



# Improving the development and deployment of rapid diagnostic tests in LMICs

## Case Study

21 November 2016, London

# Rapid Diagnostic Tests

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## Context

Rapid diagnostic tests (RDTs) have great potential to improve both clinical care and disease surveillance in low- and middle-income countries (LMICs). By identifying specific causes of infection (and in some cases antimicrobial resistance genes), such tests enable clinicians to prescribe the most appropriate treatment. This ensures that patients rapidly receive optimal treatment and prevents unnecessary use of antimicrobials, avoiding wastage and overuse that could cause antimicrobial resistance and increase healthcare costs.

In terms of surveillance, RDTs can play multiple roles. They can generate insight into local disease burdens and changing trends in disease and patterns of antimicrobial resistance, provide tools to identify and track emerging infections, and assess the impact of control and elimination programmes. However, despite much scientific and technological progress, and some notable successes, the potential of RDTs has yet to be fully realised in LMICs.

## Workshops

Against this backdrop, a one-day workshop of key stakeholders from the UK and LMICs was held on 21 November 2016, jointly organised by the Academy of Medical Sciences and the InterAcademy Partnership for Health (IAP). The workshop examined a range of barriers that are limiting the development and deployment of RDTs, and discussed possible ways in which these barriers might be overcome. Discussions focused mainly on diagnostics for infectious diseases, although it was recognised that RDTs were also urgently needed for the detection and monitoring of non-communicable diseases.

## Outputs

Following the workshop, a written report was produced and disseminated to participating countries, the UK and other LMIC stakeholders to provide a summary of the key themes that emerged during the workshop discussions. The report summarised some of the following key solutions:

- Enhancing the profile of diagnostics globally and nationally
- Economic incentivisation to overcome market failure
- Promoting locally driven, patient-focused development
- More coherent regulatory environment.
- Developing deployment 'packages'.
- Strengthening quality assurance systems.
- Engaging with the private sector.
- Boosting local research, R&D and manufacturing.
- Developing more flexible diagnostic tools.
- Supporting surveillance.
- Next-generation sequencing and disruptive technology.
- Diagnostics for non-communicable diseases.

## Top three impacts

In addition to gathering evidence, the policy workshops and report are designed to act as a catalyst for future policy activities and build the capacity for our national partners in LMICs to do policy work. Hardcopies were disseminated to key stakeholders in participating LMICs, UK and other LMIC stakeholders. The top three impacts from these workshops include:

- The top solution identified in the report to improve the development and deployment of diagnostics in LMICs was the need for a globally recognised 'Essential Diagnostics List' to provide guidance to national decision-makers. In May 2018, the WHO published its first Essential Diagnostics List - a catalogue of the tests required to diagnose the most common conditions as well as a number of global priority diseases.

This new policy will allow for better access to diagnostic services and assignment of the right treatments.

- In Morocco, the report was disseminated to universities, schools of medicine and pharmacy, health-related research institutes and biotech companies. A follow up workshop was organised in 2017 to address opportunities for TB research enhancement and translation in Morocco where RDT development and needs were addressed.

Following this additional workshop, a joint venture to address TB diagnostics was formed with the Centre de recherche Observational, a diagnostic products distributor (Masterlab) and a health strategic agency. The purpose of this collaboration is to develop a TB diagnostic concept and prototype, show the public health benefits and successfully register the diagnostic test.

- In the Philippines, the workshop catalysed a number of activities including:
  - Presenting diagnostics development projects to both Regional Unified Health Research Agenda (RUHRA) and National Unified Health Research Agenda (NUHRA) consultations in order to increase prioritisation.
  - Successfully achieving an allocation increase for research funds by the Philippine Council for Health Research and Development for diagnostics-related programmes.
  - Forming a Technical Working Group focused on diagnostic area of research and development.
  - Corresponding and meeting with the FDA and other regulatory authorities with regards to diagnostic development regulation.
  - Evaluating the actual demand and performance of diagnostic tools currently used in local settings in the Philippines.

In addition to these local impacts, the AMS and Philippines National Academy of Science and Technology (NAST) agreed to partner on a further GCRF workshop on diagnostics that would look specifically at issues in the ASEAN region. This workshop took place in October 2018.

**To read the full workshop report visit:**

<https://acmedsci.ac.uk/policy/policy-projects/rdt-workshop>

**To learn more about our GCRF work visit:**

<https://acmedsci.ac.uk/policy/gcrf>



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