



EXEMPLARS AND INNOVATIONS IN DIAGNOSTICS

EXEMPLARS OVERVIEW

The Exemplars in Global Health (EGH) program is a global coalition of partners including researchers, academics, experts, funders, country stakeholders, and implementers. Our mission is to identify positive global health outliers, analyze what makes countries successful, and disseminate core lessons so they can be adapted in comparable settings. We aim to help country-level decision makers, global partners, and funders make strategic decisions, allocate resources, and craft evidence-based policies. A small, core team supporting EGH is based at Gates Ventures, the private office of Bill Gates, and closely collaborates with the Bill & Melinda Gates Foundation.

RESEARCH PARTNERS

This project was designed by a team consisting of researchers from the EGH program, the Research Institute of the McGill University Health Centre and FIND, a non-profit diagnostics partnership.



TECHNICAL ADVISORY GROUP

Research for every Exemplars in Global Health topic is guided by a Technical Advisory Group (TAG), consisting of a diverse range of topic-specific experts. The Diagnostics TAG consists of:

- Dr. Marguerite Loembe** (Former Senior Science Manager, African Society for Laboratory Medicine (ASLM) and TAG chair);
- Prof. Kenneth Fleming** (Chair of Lancet Commission on Diagnostics);
- Dr. Pascale Ondo** (Medical Laboratory Specialist, The Global Fund to Fight AIDS, Tuberculosis and Malaria);
- Dr. Kayla Laserson** (Director for the Global Health Center (GHC), Centers for Disease Control and Prevention);
- Dr. Yogan Pillay** (Director of HIV and TB delivery, Bill & Melinda Gates Foundation);
- Dr. Kamini Walia** (Senior Scientist, India Council of Medical Research);
- Dr. Emma Hannay** (Independent Consultant in Global Health);
- Dr. Trevor Peter** (Head of Diagnostics, The Clinton Health Access Initiative);
- Prof. Andrew Vallely** and **Dr. Philip Cunningham** (Kirby Institute at the University of New South Wales (UNSW) in Sydney)

TOPIC OVERVIEW

Forty seven percent of the global population have little or no access to appropriate diagnostic services. Despite being fundamental to delivering quality care, the role of diagnostics in health care delivery has been overlooked, with substantial burden carried by low-and middle-income countries. Improving access to diagnostics is key to achieving health equity and universal health coverage.

The goal of this project is to generate evidence that can support innovators, implementers, and decision-makers in closing the diagnostics gap for communicable and non-communicable diseases. To do so, we are looking across the diagnostics value chain (Figure 1) to study Innovations and Exemplars.

- Innovations** are products or diagnostic tools that have high potential to close the diagnostics gap, ranging from upstream research and development to global policy.
- Exemplars** are countries that have successfully implemented programs to improve rates of screening, testing, and linkage to care.

INNOVATION SELECTION PROCESS

Four criteria were considered to identify innovations: a) first-in-class technologies, b) novel technologies, c) tested on nonconventional specimen types, and d) people oriented. Innovations to be studied were vetted by the TAG. Based on these criteria, three diagnostics were selected for study:

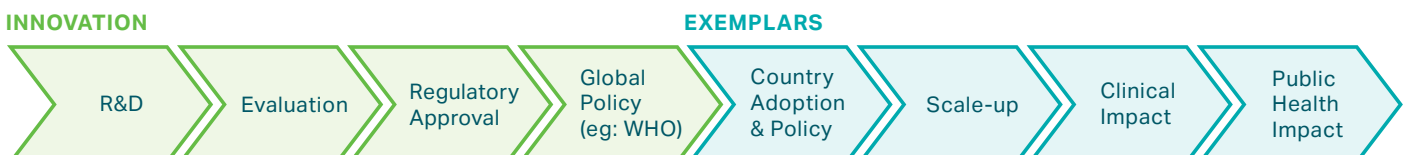
- rapid diagnostic test for human African trypanosomiasis,
- HIV self-tests, and
- continuous glucose monitoring.

EXEMPLARS SELECTION PROCESS

The Exemplars arm defined specific use cases by seeking input from stakeholders who could benefit from the findings. This led to a focus on HIV testing, integrated testing during antenatal care (ANC) visits, and diabetes testing. To select the Exemplar countries to study, a topic-specific multi-step process was used, considering improvement in the rates of testing and absolute diagnostic coverage, as well as representativeness such as disease burden and geographic region. The selection approach was vetted by the TAG. Based on these criteria, the Exemplar arm selected three countries for study:

- HIV testing in Zimbabwe,
- Integrated ANC testing in Rwanda, and
- Diabetes testing in Sri Lanka.

FIGURE 1 | INNOVATION AND EXEMPLARS ACROSS THE DIAGNOSTICS VALUE CHAIN





METHODOLOGY

When studying both Innovations and Exemplars, a mixed-methods approach was used to assess characteristics of successful innovations and learn factors that contributed to the successful delivery of diagnostics services for selected topics (Figure 2 and 3).

KEY INSIGHTS

Each case study consists of quantitative data analysis, literature reviews, and key informant interviews.

Innovations

The innovations studied improved access to testing at lower levels of care, vulnerable populations and first-time users such as MSM for HIV self-testing.

- Enablers of success include:
 - » WHO's leadership and commitment and strong global funding sources for HAT RDT to accelerate elimination.
 - » Autonomy and self-empowerment, privacy, confidentiality, convenience, opportunity to test, and ease of use for HIV self-testing.
- Regulatory systems for HIVST kit approvals both at WHO PPQ level and in-country approvals require further development. Currently, the regulatory process is lengthy and resource-intensive, which can be off-putting to manufacturers.

Exemplars

Success achieved in HIV and integrated testing during ANC visits was enabled by:

- Government ownership and increased awareness through civil society awareness action.
- Effective use of resources, removal of financial barriers to testing services, and increased availability of testing services in the community.
- Ensuring the readiness of the health system to deliver testing services through task shifting, training and mentoring healthcare providers, as well as ensuring availability of testing supplies at lower-level facilities.

FIGURE 2 | CONCEPTUAL FRAMEWORK (INNOVATIONS)

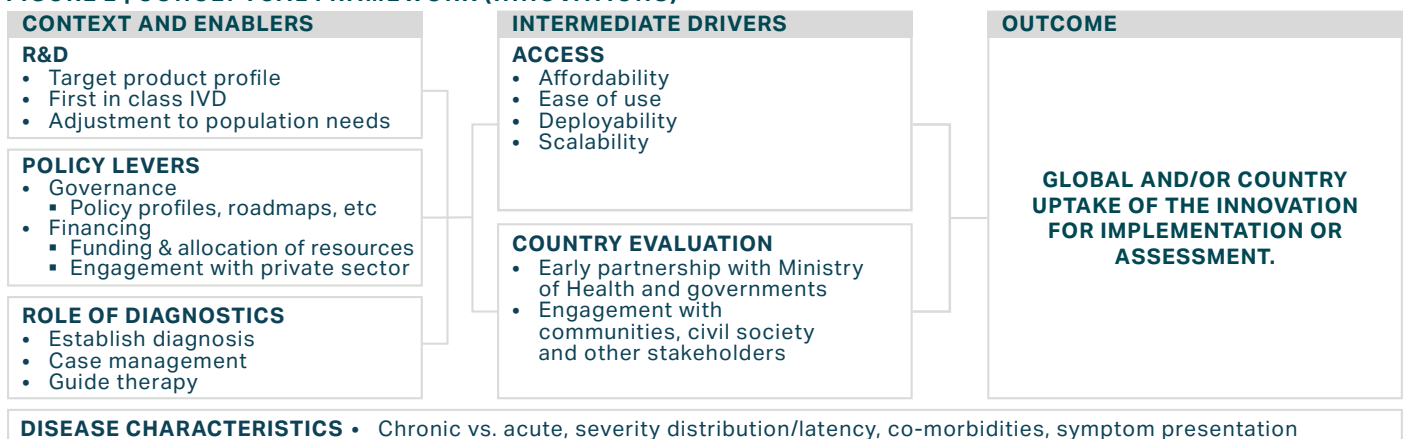


FIGURE 3 | CONCEPTUAL FRAMEWORK (EXEMPLARS)

