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Strategic framework for new diagnostics 2016-2020: Supporting *Global Plan* goals

Catharina Boehme,  FIND, NDWG Co-Chair
New Diagnostics Working Group

Fostering development of new diagnostic tools for TB

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 serving as a coordination, communication and advocacy platform for all stakeholders in TB diagnostic research and development.
Supporting the End TB Strategy and the goals of the *Global Plan to End TB 2016-2020*

- **Objective 1:** Ensure that the critical knowledge enabling the development of new diagnostic tools and solutions is available
- **Objective 2:** Develop a portfolio of new diagnostic tools coupled with a package of accompanying solutions to ensure that results translate into patient treatment
- **Objective 3:** Evaluate the portfolio of new diagnostic tools and solutions, including new detection strategies, approaches for optimized use, and innovative delivery mechanisms
- **Objective 4:** Ensure that fully validated new diagnostic tools and solutions are widely available and appropriately used in endemic countries
The roadmap to new TB diagnostics
Together with other new tools, novel diagnostics will be critical to fully realize the targets of the End TB strategy

**PRIORITY AREAS AND REQUIRED DIAGNOSTIC TOOLS**

1. Improved TB case detection
   - Tests for use at all levels of the health care system, including at the point of care
   - Task Force: Biomarkers for TB point-of-care tests

2. Universal access to DST
   - Rapid and simple tests for detection of drug resistance in decentralized settings
   - Task Force: NGS for detection of drug resistance

3. Support TB elimination
   - Tests for predicting the risk of progression from latent infection to active TB disease
   - Task Force: Tests for progression of LTBI
NDWG Core Group

Co-Chairs
• Catharina Boehme, FIND
• Daniela Cirillo, San Raffaele Scientific Institute

Core Group Members (and constituency)
• Martina Casenghi, MSF (NGOs)
• Christopher Gilpin, WHO Global TB Programme (WHO and GLI)
• Stefan Niemann, Borstel Research Center (Academia)
• Camilla Rodrigues, Hinduja Hospital (High-burden countries)
• Philippe Jacon, Cepheid (Industry)

Task Forces and Coordinators
• Biomarkers for TB point-of-care tests
  Tobias Broger, FIND
• Next-generation sequencing for detection of drug resistance
  Stefan Niemann, Borstel Research Institute
• Tests for progression of LTBI to active disease
  Alberto Matteelli, University of Brescia

Secretariat  Alessandra Varga, FIND
Thank you!

- NDWG Core Group members
- NDWG Task Force Coordinators and all Task Force members
- Lucica Ditiu and Darivianca Laloo, Stop TB Partnership
- New Vaccines and New Drugs Working Groups Chairs and Secretariats
The roadmap to new TB diagnostics
Supporting the End TB Strategy and the goals of the Global Plan to End TB 2016-2020

NDWG Strategic Framework **GOALS**

1. Reduce the gap of 3 million cases missed each year and improve TB case detection

Required Tests
Tests that can be used at all levels of the healthcare system, including at the point of care, for all populations, including children and those living with HIV

- **Biomarker test**: POC non-sputum based
- **Triage test**: simple and low-cost for screening
- **Smear replacement test**: POC sputum-based

NDWG Task Force
Biomarkers for TB point-of-care tests
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NDWG Strategic Framework GOALS

2 Enable timely and effective treatment to reduce mortality and ongoing transmission, and prevent antimicrobial resistance by ensuring universal access to DST

Required Tests
Rapid and simple tests for detection of drug resistance in decentralized settings for existing and future drugs

• Rapid DST: for use at microscopy centres to select first-line therapy

Task Force
Next-generation sequencing for detection of drug resistance
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NDWG Strategic Framework  **GOALS**

3. Support the goal of disease elimination by addressing the reservoir of TB infection and efficiently introduce targeted preventive therapy

**REQUIRED TESTS**
Tests for better detection of LTBI and for predicting the risk of progression from latent infection to active TB disease

- Test for progression of LTBI

**Task Force**
Tests for progression of LTBI to active disease