



Improving the development and deployment of rapid diagnostic tests in LMICs

Executive Summary

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Key Context

Rapid diagnostic tests 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, rapid diagnostic tests 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 enable the impact of control and elimination programmes to be assessed.

However, despite much scientific and technological progress, and some notable successes, the potential of rapid diagnostic tests has yet to be fully realised in LMICs. In discussions and breakout sessions, workshop participants identified a range of barriers to their development and deployment, and potential ways they might be overcome.

Barriers

- **Insufficient prioritisation, globally and nationally:** Despite their great value, diagnostics are not given the attention they warrant, especially at a national level.
- **Financial barriers:** Diagnostics development for LMICs is commercially unattractive, deterring investment by major diagnostics companies. Smaller companies may struggle to obtain funding to scale-up production and establish sustainable businesses.
- **Challenging demands:** The requirements of diagnostic tools for use in LMICs are challenging. As well as needing to be affordable, they must also be robust enough to cope with difficult environmental conditions, easy to use, reliable and, ideally, accessible to remote populations.
- **Evaluation shortcomings:** Evaluations of diagnostic tools currently place too much emphasis on test performance in isolation, rather than in the context of local settings, specific patient pathways and health systems, and their impact on patient outcomes. This can encourage decision-makers to focus primarily on the costs of diagnostics rather than their quality and potential impact.
- **Complex and heterogeneous regulatory environments:** In some LMICs, regulatory processes may be weak or absent entirely, leading to the use of poor-quality or unvalidated tests and discouraging investment in the development of high-quality tools. Complex approvals processes, variation between countries and a desire for country-specific data are all major challenges to diagnostics developers.
- **Quality assurance:** The long-term reliability of rapid diagnostic tests is dependent on effective national quality assurance systems, which are lacking in many LMICs.
- **Performance issues with existing tests:** Some existing tests do not achieve claimed levels of performance, undermining confidence in their results and in diagnostics testing more generally.
- **Involvement of the private and public sectors:** In many LMICs, the private sector plays a major role in delivering healthcare services; its activities may be more challenging to influence and regulate than the public sector.
- **Insufficient focus on differential diagnosis:** Many rapid diagnostic tests focus on individual pathogens; negative results may therefore leave clinicians still unaware of the specific cause of symptoms and unsure of the most appropriate treatment.

Potential solutions

- **Enhancing the profile of diagnostics globally and nationally:** Diagnostics need to be given a higher priority globally, especially given their value in surveillance and control of antimicrobial resistance as well as in improved clinical care. A globally recognised 'Essential Diagnostics List' could be considered, to provide guidance to national decision-makers. This could include diagnostics for transmissible dangerous pathogens such as the Ebola virus or SARS-CoV. A global umbrella organisation could promote sharing of resources, information and expertise, act as a coordinating body, and undertake advocacy activities. At an individual country level, 'National Diagnostics Committees' could provide strategic leadership and expert advice, promote a greater emphasis on the quality of diagnostics rather than just their cost, and underpin greater regional coordination.
- **Economic incentivisation to overcome market failure:** Drawing upon experience in areas such as vaccines, innovative economic tools ('market pull' mechanisms) could be developed to encourage diagnostics developers to focus on LMICs.
- **Promoting locally driven, patient-focused development:** Diagnostics development needs to be more strongly rooted in local clinical needs and informed by the realities of local healthcare systems, patient journeys and cultural practices – hence less technology-driven and more needs-driven.
- **More coherent regulatory environment:** Rather than focus only on test performance, evaluation of diagnostics should link more closely to patient pathways, be based on comparisons with existing pathways, and focus more on patient outcomes, to generate stronger evidence for policymakers. Strengthened national regulatory systems are required to encourage the development of high-quality tests, with more focus on international standards and consistency in approach between countries. Greater regional cooperation is needed to harmonise regulatory approvals and to minimise the requirement for country-specific data sets.
- **Developing deployment 'packages':** Diagnostics need to be implemented as part of 'deployment packages' that consider diagnostic use within the context of patient pathways, and take account of factors such as healthcare worker training, communication with patients, integration with existing healthcare systems and reporting structures, and long-term quality assurance.
- **Strengthening quality assurance systems:** To ensure the long-term reliability of diagnostics testing technology, effective national quality assurance infrastructures are required, allied to agreed international standards. Such systems should also reassess rapid diagnostic tests already in use.
- **Engaging with the private sector:** The private sector is likely to play a key role in diagnostics deployment in many LMICs; efforts are needed to promote good diagnostics practice in the private sector and its involvement in national quality assurance processes.
- **Boosting local research, R&D and manufacturing:** Local development of tests should be encouraged, supported by international collaborations. Technology transfer and the development of local manufacturing capabilities provide opportunities to minimise production costs while also contributing to local economic development. In addition, continued support for research capacity building and regional research networks will provide an important foundation for understanding local pathogens and disease outbreaks, informing the development and implementation of diagnostic tests.
- **Developing more flexible diagnostic tools:** There is a growing need for diagnostics that are better able to support differential diagnosis (e.g. multiplex diagnostics, multi-use platforms) and 'upgradable' tools that can be rapidly updated in response to new knowledge about pathogens (e.g. new resistance genes).
- **Supporting surveillance:** Diagnostics are required that support surveillance activities, from disease burden assessments to monitoring of control and elimination programmes. It is also important that results from diagnostic tests in routine clinical practice feed into national health data systems, for example by exploiting built-in networking capabilities of diagnostic tools, mobile phone technologies or by integrating testing into national reporting systems.
- **Next-generation sequencing and disruptive technology:** Given its relative simplicity, wide applicability and the rapid speed of technical developments, next-generation sequencing is a credible near-term application in LMICs, particularly for surveillance. Its potential use in LMICs should be closely monitored and assessed.
- **Diagnostics for non-communicable diseases:** Although the workshop focused mainly on infectious diseases, LMICs will also need simple and affordable diagnostic tools for non-communicable diseases. Most of the issues discussed are relevant to the development of such diagnostics. Healthcare apps, with which diagnostics are becoming increasingly integrated, were discussed at another Academy workshop¹ and are not covered here.

1. World Health Organization (2014). Non-Communicable Diseases (NCD) Country Profiles, 2014. http://www.who.int/nmh/countries/zaf_en.pdf?ua=1



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