



THE MOST EFFECTIVE WAY TO DEAL WITH THE THREAT FROM THE SPREAD OF INFECTIOUS DISEASES IS AT THEIR SOURCE. ACCORDINGLY, DIAGNOSTICS SHOULD BE AT THE FIRST LINE OF DEFENSE.

GUEST COMMENTARY

CLARION CALL FOR DIAGNOSTICS

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As the world continues to become more interconnected, the ability of health organizations to deal with world health threats is growing ever more complicated. Existing and emerging pathogens, which do not respect national borders, will rapidly create epidemics, and the world health community will continue to be insufficiently prepared to deal with them effectively.

It is obvious that the most effective way to deal with the threat from the spread of infectious diseases is at their source. Accordingly, diagnostics should be at the first line of defense. Diagnostics play a crucial role in case management, disease control and surveillance, and the absence of effective diagnostics inhibits populations from receiving effective treatment. When there are no effective vaccines or therapeutics, the only measure available to stop the spread of infections is the rapid identification of infected patients.

The Ebola epidemic, spread through physical contact and claiming over 10,000 lives, is just one of several flare-ups this century. Many of the lives lost could have been saved had an effective rapid diagnostic test been available to confirm suspected infection, isolate infected individuals for treatment and prevent them from continuing to infect others.

Imagine what the death toll would have been if Ebola were spread through the air, like Middle East respiratory syndrome coronavirus (MERS-CoV), with a single infected individual in a public place capable of infecting an untold number of persons. The MERS-CoV outbreak in South Korea quickly claimed 24 lives and required quarantining of villages and the closure of thousands of schools.

Emerging diagnostics also have the potential to be at the forefront of battling antimicrobial resistance by providing rapid and precise diagnosis, enabling early refinement of the antibiotic therapy. It is estimated that

more than 500,000 deaths from resistant infections occur in the world annually. This is caused to a large extent by a failure to accurately diagnose the infections, resulting in the overuse of the already dwindling arsenal of effective antibiotics and the further spread of resistance.

In addition, experience has shown that disease threats can impose a devastating impact on health systems in low- and middle-income countries, as well as enormous economic impact on the global economy. The economic impact from Ebola on West Africa has yet to play out, but a report from the United Nations estimated that it will cost up to \$15 billion over the next three years from the loss of trade, investment and tourism.

On a global scale, the SARS breakout is estimated to have cost the world's economy \$40 billion in a mere four months. And a worldwide flu epidemic, according to the World Bank, would reduce global wealth by as much as \$3 trillion.

The world health community has acknowledged that effective diagnostics are needed to address the diseases afflicting low- and middle-income countries. However, meaningful efforts to provide resources for their development are lacking.

Take for example the Global Health Security Agenda, organized in 2014 by the Centers for Disease Control and Prevention to track the spread of infections and enable the deployment of effective countermeasures. While diagnostics were recognized as an important ingredient to success, the initiative is pitifully underfunded in general and is thus hampered from providing meaningful funds for diagnostic development.

Other strategies need to be pursued to bring additional resources to bear on the problem.

SOURCES OF SUPPORT

While the time, expense and development complexity for a diagnostic is significantly less than the cost of developing a vaccine or therapeutic, it can run into the tens of millions of dollars and is a significant barrier for diagnostic manufacturers, many of which are small companies with novel technology but only limited capital.

The Ebola crisis, perhaps because of the fear it engendered around the world, has been a catalyst for over 70 companies to include Ebola diagnostics in their R&D portfolios, despite the dearth of external funding to defray investment costs.

However, other infections that take an even greater toll on world health do not garner sufficient funding for diagnostics, such as those targeted by the London Declaration on Neglected Tropical Diseases: HCV, tuberculosis, malaria and HIV.

Take for example HCV. There are an estimated 130-150 million infected individuals worldwide and 350,000-500,000 deaths annually, mostly in low- or middle-income countries. There is a need to rapidly identify patients who are eligible for treatment; however, HCV is severely underdiagnosed because the existing tests are complex, expensive and can be performed only at centralized laboratories, which are lacking in many of these countries.

Historically the public sector and the [Bill & Melinda Gates Foundation](#) have been the principal funders of diagnostics for the developing world; however, there is no reason why industries with a high burden of incidence of these communicable diseases among employees cannot be tapped to provide funding. For example, the mining industry in South Africa and other endemic countries should have an economic and humanitarian interest in safeguarding the health of employees.

Also, while many governments in countries where certain diseases are endemic may not be able to provide funding for diagnostics, they may have the ability to contribute clinical trial support in their own facilities, thereby defraying a good part of the cost of diagnostic development.

Even if economic programs can be devised to induce manufacturers to undertake development of diagnostics, the challenge of successful development and introduction should not be underestimated. For a diagnostic to be effective in low- and middle-income countries, it needs to meet the [World Health Organization's](#) ASSURED criteria: affordable, sensitive, specific, user-friendly, robust and rapid, equipment-free and deliverable.

In addition, these diagnostics need to perform under difficult conditions such as villages across Africa and other parts of the world where there may be a dearth of health facilities with access to reliable power sources.

Meeting a target product profile for these settings is a major challenge for developers. Thus providing manufacturers with scientific and regulatory expertise through not-for-profit organizations, such as FIND (the Foundation for Innovative New Diagnostics), can reduce costs and development time.

Organizations such as FIND can catalyze development by identifying needed diagnostic solutions; and provide technical, disease and market and regulatory expertise; and remove barriers to development. They also can guide policy on use and market entry, support uptake and appropriate use, and help improve understanding of the value of diagnostics and strengthen commitment to their funding and use.

An example of the success of this type of support from FIND is the Xpert MTB/RIF tuberculosis assay from [Cepheid Inc.](#) It transformed drug susceptibility tests to enable detection of TB and resistance to rifampicin, the key component in the established first-line treatment regimen. Xpert replaced a test that used to take 120 days at a reference-level laboratory; now test results are available in 90 minutes and can be done at local laboratories. The test was rolled out to over 120 countries in less than two years. Other examples of diagnostics that were developed by FIND for low- and middle-income countries were in malaria and sleeping sickness.

A broad coalition of stakeholders, including diagnostic-focused product development partnerships, the WHO, governments, ministries of health and public and private donors — if collaborating regularly — can leverage their respective resources and expertise to enhance the development, introduction and rapid uptake of a new diagnostic. [BC](#)

COMPANIES AND INSTITUTIONS MENTIONED

[Bill & Melinda Gates Foundation](#), Seattle, Wash.

[Cepheid Inc.](#) (NASDAQ:CPHD), Sunnyvale, Calif.

[FIND](#) (Foundation for Innovative New Diagnostics), Geneva, Switzerland

[U.S. Centers for Disease Control and Prevention](#) (CDC), Atlanta, Ga.

[World Bank](#), Washington, D.C.

[World Health Organization](#) (WHO), Geneva, Switzerland