New Diagnostics Working Group

Our vision

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

Our 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.

Our operating principles

1. Setting strategic direction and providing guidance
2. Assuring coordination among partners
3. Establishing mechanisms for strategic information and knowledge sharing
4. Identifying and promoting promising innovation
5. Developing technical resources to support TB diagnostic researchers and developers
6. Advocating for new TB diagnostics, for increased funding for TB diagnostics R&D and for evidence-based decision making to drive WHO policy.

Fostering development and evaluation of new diagnostics for tuberculosis

The New Diagnostics Working Group (NDWG) is one of the seven working groups of the Stop TB Partnership and supports the Partnership in its goal of TB elimination, in particular by promoting the development and evaluation of rapid, simple and cost-effective diagnostic tools. The NDWG is a network of over 400 experts representing stakeholders from academia and research institutions, government and technical agencies, multilaterals, NGOs, industry and the patient community. The NDWG serves as a forum for all stakeholders committed to the development of better TB diagnostics, providing a coordination and communication platform for effective collaboration towards delivery of much needed new tools.

Serving as a communication platform for all stakeholders in TB diagnostics R&D

Extensive advances in research and technology are still required to enable development of new TB diagnostics to achieve the targets of the End TB Strategy and reach the “missed” 3 million people with TB who every year are left undiagnosed. The role of the NDWG is to provide a neutral and overarching platform for increased collaboration in the field of TB diagnostics in order to expand and accelerate research efforts. To this end, the working group convenes experts and global stakeholders to promote knowledge sharing, generate consensus and foster collaboration with a focus on priorities defined by the *Global Plan to End TB 2016-2020*.

Objectives

The following objectives are designed to guide progress toward the overall goals for the 2016-2020 period:

Objective 1: Ensure that the critical knowledge enabling the development of new diagnostic tools and solutions, including alternative approaches for case finding, 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, demonstrate patient benefit and predict likely impact for entire health systems and populations

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

The overall vision of the New Diagnostics Working Group's Strategic Framework 2016-2020 is to achieve early and universal diagnosis of all patients with all forms of TB to foster progress towards TB elimination, by making appropriate and affordable diagnostic solutions available at the right setting and ensuring that diagnostic results are linked to treatment.

The Framework sets the following goals and corresponding diagnostics that will be required to reach the goal of ending TB by 2035:

1. **Reduce the current gap of 3 million cases missed each year and improve TB case detection.** This will require a range of tests that can be used in a patient-centered fashion and deployed at all levels of the healthcare system, including at the point of care, for all populations, including children and those living with HIV, as well as innovative diagnostic strategies that will ensure better outreach to patients.
2. **Enable timely and effective treatment to reduce mortality and ongoing transmission, and prevent antimicrobial resistance by ensuring universal access to DST.** This will require rapid and simple tests for detection of drug resistance in decentralized settings for existing and future drugs, as well as tests to assess response to therapy and cure.
3. **Support the goal of disease elimination by addressing the reservoir of TB infection and efficiently introduce targeted preventive therapy.** This will require tests for predicting the risk of progression from latent infection to active TB disease.

NDWG Governance and Task Forces

Co-Chairs

- Catharina Boehme, FIND, Switzerland
- Daniela Cirillo, San Raffaele Research Institute, Italy

Core Group

It is the constituency-based decision-making body of the NDWG. Members contribute on a voluntary basis with their time and expertise.

- Martina Casenghi, Médecins sans Frontières (NGOs)
- Christopher Gilpin, WHO Global TB Programme & GLI
- Philippe Jacon, Cepheid (Diagnostic industry)
- Stefan Niemann, Research Center Borstel (Academia)
- Camilla Rodrigues, Hinduja Hospital, Mumbai (High-burden countries)

Task Forces and Coordinators

Three time-limited and focused Task Forces have been established to support NDWG strategic priorities and main goals, and to foster development and evaluation of the relevant diagnostic tools.

① **Build consensus and foster knowledge sharing to enable the identification of suitable biomarkers or biosignatures for TB point-of-care tests**
Tobias Broger, FIND

② **Use of next-generation sequencing for detection of drug-resistance and correlation of specific mutations with in vitro MICs**
Stefan Niemann, Borstel Research Institute

③ **Foster development and evaluation of tests for progression of LTBI to active disease**
Alberto Matteelli, University of Brescia

Secretariat Alessandra Varga, FIND

www.stoptb.org/wg/new_diagnostics

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