Keeping our feet on the ground: the role of innovation in scaling up diagnosis to counter antimicrobial resistance

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At the second UN General Assembly High-Level Meeting on antimicrobial resistance (AMR) held on September 26, 2024, UN member states made important commitments to strengthen global efforts to counter drug-resistant infections, including to "[i]mprove access to diagnosis and care, so at least 80% of countries can test resistance in all bacterial and fungal GLASS [World Health Organization (WHO)'s Global Antimicrobial Resistance and Use Surveillance System] pathogens by 2030".[1] Access to quality-assured microbiology laboratories is indispensable for any successful effort to identify and counter AMR, and yet, scarce in many countries in sub-Saharan Africa, south Asia, and the Middle East, particularly in the least-resourced tiers of health-care delivery.[2,3]

These regions bear the highest burden of AMR globally, and Médecins Sans Frontières (MSF) runs medical humanitarian projects here.[3,4] Although the attention that the high-level meeting and global health actors such as the Fleming Fund are bringing to diagnostics is crucial, we are concerned that any confusion regarding the role of innovation in scaling up AMR diagnostics could lead to the misallocation of scarce resources. As world leaders consider policies and programmes to fulfil their commitment to improve AMR diagnosis, they need to do so with a thorough understanding of the current state of diagnostic innovation; the extent to which inequitable access to and capacity to use current diagnostic technology drives AMR and warrants urgent remediation; and the ways in which research and development (R&D) for new tools can either help to diminish or perpetuate inequitable access depending upon how the R&D is funded, structured, and directed. Of note, although no platform available as of now or near emergence from the innovation pipeline can entirely replace culture-based antibiotic susceptibility testing, readily available, cost-effective means of expanding access to diagnostic microbiology in almost all contexts already exist.

A November 2024 report of the World Innovation Summit for Health (WISH) AMR Forum, drawing on a *Lancet* article published in October, 2024, suggested that progress towards appropriate use of antimicrobials is being hindered in some contexts by a failure to embrace new tools. "In some cases", the report concluded, achieving this goal will "require a change of mindset and a movement away from traditional approaches such as the use of blood cultures".[5,6] The report also emphasised the importance of "improving laboratory capacity and staffing capabilities" and that low-income and middle-income countries (LMICs) will need additional support. However, we believe that the concern expressed in the article echoed in the report regarding an "entrenched culture of blood culture" is misplaced and confuses the prioritisation of actions needed for scaling up diagnostics.

MSF continually scans the landscape of novel diagnostic tests that could be adapted to the constraints of LMICs, including culture-independent diagnostics. Although a long-standing consensus exists on the need for a diagnostic technique or biomarker, or both, that detects bloodstream infections (along with identification and antimicrobial susceptibility testing [AST] of the pathogen) directly from blood without the need for culture, we dispute the view that the reluctance to adopt alternative technologies is owing to professional inertia, outmoded clinical guidelines, and little awareness of new technologies.

In our view, key technical shortcomings of novel non-culture-based platforms, in combination with their high cost, restrict their utility. Existing culture-free systems that perform both identification and AST are highly restricted in scope and can identify only a narrow range of bacteria or therapeutic options. A negative result often requires additional testing and integration into a context-specific algorithm to guide appropriate interpretation and action. Many of these systems rely on genotypic methods to assess susceptibility by detecting resistance genes, which might not correlate directly with the phenotypic expression of resistance and might result in inappropriate utilisation of broad-spectrum options, particularly in the absence of local surveillance data. Although the mindset targeted for change by the WISH report is presumably that prevailing among health-care providers in the high-income country (HIC) contexts and the adoption of culture-independent diagnostics is often even less feasible in low-resource settings (where local surveillance data are often insufficient), technical limitations restrict the contribution of existing culture-free systems in all contexts.

The other primary barriers to the utilisation of new diagnostic technologies are cost and availability. The expense of using and maintaining new systems can be prohibitive, even in HIC contexts. However, in the case of LMICs, access to novel diagnostics in general (as with vaccines, antimicrobials, and other drugs) is severely restricted owing to high product prices and low interest of the private sector in registering their products here, despite the higher burden of infectious diseases in LMICs than in HICs.[7] For example, MSF has long sought a reduction in the price of Cepheid's GeneXpert Diagnostic Testing Technology, which revolutionised the diagnosis of tuberculosis, among other infections.[8] Novel technologies and multiplex platforms that show potential utility in MSF contexts are also unaffordable, such as the T2Dx Instrument (US$100 000 for the instrument, $125–$200 for each T2Bacteria test; T2Dx Instrument figures from an exchange with T2Dx, 2023) or bioMérieux's BioFire ($3210 for the BioFire Respiratory Panel Kit, $107 per test).[9]

Although R&D for new diagnostic tools that will aid diagnosis in both LMICs and HICs meaningfully is crucial, the most immediate priority is scaling up access to microbiological capacity. We echo the conclusion of Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP): "[p]ending the availability of leapfrog technology innovations… we [recommend focusing] on improving, adapting, and implementing conventional, culture-based techniques, including at select districts or first-level referral hospitals…"[10]

The experience of MSF in building microbiology capacity in such first-line contexts (in which development actors are generally absent) confirms the presence of tremendous untapped potential to improve and expand diagnostics through capacity building, even without substantial new outlays of resources.

Technological innovation can also support such capacity building in microbiology; we have developed an artificial intelligence-powered mobile phone-based app called Antibiogo (cited in the WISH report) that allows non-expert laboratory technicians to interpret AST and have witnessed how the same can extend existing capacity when combined with optimised guidance, e-learning, and bench-side training for laboratory technicians.[11]

Innovation needs to be context-adapted and support human resources rather than confound them and drain scarce funds. Resources expended in placing machines for automated AST (such as bioMérieux's Vitek) in laboratories that cannot maintain or sustain them—including by purchasing costly replacement cartridges—might be better channelled towards generating simplified guidance for susceptibility testing tailored to the use of laboratory technicians. Affordable and sustainable access to culture-based diagnostics also requires more diversified production for some sample types than what exists. The automatic blood culture landscape is dominated by two manufacturers (bioMérieux and BD), resulting in high prices and concentrated production that impede access. Pricing and other barriers affect access even to simple, essential tools such as analytical profile index (API) tests.

For many countries, AMR National Action Plans remain unfinanced, given the competing demands for AMR resources. As leaders and global health actors work to operationalise commitments to fight AMR and establish an Independent Panel on Evidence in 2025 to inform action and track progress, expanding access to microbiological capacity, alongside infection prevention and control and antimicrobial access and stewardship, needs to be a priority.[10] We strongly support MAAP's proposal that "tests for pathogen isolation, identification, and AST should be made available in at least 50% of clinical laboratories or accessible to at least 80% of the population".[2] With a scope that goes beyond sentinel sites and accounts for population-based needs, this target can deliver not only surveillance data but also clinical benefit for the affected individuals when implemented alongside other forms of context-adapted capacity building. World leaders should recognise how indispensable this target is in the global struggle against AMR and make every effort to meet the target forthwith, keeping the current and future contributions of technological innovations to diagnosis in perspective.

Although the parallel pursuit of diagnostic R&D towards the future goal of freeing providers from traditional microbiology methods is important, governments (especially those that are major funders) should also recognise their key role in preventing the access gap that routinely characterises the distribution of novel products. Severe, repeated crises in access to medical technologies in LMICs have led the MSF to call for effective monitoring of access gaps, support for pooled procurement efforts, and changes in the R&D ecosystem that would be conducive to timely and affordable access, including enabling geographically diversified production of diagnostics, and therefore, less reliance on a narrow set of nations for these tools.[12–14] Governments have substantial power in the field of R&D

on AMR particularly, in which private sector neglect has prompted public funders to play an increasingly active role.[15,16]

Funders can prioritise products that will meet the most pressing public health needs globally and be most rapidly scalable in diverse contexts (as per WHO-adopted Real-time connectivity, Ease of specimen collection, Affordable, Sensitive, Specific, User-Friendly, Rapid and Robust, Equipment-free, Deliverable to end-users [REASSURED] criteria)[17] and build provisions into R&D funding agreements to ensure that the resulting products will be registered in countries with need, priced affordably and transparently, and licensed in a manner that diversifies manufacturing.[18]

Diagnostic innovation has not transcended the need for culture-based microbiology, but if and when transformational new products do emerge, such products cannot meaningfully advance the struggle against AMR unless they are affordable and accessible in LMICs.

We declare no competing interests. NM is the Scientific Lead for Antibiogo, and Antibiogo was developed by MSF. All the authors currently work or have worked for MSF.

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