

Diagnostic Needs for Meeting the WHO New NTD Roadmap Goals of 2030

Session Date & Time:	Monday, November 18; 1:00 PM to 4:00 PM
Session Location:	Bellagio 2
Session Description:	Diagnostics remain a challenge for many neglected tropical disease (NTD) programmes. Advances in the development of diagnostics should allow us to develop diagnostics that meet programmatic needs rather than designing control and elimination interventions around the available diagnostics. This session will focus on identifying the major diagnostic gaps for NTDs programmes, the World Health Organization (WHO) process for development of target product profiles that should help focus development of priority diagnostic tools for each stage of the program and advances in the development of diagnostics that can be taken advantage of to develop better targeted diagnostic tools.
Session Chairs:	Daniel Argaw Dagne and Joseph Ndungu
Session Rapporteur:	Camilla Ducker

KEY DISCUSSION POINTS

There were four presentations spanning:

- Diagnostic Needs in NTDs by WHO
- New WHO/Target Product Profile (TPP) process
- Required attributes of a diagnostic
- Advances in biomarker identification and development of diagnostics for selected NTDs addressed via preventive chemotherapy (PC-NTDs).

These presentations set the scene for the diagnostic needs across all NTDs, the processes in place to try and address the gaps and needs and also the process of developing diagnostics both from a scientific point of view and also epidemiological and meeting the public health targets' point of view.

The discussion was around how these diagnostic gaps could be addressed in a timely and field appropriate manner. The participants acknowledged that there were critical diagnostic needs that would need addressing very quickly to ensure that the gains that had been made to date in programmes was not lost but that there was no NTD which did not have a diagnostic need to be addressed.

The issues around finding manufacturers interested in making diagnostics which may have a very small market was discussed. Links to health systems and universal health coverage were discussed and that diagnostics may need to address more than one disease. There is less and less interest in vertical programming. An absolute requirement was to be specific about diagnostic with a list of priorities and the impact and that should be driven by 2030 goals.

KNOWLEDGE GAPS IDENTIFIED

The group expressed a lack of understanding across all NTDs as to what was being discovered, what had been developed and how that might impact the formation of a diagnostic. The group felt that the process of diagnostic development was potentially very long and fragmented and although people felt WHO's move around diagnostics was positive it was still unknown how it would work. The market for diagnostics is very unknown and also the economic impact of having diagnostics to support the business case.

RECOMMENDED NEXT STEPS

- A more comprehensive landscape exercise on what is being developed should be carried out to give a full picture
- The development pathway should be mapped out and ways to fastrack it – TPP through to field trials and how many trials would be needed
- Comprehensive work on the diagnostic market so that economic understanding and modelling can be achieved to strengthen a business case
- Comprehensive understanding of the use cases and where in the health system the diagnostic will be used so that the end product is fit for purpose