



***The New Diagnostics Working
Group:
purpose, organization,
accomplishments***

Dr. Giorgio Roscigno, CEO

Partnering for better diagnosis for all

WGND mission

- Facilitate the development of a toolbox of widely accessible diagnostics tests
- Support product development to enhance control of the global TB epidemic
 - directly (product-specific development partnerships) and
 - indirectly (creating a stimulating and enabling framework)
- Advocate Research and/or Operational activities
- Create a synergy and add value to the actions taken by the STOP TB partnership Working Groups
- Provide direct impact through financial and logistics support to projects across all levels of the public health system in HBC



Products sorely needed

- Improve TB case detection at POC with affordable, same-day results, high sensitive and specific diagnostic tests
- Identify drug resistant TB to allow time efficient treatment and reduce morbidity and transmission
- Identify latent TB and define risk of progression to active disease



Global Plan Objectives

1. Address existing gaps in knowledge that are obstructing development of new diagnostic tools
2. Develop and evaluate a portfolio of new diagnostic tools and demonstration of impact
3. Implement new diagnostic tools and ensure access

Objective 1- achievements so far

- Sensitive and early detection of active disease is still an on-going process but **notable progress** has been made.
- Systematic reviews of the literature have been used very successfully to inform global policy and to **forge an urgent research agenda**.
- Evaluation of 19 commercially-available rapid serological tests for Tb show that **no currently-available serological test can replace smear microscopy**.
- Performance and combinations of current antigens have been tested. Much original **research is ongoing to identify new antigens**. A wide range of research institutions is involved but lack of funding has hampered the work
- The development of new diagnostics for the early detection of TB is held back by our **lack of understanding of the basis of latent TB infection**, and the processes involved in latency.
- The NDWG has recently created a specific subgroup to deal with **Evidence Synthesis** for Tuberculosis Diagnostics

Objective 2- achievements so far

- The NDWG continues to nurse through its members an expanding pipeline of new diagnostic tools like:
 - optimized smear microscopy approaches
 - culture-based methods
 - nucleic acid amplification tests
 - point-of-care tests
 - tests for latent TB infection

- Specific subgroups within the NDWG have recently been created to focus on activities under each of these categories.

- Three separate subgroups have been created to focus on the diagnostic needs and the likely impact of new diagnostics on key populations, namely children, the HIV co-infected, and the poor.



Objective 3 - achievements so far

- **Novel approaches** have been endorsed by WHO in the last 2 years:
 - New, more sensitive definition of a sputum smear positive TB case
 - Reduction of the minimum number of sputum specimens examined in investigation of suspected TB
 - Use of liquid TB culture in low- and middle-income settings
 - Lateral flow test for rapid identification of M tuberculosis complex in cultures
 - The use of line probe assay for screening patients at risk of MDR-TB

- **Tools being rolled out** in the MDR-TB highly endemic countries.

- The NDWG works very closely and productively with:
 - The **Retooling Task Force** (RTF)
 - The **Global Laboratory Initiative** (GLI).

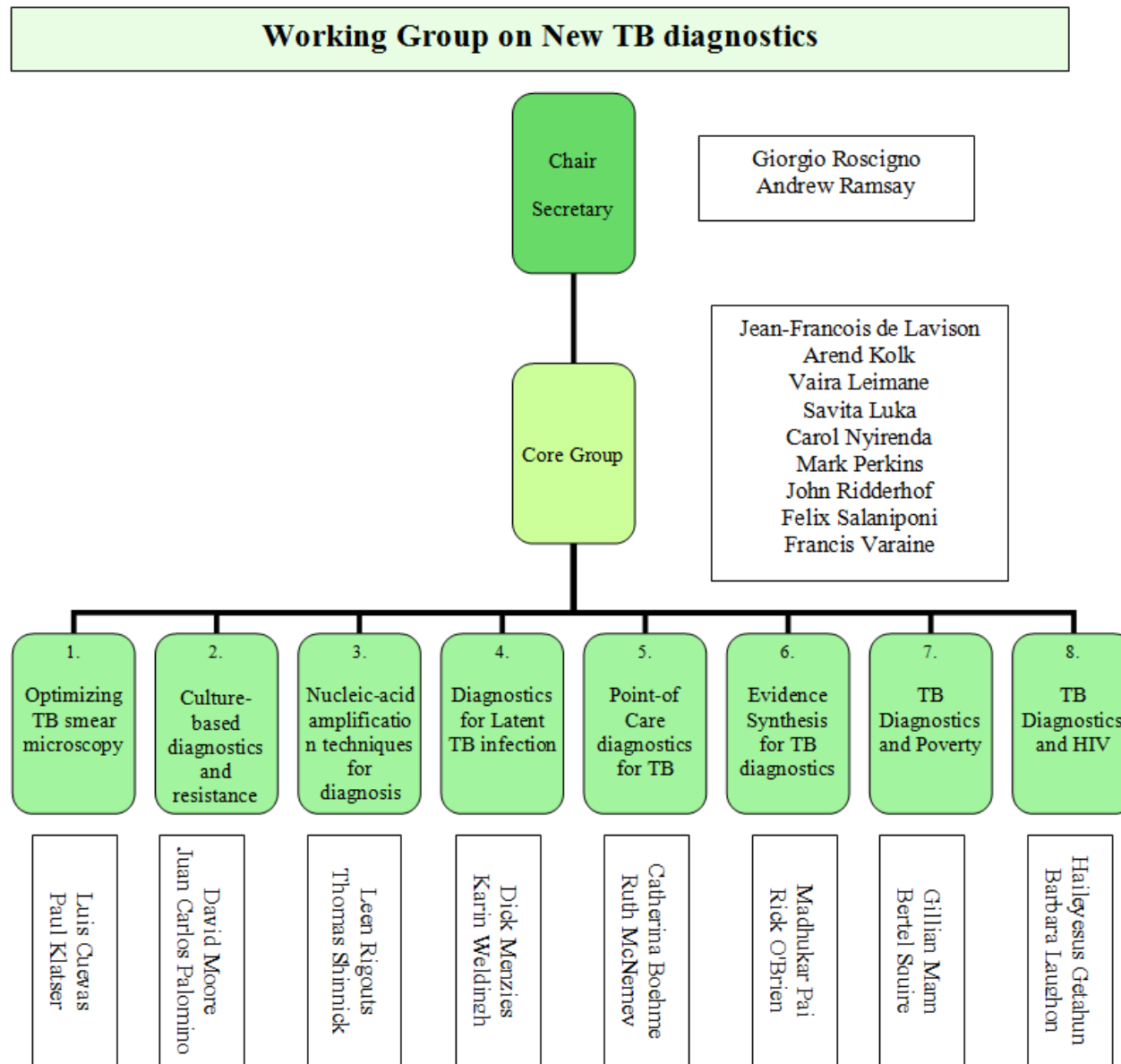
- **A guide to the diagnostics pipeline** for national TB control programme staff has recently been produced by the RTF, GLI and NDWG to be published in November 08

WGND re-organization

- Structure based upon a core group of key stakeholders
 - Patients organizations
 - Academia
 - Test developers
 - Diagnostic manufacturers
 - NTP directors
 - NGOs
 - Laboratory capacity strengthening experts
- Eight new subgroups vs. specific technologies (e.g. NAT) or issues (e.g. poverty)



WGND structure



WGND priorities

1. Facilitate WG member collaboration in support of creative funding mechanisms likely to come
2. Intensify collaborations between the WG and Stop TB Partnership
3. Develop clear criteria for candidate diagnostics tests
4. Describe an expanded diagnostics pipeline to reflect explosion in development activities
5. Develop a [Scientific Blueprint](#) to lay out development and evaluation stages in the value chain leading to global implementation
6. Develop criteria to place specific technologies at particular stages of the value chain of development and evaluation
7. Work with the STP re-tooling Task Force and the Subgroup on Laboratory Capacity Strengthening to predict capacity required for implementation

WGND accomplishments

- The WGND has supported major developments in the field of diagnostics in recent years
- Today at least 15 candidate tests are in the pipeline
- Endorsement by WHO in low and middle income countries:
 - More sensitive definition of a smear positive case
 - Reduction of the minimum number of sputum specimens examined in investigation of suspected TB
 - Liquid culture system
 - Speciation assay
 - Line probe assay



Budget needs

- Despite active advocacy efforts, funding for TB diagnostics remains a low priority for donors:
 - urgent massive financing is needed for biomarker discovery research
 - urgent massive financing is needed for support to evaluation and demonstration studies

Challenges remaining

- More research is required into the use of existing diagnostics (or combinations of diagnostics) within clinical algorithms
- More biomarker basic research for antigen discovery needed.
- More funding is needed for establishing and maintaining a platform of clinical trial sites for evaluation and demonstration studies

Thank you



Together, we can end TB by 2050

