

## MEETING REPORT

# Achieving equitable access to infectious diseases diagnostics: Learnings and pathways forward

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On 18 May 2026, the Access to Medicine Foundation hosted a high-level expert session (*Amsterdam Session*) on the sidelines of the 79th World Health Assembly. The session brought together senior representatives from diagnostics manufacturers, pharmaceutical companies, implementing partners and international organisations to explore solutions for expanding access to essential diagnostic tools for infectious diseases in low- and middle-income countries (LMICs).

Held under the Chatham House Rule, the session took the form of a moderated roundtable discussion organised around two thematic rounds. The first, titled “*How can access to diagnostic tools be scaled? Learning from industry experience,*” explored practical examples from manufacturers on improving access through research and development (R&D), partnerships, integrated business models and the development of tools tailored to low-resource settings. The second round, titled “*What enablers are needed for increasing access at scale and enabling global health security?*” focused on the wider enabling environment, exploring how local manufacturing, improved procurement models and stronger coordination among governments, donors, non-governmental organisations and manufacturers can accelerate access to diagnostics in LMICs.

### ABOUT THE EVENT

During the session, participants examined access to diagnostics across the entire value chain, sharing experiences, examples of successful partnerships and key challenges. The following recurring themes emerged and are explored in this report:

1. Access considerations need to be embedded early in research and development (R&D), supported by compelling evidence on clinical utility, usability and value.
2. Vertically funded programmes have expanded access in areas such as HIV and tuberculosis (TB), but gaps remain in traditionally overlooked areas, including antimicrobial resistance (AMR).
3. Local capacity building, coordinated procurement and greater market security are needed to support sustainable manufacturer engagement in LMIC markets.
4. Addressing persistent diagnostic gaps requires coordinated, multi-stakeholder action and long-term, sustainable financing.

## SPEAKERS AND CONTRIBUTORS

A diverse group of stakeholders joined the session, including representatives from diagnostic manufacturers (bioMérieux, Cepheid, Global Access Diagnostics, Hemex Health, Hologic, Molbio Diagnostics, Qiagen, Roche Diagnostics, Sysmex Astrego and Waters Corporation), pharmaceutical companies (Pfizer and Otsuka), implementing and funding partners (Foundation for Innovative New Diagnostics (FIND), Fleming Initiative, Global Antibiotic Research & Development Partnership (GARDP), the Gates Foundation and PATH) and international organisations.

## DISCUSSION AROUND KEY THEMES

### **1. Access considerations need to be embedded early in research and development (R&D), supported by compelling evidence on clinical utility, usability and value.**

Participants agreed that access considerations must be embedded from the earliest stages of diagnostics development. Health systems in LMICs face specific infrastructure, resources and end-user constraints that cannot be addressed effectively once a product has been designed. Participants identified several areas for further action:

- Participants emphasised that diagnostic tools should be designed around the needs of users in lower-income settings and lower-levels of the health system, grounded in a clear understanding of end-user realities and requirements. This includes strong in-country engagement, direct clinician feedback, iterative prototyping and adaptation to field environments rather than “idealised” healthcare settings.
- Manufacturers can also play a crucial role during the R&D stage in reducing costs. Participants highlighted several strategies, including more efficient sourcing practices, prioritising software-based solutions over hardware where feasible and limiting custom engineering to functions essential for performance and affordability.
- Environmental resilience emerged as a critical design requirement, with one manufacturer sharing their experience of developing a device engineered to operate in high temperatures, dusty conditions and settings with unreliable electricity supply, including use of rechargeable battery systems compatible with common mobile phone chargers.
- The availability of a trained workforce is also a key consideration. Rather than assuming access to specialised laboratory expertise, diagnostic tools should be designed for use by entry-level healthcare workers, with embedded training tools and procedural guidance integrated directly into clinical workflows. One participant noted that, in several African countries, diagnostic testing is legally and operationally restricted to trained laboratory personnel, limiting the deployment of point-of-care tools by nurses and community health workers.
- Lastly, one manufacturer noted that establishing trusted, in-country partner networks requires significant long-term investment but is essential for implementation, training, service support and market adoption. This process should start from the earliest stages of R&D to ensure tools are rapidly available and deployable in LMICs once approved.

**2. Vertically funded programmes have expanded access in areas such as HIV and tuberculosis (TB), but gaps remain in traditionally overlooked areas, including antimicrobial resistance.**

Many advances in diagnostics over the past two decades – from molecular testing for TB to rapid HIV tests – have emerged through vertically funded programmes. Outside these programmes, however, innovation and deployment have remained limited.

- Vertical programmes, including those for TB, HIV and malaria, have created dedicated end-to-end diagnostic ecosystems – encompassing funding, training, procurement and demand planning – while integrating diagnostics into clinical algorithms and helping to drive down costs. At the same time, participants noted that these programmes have contributed to fragmentation across broader diagnostic systems, as funding has become increasingly siloed.
- Multi-disease, syndromic platforms that enable rapid detection of multiple conditions through a single diagnostic system could help address some of the limitations created by vertically funded programmes. By supporting simultaneous screening for multiple diseases and pathogens, they could enable more integrated approaches to service delivery and, in the future, more coordinated procurement. However, participants agreed that, without clear evidence demonstrating clinical utility and value to different stakeholders, these tools risk remaining outside established clinical pathways and may not be widely adopted.
- Affordability remains a major barrier. While diagnostics for some diseases are heavily subsidised, others remain financially inaccessible. This challenge also applies to multi-disease platforms, as multiple indications may fall under different reimbursements pathways (e.g. HIV and hepatitis C). Even where a platform can test for multiple pathogens, the required reagents may be prohibitively expensive if they sit outside traditional procurement pathways.
- In the specific case of antimicrobial resistance (AMR), participants saw partnerships between diagnostic and pharmaceutical manufacturers as pivotal across multiple dimensions, including integrated clinical pathways and shared stewardship efforts. However, AMR diagnostics remain an R&D blind spot, with limited point-of-care options, significant unmet need for innovation and no clear procurement pathways. Including AMR diagnostics in centralised procurement mechanisms was identified as one potential way to improve access by aggregating demand and reducing costs.
- Participants highlighted a core structural challenge: in many LMICs, Ministries of Health lack ringfenced budgets for diagnostics, as well as the operational framework needed to integrate these tools into healthcare settings. They agreed that policy reform is needed, alongside new approaches to how governments prioritise, fund and integrate diagnostics into the broader health ecosystem.

**3. Local capacity building, coordinated procurement and greater market security are needed to support sustainable manufacturer engagement in LMIC markets.**

Weak supply chains, fragmented procurement, particularly outside vertical disease programmes, and limited demand aggregation continue to constrain access to diagnostics in LMICs. Participants highlighted

stronger public–private partnerships, technology transfer, local manufacturing and more integrated procurement systems as critical to addressing these barriers.

#### **Local manufacturing can offer opportunities to strengthen the availability of diagnostic tools**

- Building manufacturing capacity in LMICs and supporting technology transfer can improve resilience by bringing production closer to high-burden settings and aligning development with local health priorities. To be sustainable, however, these initiatives must extend beyond end-product manufacturing and include investment across the wider ecosystem, including R&D, workforce training and operational capacity.
- South–South collaboration was highlighted as increasingly important. Participants noted that sharing lessons from similar low-resource contexts can accelerate innovation and strengthen diagnostics R&D and production capacity, complementing traditional North–South models.
- Strong national and regional government involvement was also seen as essential, including sustained funding and coordination. Participants stressed the need to move away from temporary, epidemic-driven solutions and toward long-term, sustainable and self-sufficient systems.

#### **Streamlined procurement and better demand visibility are critical for scale**

- Diagnostics procurement is more complex than pharmaceutical procurement, requiring not only tests, but also equipment, consumables, maintenance and training. Procurement models therefore need to account for these full lifecycle costs.
- Supply chain challenges – including the short shelf life of consumables, temperature sensitivity, customs delays and currency fluctuations – remain major barriers to reliable access. Small and fragmented markets also weaken commercial incentives, particularly for diseases often overlooked in diagnostics investment. Participants therefore underscored the need for demand aggregation and economies of scale. As one participant noted, “innovation is faster than implementation,” highlighting the gap between technological advances and health systems’ ability to adopt them effectively.
- Participants also identified a critical need for more centralised procurement mechanisms and funding that covers the entire diagnostic value chain, especially as donor support declines. Financing remains challenging, with suppliers requiring upfront payments while governments and agencies often lack the liquidity to procure at scale. This underscores the potential value of innovative financing mechanisms, including revolving or bridge financing.
- Volume guarantees and provision models that bundle equipment, consumables, training, maintenance and spare parts into a single package were highlighted as potential avenues to improve affordability and sustainability.

#### **4. Addressing persistent diagnostic gaps requires coordinated, multi-stakeholder action and long-term, sustainable financing.**

Across the session, participants highlighted the complexity of diagnostic markets and their strong interdependence with broader health system structures. They emphasised the importance of system-level

enablers and coordinated initiatives to address persistent structural barriers to access. Participants also noted the continued undervaluation and underfunding of diagnostics, stressing that access remains fundamentally a question of policy and prioritisation.

- Partnerships across public- and private- sector stakeholders were identified as essential for designing new strategies to advance access to diagnostics. One participant noted fragmentation not only among buyers, but also across the diagnostics industry itself. One proposal was to establish a coalition similar to the Developing Countries Vaccine Manufacturers Network to help coordinate and strengthen the diagnostics sector. In AMR, the Global Diagnostic Compact and DxAMR were recognised as important mechanisms for shaping demand and strengthening advocacy efforts.
- Reliance on limited, ad hoc financing that does not cover the full diagnostics ecosystem risks deepening access gaps and has implications for national and global health security. Because diagnostics operate within complex networks, Ministries of Health and financing bodies in LMICs have a crucial role in developing national action plans that include diagnostics and allocate dedicated budgets for them. Participants also noted the importance of National Essential Diagnostics Lists to define which tests are needed at each level of the health system and to support longer-term agreements with suppliers. South Africa was highlighted as an example of using coordinated multi-year planning to strengthen procurement and investment decisions.
- Manufacturers also have a role to play in building robust evidence on cost-effectiveness, usability and integration into clinical pathways to support financing and reimbursement decisions. At the same time, assessing the value of diagnostics is more complex than assessing the value of medicines or vaccines. New evaluation frameworks and broader multi-stakeholder agreement on how value should be defined are therefore needed. This challenge is compounded by uneven regulatory systems and limited health technology assessment capacity for diagnostics across many LMICs. Data-driven prioritisation and coordination were seen as critical, with participants citing Egypt's hepatitis C mass-screening programme as a successful example in which access to testing was linked to prompt access to free treatment.

## LOOKING AHEAD

The roundtable provided an opportunity for stakeholders to exchange practical experiences and identify opportunities to strengthen access to infectious disease diagnostics across LMICs. A clear need emerged for stronger coordination across the diagnostics ecosystem, alongside more sustainable financing models, improved demand visibility and greater alignment between manufacturers, donors, governments and implementing organisations. Participants also highlighted the importance of recognising diagnostics as a core component of health security, antimicrobial stewardship and resilient health systems more broadly.

Insights from the discussion will inform the Foundation's ongoing work on access to diagnostics and AMR, including future engagements with manufacturers, governments, international organisations and civil society stakeholders. In 2027, the Foundation will release a thematic report analysing the strategies and

actions of a selected set of diagnostic manufacturers aimed at expanding access to diagnostic tools in LMICs. It will also identify opportunities and next steps for other sector stakeholders.

We encourage participants to continue sharing updates, experiences and perspectives with the Foundation as this work develops.

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### **About the Amsterdam Sessions**

*Convened by the Foundation, the Amsterdam Sessions bring together senior stakeholders from across the healthcare ecosystem, including industry representatives, global health organisations, governments, investors and technical experts, to discuss key access-to-medicine challenges. The Sessions are designed to foster open and structured dialogue under the Chatham House Rule, enabling participants to identify practical solutions, share best practices, and explore barriers to improving access to health products. Insights generated through these discussions help inform the Foundation's research and publications.*