



EXEMPLARS AND INNOVATIONS IN DIAGNOSTICS

EXEMPLARS OVERVIEW

Exemplars in Global Health (EGH) brings together experts, funders, and partners around the world with the mission of identifying positive global health outliers, analyzing what makes countries successful, and disseminating core lessons so they can be adapted in comparable settings. EGH aims to help country-level decision makers, global partners, and funders make strategic decisions, allocate resources, and craft evidence-based policies. EGH is based at Gates Ventures, the private office of Bill Gates, and collaborates with the Bill & Melinda Gates Foundation.

INNOVATION SELECTION PROCESS

When considering which innovations to study, we focus on four key requirements:

1. Be first-in-class technology
2. Have no previous diagnostics (i.e., novel technology)
3. Been tested on nonconventional specimen types
4. Be people oriented

COUNTRY SELECTION PROCESS

To select Exemplar countries, we are using a unique country selection process for each case study based on the topic or disease being studied. For the first Exemplar case study, we used a four-step approach outlined in Figure 2 and vetted the final top candidates with experts and the TAG before selecting the Exemplar country.

EXEMPLAR COUNTRY AND INNOVATION CASE STUDIES

The first case studies focused on: (1) the innovation of rapid diagnostic test (RDT) for human African trypanosomiasis (HAT), and (2) studying the positive outlier in HIV testing where Zimbabwe emerged as the Exemplar country. The second case studies are exploring: (1) HIV self-tests as an innovation, and (2) the Exemplar country in diagnostics during antenatal care visit. Future case studies will be selected based on information need from stakeholders.

TOPIC OVERVIEW

47% 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 (LMICs) and low-income groups in high-income countries. Improving access to diagnostics is key to achieving health equity and Universal Health Coverage (UHC).

This project has two aims:

1. Identify **innovations** (e.g., products or diagnostic tools) that have high potential to close the diagnostics gap and ranges from R&D to global policy.
2. Identify **Exemplars** (e.g., countries that successfully implemented programs in screening, testing, and linkage to care within the cascade of care). This spans from global policy to clinical and public health impact on the diagnostics value chain (Figure 1).

This project will be conducted in "sprint" format case studies (each with a ~3-4-month study duration). Exemplar countries and innovations are chosen based on the information need identified by stakeholders and partners.

Findings will describe key lessons from each innovation or Exemplar country. This work will generate evidence to support innovators, implementers, and decision-makers in designing strategies (such as the development of new technologies, the formation and prioritization of new policies, and resource mobilization and optimization) to close the diagnostics gap within the cascade of care for infectious diseases and non-communicable diseases (NCD).

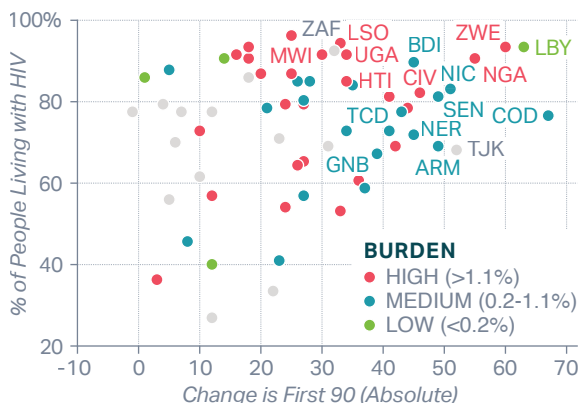
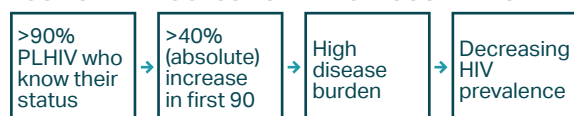
Technical Advisory Group

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 (Senior Science Manager, African Society for Laboratory Medicine (ASLM) and TAG chair); **Prof. Kenneth Fleming** (Chair of Lancet Commission on Diagnostics); **Dr. Pascale Ondo** (Director of Science and New Initiatives, ASLM); **Dr. Kayla Laserson** (Deputy Director of Infectious Diseases and Vaccine Delivery, Bill and Melinda Gates Foundation, India); **Dr. Yogan Pillay** (Director of HIV and TB delivery, Bill and Melinda Gates Foundation); **Dr. Kamini Walia** (Senior Scientist, India Council of Medical Research); **Dr. Emma Hannay** (Chief Access Officer, FIND); **Dr. Trevor Peter** (Head of Diagnostics, CHAI); **Prof. Andrew Vallely** and **Dr. Philip Cunningham** (Kirby Institute at the University of New South Wales (UNSW) in Sydney)

FIG. 1 | INNOVATION AND EXEMPLARS ACROSS THE DIAGNOSTICS VALUE CHAIN




**FIG. 2 | APPROACH TO SELECT HIV
DIAGNOSTICS EXEMPLAR**

FOUR STEP PROCESS TO NARROW COUNTRIES

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.



McGill
UNIVERSITY

FIND 
Diagnosis for all

METHODOLOGY

When selecting and studying the Innovations and Exemplars, we are using a mixed methods approach to assess characteristics of each innovation that enable its potential to accelerate progress in diagnosis and learn how Exemplar countries achieved successful diagnostics service delivery by testing everyone who needed to be tested (Figures 3 and 4).

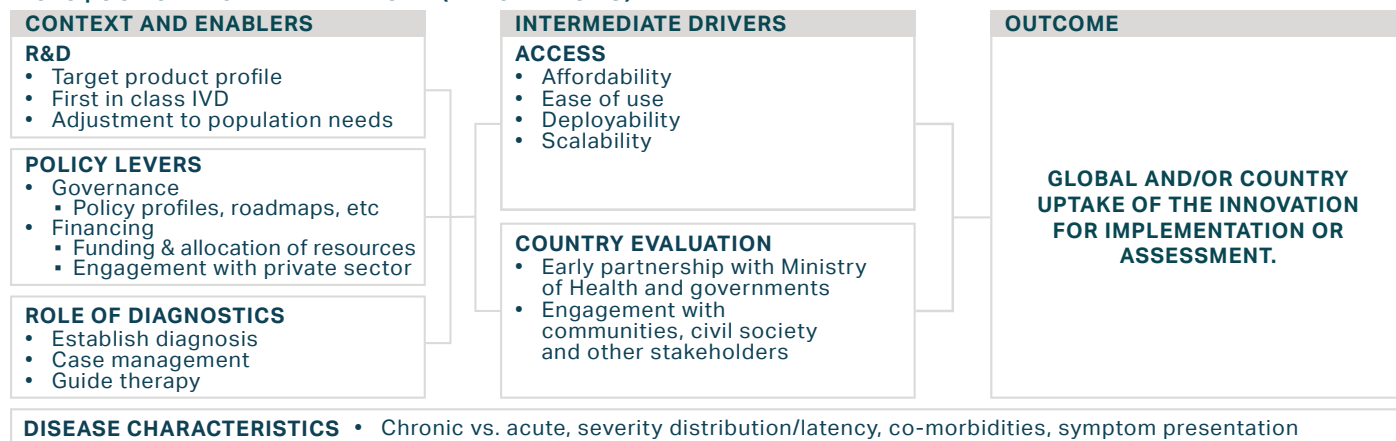
EMERGING FINDINGS
Rapid diagnostic test (RDT) for human African trypanosomiasis (HAT)

- HAT RDTs improved access to HAT screening at lower levels of care and hard-to-reach populations
- Success was enabled by the World Health Organization's leadership and commitment to accelerate the control and elimination of HAT in combination with strong global funding sources
- Early engagement with different governmental and non-governmental country stakeholders to complete development and obtain regulatory approvals contributed to the success of this HAT RDTs

HIV testing in Zimbabwe

Success achieved in HIV testing was enabled by:

- High knowledge of HIV and where to go get tested among residents
- Increased community-based testing and anonymous HIV testing that reduced stigma
- Government and civil society awareness campaigns
- Testing of key population groups such as pregnant women
- Effective use of resources

FIG. 3 | CONCEPTUAL FRAMEWORK (INNOVATIONS)

FIG. 4 | CONCEPTUAL FRAMEWORK (EXEMPLARS)
