**

#### **Discussion: The way forward**

Platform and floor

- ☰ Home
- ☰ HOT TOPICS
- ☰ What is the POC-SG?
- ☰ What is a POC test?
- ☰ Why POC TB tests?
- ☰ TB Meetings and Events
- ☰ The ideal test?
- ☰ Discussion site
- ☰ Contact us
- ☰ Continuing Education
- ☰ Activities
- ☰ LINKS



**Welcome to the website of the 'point of care' subgroup of the STOP TB Working Group on New Diagnostics.**

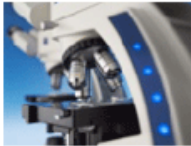
**This website is for sharing information and ideas about developing simple rapid tests to diagnose tuberculosis.**

**We also have a HOT TOPICS page for current areas of debate in TB diagnostics and a calender of TB meetings.**

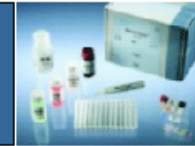
# New Diagnostics Working Group website updated

## Working Group on New Diagnostics

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### News



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#### Affiliations

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[TDR](#)

[Royal Tropical Institute](#)

[CDC](#)

[Médecins Sans Frontières](#)

[Merieux Alliance](#)

[The International Union of TB and Lung Diseases](#)

[McGill University](#)

[World Health Organization](#)

[Liverpool School of Tropical Medicine](#)

25 November 2009

### 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**  
By the New Diagnostics Working Group of the Stop TB Partnership



### 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](http://www.tbevidence.org)

## Evidence-Based Tuberculosis Diagnosis

A comprehensive resource for evidence syntheses, policies, guidelines and research agendas on TB diagnostics



- Home
- About NDWG
- What is E-B TB Dx?
- TB Diagnostics Pipeline
- Systematic Reviews
- WHO Policies
- Guidelines for TB Dx
- Research Agendas
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[www.tbevidence.org](http://www.tbevidence.org)

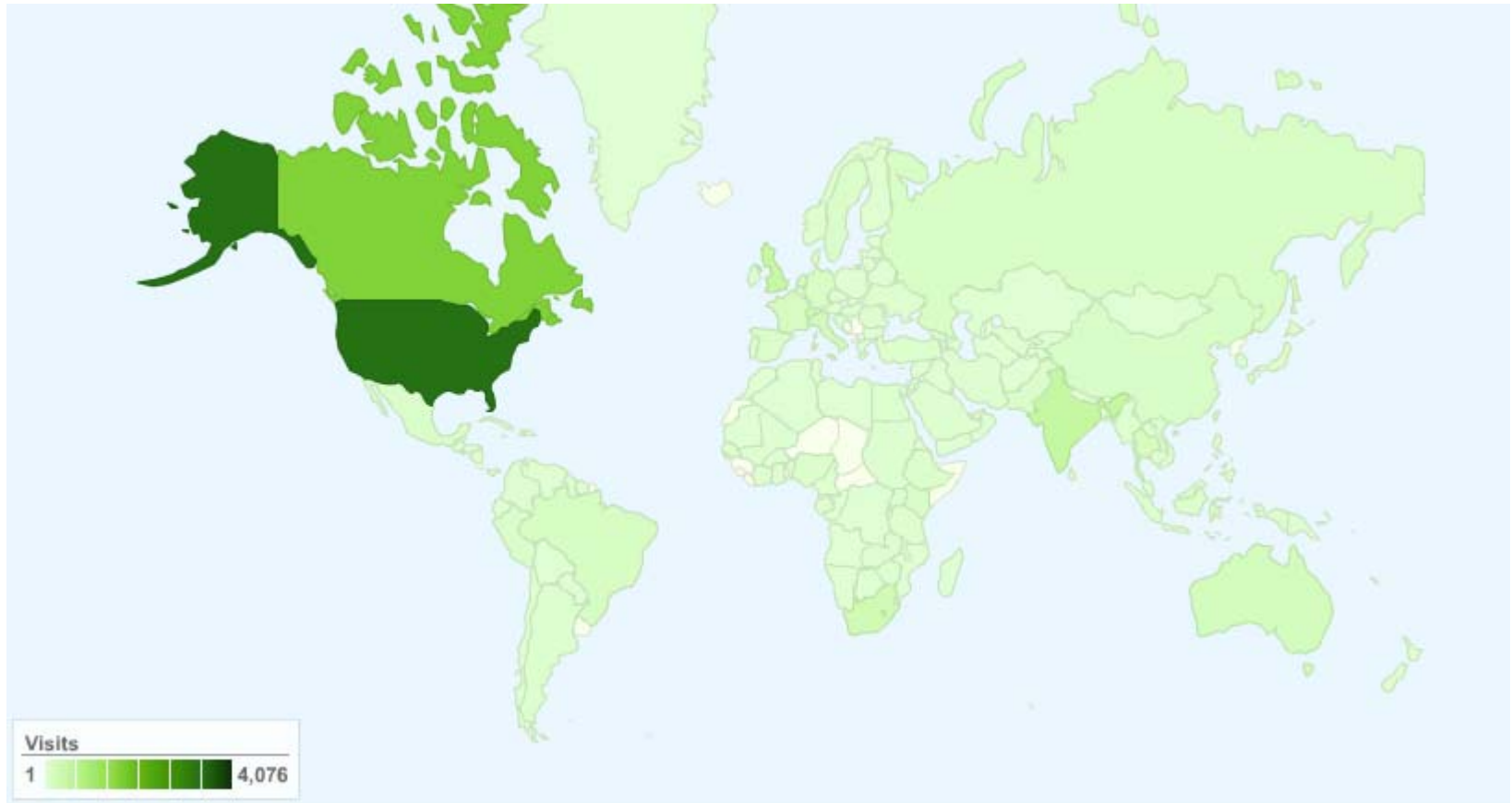


Developed with the support of:

Stop TB Partnership's New Diagnostics Working Group (NDWG)  
 World Health Organization (WHO)  
 Foundation for Innovative New Diagnostics (FIND)  
 Special Programme for Research and Training in Tropical Diseases (TDR)  
 Global Laboratory Initiative (GLI)  
 Public Health Agency of Canada (PHAC)  
 Francis J. Curry National Tuberculosis Center, UCSF  
 McGill TB Research Group



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Working Group on New Diagnostics:  
**Child TB Subgroup**



#### Main Menu

- [Home](#)
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- [Membership](#)
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## 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:





# 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