

The Global Process and challenges to coordinating TB diagnostic research and development

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New Diagnostics Working Group: Moving to point of care;
symposium and panel discussion

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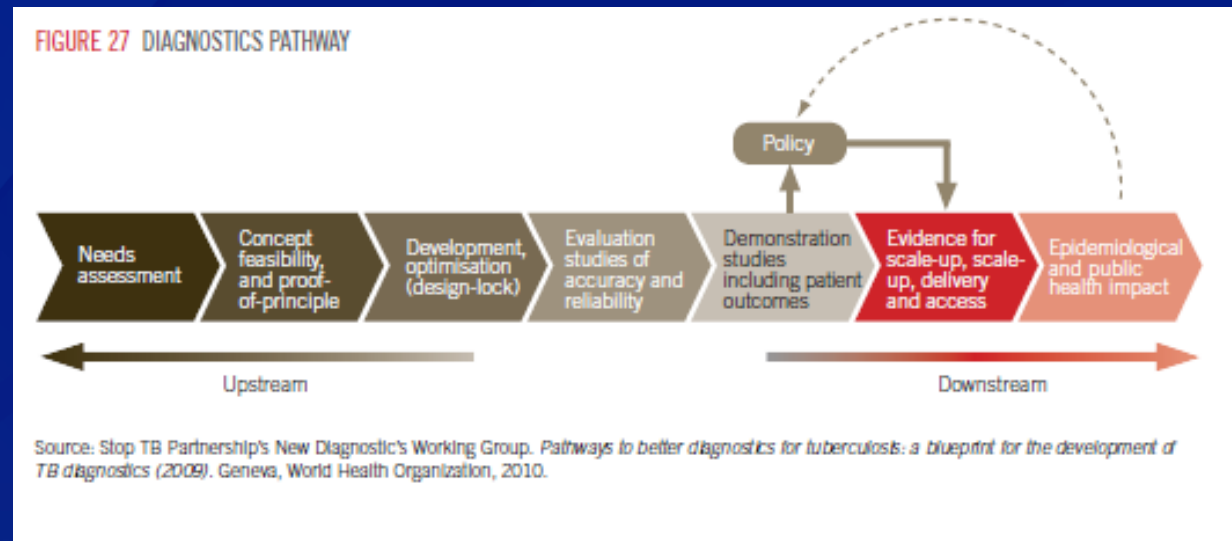
Outline

- **Background - past activities of the NDWG**
- **2013 NDWG strategic planning**
- **Current priority activities**
- **Next Steps**

* Citations, references, and credits

Past activities of the NDWG

- Earliest forum focusing efforts on new diagnostics for TB
- Increased recognition of the spectrum of activities required from R&D → country implementation (“diagnostics pathway”)



- Convening forums/subgroups for specific diagnostic areas

Global Plan to Stop TB 2011-2015

New Diagnostics Working Group

Global Objectives in TB Diagnostic Development



1

Address existing knowledge gaps obstructing development of new diagnostic tools

2

Develop a portfolio of new diagnostic tests

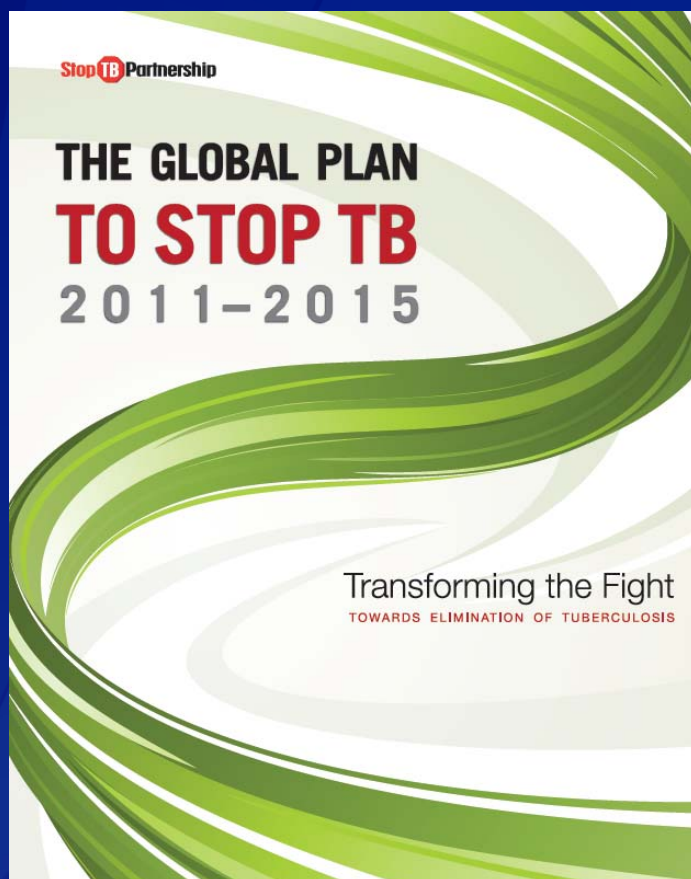
3

Evaluate the portfolio of new diagnostic tools, demonstrate patient benefit and predict likely impact

4

Ensure that fully validated new diagnostic tools are widely available and appropriately used in endemic countries

New diagnostics component of the Global Plan 2011–2015



Overall goals:

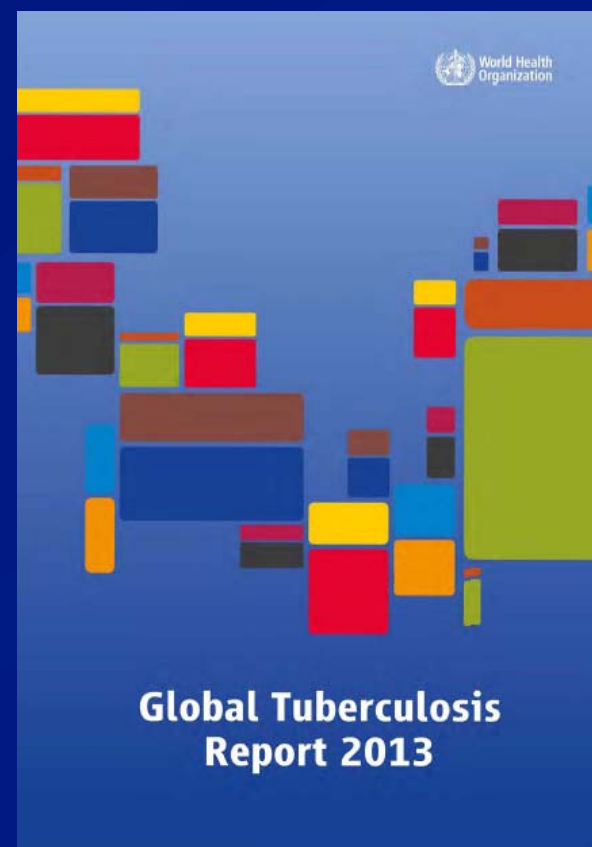
- increase detection of active TB at point-of-care level
- screen for MDR- and XDR-TB, HIV associated TB and pediatric TB
- diagnose latent TB infection and predict disease progression

Global Report 2013

Priority #1

Reach the missed cases. About 3 million people who developed TB in 2012 were missed by national notification systems. Key actions needed to detect people with the illness and ensure that they get the right treatment and care include: expanded services (including rapid tests) throughout health systems.....

Ref: WHO Global Tuberculosis Report 2013, Executive summary, page IX



2013 NDWG Strategic Planning

- **Major changes in the Stop TB Partnership, severe reductions in funding, and proposals to combine, reduce, or eliminate technical working groups**
- **Re-examined the core mission of the NDWG in the new environment**

Observations

- **Organizations and investigators have to seek funding from multiple sources outside of the Partnership.**
- **Key role of the partnership: not to do the work but rather develop strategic direction and technical resources that enable R&D performed by organizations and investigators**
- **Working groups must identify gaps and propose priority activities that represent the consensus of global stakeholders and donors are willing to fund.**
- **Working groups have a unique capacity in leveraging strengths and integrating visions from multiple partners**

NDWG Vision and Mission

Vision

High quality diagnosis of tuberculosis and drug resistance is available for all people in all settings.

Mission

Foster development and evaluation of new diagnostics for tuberculosis by providing strategic direction and serving as a coordination, communication and advocacy platform for all stakeholders in TB diagnostic research and development.

Recent activities

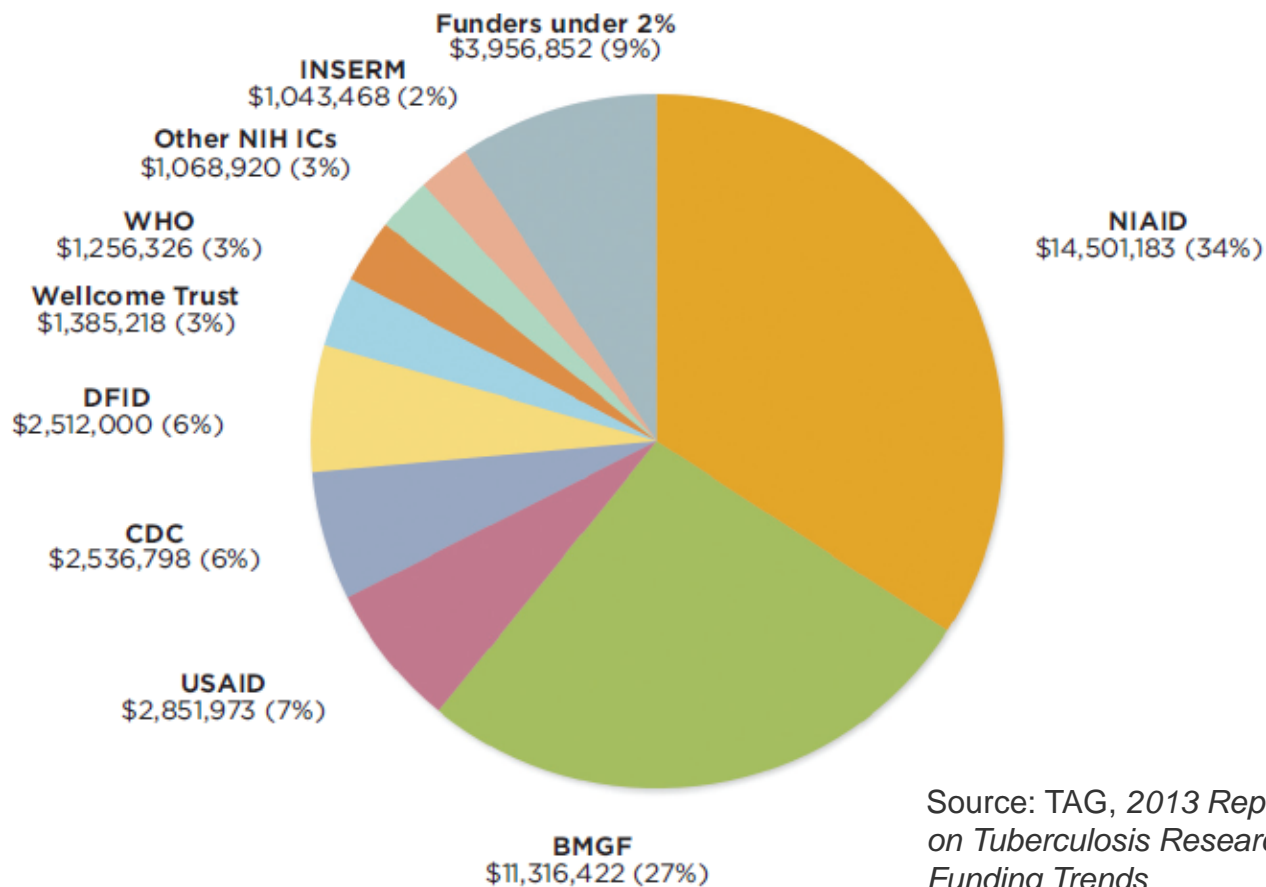
- **NDWG has been developing plans for strategic activities that appeal to stakeholders and donors to accomplish goals.**
- **Key areas are overarching research strategy and mechanisms to improve information and data sharing that is often a barrier in the field of research.**
- **Many others have begun efforts to promote visibility, coordination and greater information sharing.**

Concurrent Efforts

- **WHO – Research Roadmap**
- **Clinical Path to TB Drug Regimens (CPTR) – collaboration between USG agencies, WHO, FIND and others to collaborate on diagnostics R&D with emphasis on DST/new regimens**
- **Treatment Action Group (TAG) - advocacy for research, monitoring finance of R&D**
- **UK Government 100,000 Genomes project TB pilot**

Funding for TB Diagnostic R&D in 2012

TB Diagnostics: \$42,429,160



Source: TAG, 2013 Report on Tuberculosis Research Funding Trends

Barrier: Intellectual Property

“Although there would be a substantial advantage in polling our existing knowledge about biomarkers, such a collaboration is discouraged by the need to possess intellectual property with which to level funds for research and for building manufacturing capacity.”

R. McNerney, and P. Daley, Towards a point-of-care test for active tuberculosis: obstacles and opportunities. Nature 9 204-213. (2011)

Challenges

- **Where should competition begin and end given the intent of donors to accomplish the goal of developing new diagnostics?**
- **Most donors such, as governments, expect organizations and investigators to collaborate if it increases the chances of accomplishing the goal.**
- **How to increase data sharing, information sharing, and coordination that enables investigators and industry while also recognizing the independence of organizations and intellectual property?**

Stakeholder Forum

Coordination in TB diagnostic research: facilitating data sharing

Objectives

- Improve access to research information and reference data to accelerate progress in biomarker discovery and whole genome sequencing
- Review existing databases and explore strategies to increase the level and quality of data sharing

Program Outline

- Review priority needs for TB testing
- Update on current initiatives in the area of data collection and map existing databases with genotypic and phenotypic information
- Assess gaps in available reference data and barriers to widespread access
- Discuss strategies for integration of different databases and identify mechanisms for expanded data sharing
- Review current funding strategies in the area of data sharing, identify uncovered funding needs

Expected Outcomes of Stakeholder Forum

- **Greater transparency and sharing of ongoing research efforts**
- **Support and accessibility for TDR/FIND specimen bank**
- **Shared databanks for the many emerging efforts for sequence data**
- **Standards for data and information sharing**
Example: Standard linkage of sequence and drug resistance data

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