

## THE IMPORTANCE OF DIAGNOSTICS

Diagnosis is the first step on the path to health. Testing is essential not only for individual disease management but also for protecting public health more broadly. Diagnostics save lives, enable health systems to make better use of their resources, and provide early warning of emerging health threats.

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### WHAT IS ANTIMICROBIAL RESISTANCE?

Antimicrobial resistance (AMR) is one of the top three threats to global health security. In 2021 alone, it directly caused 1.14 million deaths, with nearly 5 million associated deaths when considering related infections. If current trends continue, AMR could directly cause 39 million deaths globally between 2025 and 2050.

Antimicrobials, which include antibiotics (inhibit bacterial growth) and antifungals (inhibit fungal growth), are used to treat and prevent infectious diseases in humans, animals, and plants. AMR arises when microorganisms adapt to survive exposure to these drugs.

Overuse or misuse of antimicrobials accelerates resistance: susceptible microorganisms are killed, while resistant strains survive and multiply, making infections harder to treat. Resistant infections lead to increased morbidity and mortality, longer hospital stays, and higher healthcare costs.

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### THE IMPORTANCE OF DIAGNOSTICS IN AMR

Without timely and accurate diagnostics, healthcare providers often rely on empirical treatment with broad-spectrum antibiotics. While intended to provide immediate care, this approach can be ineffective if infections are viral or caused by resistant bacteria, and this increases the risk of AMR.

#### Diagnostics are essential for:

- **INDIVIDUAL PATIENT CARE:** Diagnostics enable identification of specific pathogens and their susceptibility or resistance, ensuring patients receive the most effective treatment. This improves outcomes, prevents complications, reduces healthcare costs, and minimises the risk of missed or delayed diagnoses.
- **PRESERVING EXISTING AND NEW ANTIBIOTICS:** By ensuring that appropriate and effective treatments can be initiated promptly, they safeguard the long-term effectiveness of existing antimicrobials.
- **PUBLIC HEALTH PROTECTION:** By facilitating early detection of resistant microorganisms, they enable effective outbreak investigation and inform surveillance networks.

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### HOW FIND ADDRESSES ANTIMICROBIAL RESISTANCE

FIND aims to reduce the public health threat of AMR in LMICs by ensuring diagnostics are available, accessible, and effectively utilised across all levels of the health system. Key outcomes of this effort include promoting the appropriate use of antimicrobials and improving patient outcomes.

FIND's efforts focus on areas where diagnostics can have the most substantial and immediate public health impact within LMIC health systems.



➤ **Every year in sub-Saharan Africa, there are 600 million cases of childhood fever.**

Without access to diagnostic testing at the primary health care level, parents and healthcare providers cannot be certain whether the fever is due to malaria, Ebola, yellow fever – or just a common cold that may not need treatment at all. And because the treatment for each is different, prescribing the wrong medicine may not only make the child's health worse but it could also lead to AMR.

## STRATEGIC OBJECTIVES

- 1 Preserve new and existing antibiotics by diagnostic-driven stewardship at the primary healthcare level
- 2 Close the gap around the lack of diagnostics to manage serious bacterial infections (Level 2)
- 3 Support use of AMR data for action (surveillance)

## KEY FOCUS AREAS FOR DIAGNOSTIC IMPACT

- Sexually transmitted infections (STIs)
- Newborns with suspected severe infections
- Serious bacterial infections (Bloodstream infections/resistant infections)
- Viral vs. bacterial infections

## PILLARS OF THE APPROACH

- **ENGAGE & DEFINE NEEDS:** Work with countries and global stakeholders to identify AMR diagnostic priorities.
- **IMPROVE ACCESS & ADAPTATION:** Increase availability and appropriate use of existing diagnostics; adapt tools for LMIC contexts.
- **INNOVATE & EVALUATE:** Develop affordable, fit-for-purpose diagnostic solutions; integrate AI and machine learning tools to provide diagnostic accuracy, clinical decision support, and for predictive surveillance; evaluate performance, impact, and cost-effectiveness in real-world settings.

## HOW FIND SUPPORTS COUNTRIES IN TACKLING AMR

### CASE STUDY 1: DEVELOPMENT OF A NEISSERIA GONORRHOEAE (NG) LATERAL FLOW ASSAY

The project began in 2018 with a review of existing diagnostics and the development of a target product profile in collaboration with WHO and GARDP. FIND partnered with DCN DX to develop the lateral flow assay (LFA), alongside an affordable reader adapted for low-resource settings. Pilot clinical evaluations started with the University of Alabama, and the LFA design was finalised in March 2021.

Subsequent clinical, usability, and acceptability studies were conducted in South Africa, with additional evaluations for asymptomatic cases in South Africa and Zimbabwe (2023–2024), and antenatal care studies initiated in Papua New Guinea and South Africa in 2025. Technology transfer and an investment case for South Africa are currently being implemented. Commercialization of the LFA is due in 2026.

The project is now advancing an LFA for chlamydia, aiming to develop a multiplex test that could potentially diagnose NG and chlamydia in a single assay. This work is being conducted with the U.S. CDC and the University of Southern California, with verification, validation, regulatory approval, and market strategy expected in 2025–2026.

### CASE STUDY 2: DEVELOPMENT OF ONE HEALTH AMR SURVEILLANCE SYSTEM IN KENYA AND NEPAL

In Kenya, FIND supported integration of human and animal health (the “One Health” approach) AMR data at the national AMR data repository and developed the One Health AMR Surveillance System (OHAMRS). The OHAMRS comprises two core digital components: interoperability middleware for integrating data from various sources and a DHIS2 web portal for the analysis and visualization of AMR surveillance data from the human and animal health sectors.

These components are scalable for future inclusion of data from other One Health sectors, e.g., the environment, food/feed, and aquaculture sectors. The priority pathogen dashboards provide visualization of antimicrobial susceptibility patterns, resistance and susceptibility trends, resistance tables, and geospatial susceptibility maps. Other dashboards include surveillance sites and specimen reports, data completeness, data reconciliation, sample testing workload, a One Health intersectoral dashboard, and other reporting tools for diverse stakeholders.

➤➤ **Five IVD products**  
in the pipeline

➤➤ **Seven IVD studies**  
in sub-Saharan Africa and Asia

➤➤ **516 clinicians**  
trained on antimicrobial and diagnostic stewardship initiatives as well as surveillance of both hospital-acquired infections and antimicrobial resistance

➤➤ **58 health facilities**  
in India and Kenya assessed for AMR diagnostic capacity

➤➤ **Supported WHO with pilot national survey**  
carried out in an LMIC to determine the prevalence of AMR in bloodstream bacterial infections

➤➤ **Five diagnostic landscapes published**  
on neonatal sepsis, STIs, fungal infections, blood culture/ID/resistance and ESKAPE GBS Resistance.