GARDP

Global Antibiotic Research & Development Partnership

GLOBAL CHALLENGES

DIAGNOSTICS FOR DRUG-RESISTANT INFECTIONS

CHALLENGES TO DEVELOPING DIAGNOSTIC SOLUTIONS FOR DRUG-RESISTANT INFECTIONS

One of the biggest challenges to stopping the rise and spread of drug-resistant infections is the lack of global access to suitable diagnostics. Having reliable and timely access to diagnostics is essential to ensure that drug-resistant infections are treated with the appropriate antibiotics. By supporting surveillance and patient diagnostic testing, in-country access to diagnostics can facilitate the optimal and appropriate use of antibiotics. Diagnostics also have a key role to play in the development of new antibiotics and in determining the antibiotic needs of countries and healthcare centres, both of which are essential in the fight against antimicrobial resistance (AMR).

Yet, currently, and most acutely in resource-limited settings, there is a lack of access to the diagnostics needed to identify and treat drug-resistant infections, with 47% of the world's population having little or no access to even the most basic diagnostics.[1] In low-income countries, the situation is even worse with this figure rising to 81%. Until suitable and affordable diagnostics are developed and made accessible to clinicians and researchers who are attempting to tackle AMR, we cannot optimally treat patients.

THE BARRIERS

Currently there are huge access gaps in antibiotics across the world and a lack of data is hindering our ability to effectively address this. What we do know is that around 80% of the global AMR burden of disease occurs in low- and middle-income countries (LMICs), and that, according to some estimates, just 6.9% of multidrug-resistant infections in these countries are being treated appropriately because of a lack of access to health care, diagnostics and appropriate antibiotics.[2]

By strengthening our global diagnostic capacity, many of these data gaps could be filled, but doing so presents its own challenges. With only 1–2% of clinical laboratories in 14 countries across sub-Saharan Africa currently undertaking bacteriology testing, many of the countries most in need of diagnostics lack the required facilities and funding.[3] Diagnostics are often developed with high-income country markets in mind. So, given the unprecedented levels of debt many LMICs are now facing, there is a real need for affordable diagnostic tools that are suitable for the needs of high-burden countries.[4]

In the absence of any form of comprehensive global funding for bacterial diagnostics, this will require collaboration among many groups. At the national level, politicians; physician organisations, health professionals, and patients; experts in health technology assessment in public health and in regulation; researchers; diagnostics manufacturers; and the public need to be involved and informed.

GARDP'S ROLE

While GARDP does not directly develop diagnostics, they do form an important part of our mission and underpin our ability to develop and improve global access to much-needed new and effective antibiotic treatments. That is why GARDP supports the development of simple,

low-cost diagnostic tools to identify drug-resistant infections, by working directly and indirectly with partners, and through advocacy efforts. This also includes supporting activities directly related to our products, as well as multi-stakeholder and country-led collaborations like the Global AMR Diagnostics Collaborative (see box).

Part of GARDP's work on diagnostics involves pre-market development support, such as facilitating the biobanking of bacterial samples used in studies to help validate tests, as well as working with partners like the World Health Organization (WHO) to landscape pipeline test products of interest. Similarly, GARDP drives the development of diagnostic tests for antibiotics in our portfolio, such as antibiotic susceptibility tests for zoliflodacin.

On post-market development, our support is more focused on working with countries to align policies and product preferences, to ensure programmatic solutions are built into GARDP's early introduction projects for our portfolio of treatments. For example, with cefiderocol we are conducting novel rapid test performance work with the Pan-American Health Organization (PAHO) and carrying out studies in countries to validate existing susceptibility tests for cefiderocol for test implementation ahead of antibiotic use. Our observational care pathway studies in South Africa and Thailand for gonorrhoea also involve a diagnostic component, as do many of our other studies.

Finally, we also carry out work to support in-country capacity for diagnostics, surveillance and stewardship linked to our antibiotic portfolio. By working with countries and partners, we do facility-mapping, which includes lab capacity and diagnostic capability assessments, to improve our understanding of how clinicians and countries use diagnostics to support their antibiotic guidelines. This kind of work makes it possible to support surveillance and patient diagnostic testing in healthcare settings within priority countries. It also facilitates the optimal and appropriate use of GARDP portfolio antibiotics, and supports data gathering to inform guidance and use.

GLOBAL AMR DIAGNOSTICS COLLABORATIVE

The Fleming Initiative, with the support of GARDP and others, launched a new global collaboration in 2025 that aims to support advances in innovation and accelerate access to diagnostics and their effective use to address AMR. Working with funding partners, implementing countries and regional bodies, this initiative aims to build a coalition of the willing. GARDP is helping to shape the structure and governance of the Global AMR Diagnostics Collaborative, and will be a member of the relevant technical working groups. We will ultimately help build an end-to-end pathway that will make it possible to feasibly embed affordable diagnostics at every level of healthcare.

For more information, visit **www.dxamr.com**.

1. *https://doi.org/10.1016/ S0140-6736(21)00673-5*
2. *https://doi.org/10.1016/ S1473-3099(25)00166-5*
3. *https://doi.org/10.1016/j.lanmic.2024.100976*
4. *Landscape analysis of commercially available and pipeline in vitro diagnostics for bacterial priority pathogens. Geneva: World Health Organization; 2025.*