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Back to the Future of Global Health Security

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Growing populations, rising global temperatures, urbanization, and easier trade and travel are all changing the world in ways conducive to the spread of infectious disease. The recent **Ebola** and **Zika** outbreaks have dominated news headlines and their toll has been terrible, but a more lethal infectious disease could do **far worse** harm.

"For infectious diseases, you cannot trust the past when planning for the future," **warned Margaret Chan**, the head of the World Health Organization (WHO), at the World Health Assembly last week in Geneva. "What we are seeing," she said, is "a dramatic resurgence of the threat from emerging and reemerging infectious diseases. The world is not prepared to cope."

A health worker fumigates inside a home in a neighborhood after Nicaragua's government declared an epidemiological alert due to the increase of dengue cases and Zika in Managua, Nicaragua May 9, 2016. (Photo: Oswaldo Rivas/Reuters)

To improve pandemic preparedness we must embrace the hard-won lessons of the past decade in

global health, not ignore them. This is true in deploying people and resources to prepare for the inevitability of future outbreaks, but even more so when it comes to accelerating the development of the medical tools to diagnose, treat, and prevent those infectious disease outbreaks from turning into epidemics, or even pandemics.

After Ebola and Zika

After widespread concerns over the global response to the Ebola crisis, four separate review panels convened and made **similar recommendations** for improving the WHO's capacity to manage dangerous disease events. Most of the proposed reforms are sensible, but depend on institutional, financial, and legal commitments that WHO member countries have been unwilling to make **for more than a decade**.

While the Ebola and Zika epidemics and rising alarm over **yellow fever** should motivate WHO member countries to do more, it is not self-evident that they will. Similar concerns were also expressed following outbreaks of **SARS (2003)**, **H1N1 (2009–2010)**, **MERS (2012)**, and **Chikungunya (2014–15)**. There may be more hope for creative approaches to capacity building. The new **World Bank Pandemic Emergency Financing Facility** (a $500 million outbreak insurance mechanism for poor countries) and **the alliance** for country-led assessment of compliance with the International Health Regulations (the legal rules supporting global health security) must be expanded and better resourced, but they are moves in the right direction.

Particularly given the slow pace of WHO reform and lagging improvements in countries' surveillance and response capabilities, the role of groundbreaking innovations in medical technologies will be critical. Diagnostics, prophylactics, and treatment aren't the only answers to the increasing threat of emerging infectious disease, but they can help control epidemics early and ensure the sustained engagement of medical personnel and volunteers.

Successfully spurring more development of medical tools won't come primarily from extending the capacities of governments or intergovernmental institutions. Instead, it depends on inspiring, enabling, and coordinating the activities of the private sector, academia, and nonprofits. Each participant has a critical role to play. Governments bring their public health mandate, resources, and regulatory oversight. The private sector offers critical technologies, manufacturing assets, and expertise in commercializing and scaling innovations. Nonprofits and academic institutions have research and development capabilities, global reach into poor communities, and the mission to work on tough issues where markets otherwise fail.

All of these roles are essential, but they aren't often well aligned. In the two years since the Ebola

outbreak in West Africa began, hundreds of millions of dollars have been invested in clinical trials for **more than a dozen** drug and vaccine candidates, but no vaccine or drug for Ebola has been submitted for regulatory approval. And while it's been nearly **a year** since reports first linked birth defects to the Zika virus in Brazil, there are still no adequately sensitive diagnostics to test for the virus and no clear vaccine candidate to prevent it.

Lessons From the Last Decade in Global Health

With more outbreaks on the horizon, we can't afford to repeat this cycle of uncertain priorities and wasted time and investments. International mechanisms must be established to coordinate the upstream research and development (R&D) of new medical tools to respond to priority pathogens and the downstream testing, manufacturing, and delivery of those tools as part of the larger humanitarian response to an ongoing outbreak. These mechanisms may need to be governed separately, with the former operated as an independent entity or R&D network and the latter attached to an intergovernmental institution with the mandate and credibility to work with manufacturers and pandemic response and regulatory authorities.

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The following four lessons from past efforts to spur more technological innovation to address health needs of the world's poor may provide ideas on how these mechanisms might function.

Lesson 1: Ensure adequate and sustainable long-term investment

Technological innovation requires predictable, sustained, and sufficient investment. Annual R&D funding for HIV/AIDS, malaria, and other infectious diseases rose to **nearly $3.4 billion** in 2015, a more than thirtyfold increase from a decade ago. While still a modest amount when measured against the wide range of health challenges that disproportionately affect the 5.7 billion people living in low- and middle-income countries, it is driving significant improvements in everything from maternal and childhood mortality to life expectancy. Perhaps the most dramatic example is the **MenAfriVac vaccine**. Developed and introduced by PATH and the WHO in 2010 for just 50 cents per dose, after years of sustained investment it has now been given to more than 230 million people and nearly eliminated the epidemics that regularly killed thousands in the African meningitis belt.

Ad hoc funding requests are not conducive to an effective pandemic response, and they all but guarantee that the essential work of medical R&D will not be successful. Even amid political wrangling between the White House and the U.S. Congress over the latest emergency funding request (for Zika)

there is bipartisan interest in medical R&D. The negotiators should take advantage of that interest to pursue a more flexible, robust, and long-term appropriation of R&D funds. Those resources should not come at the expense of U.S. investments in health systems and surveillance needed to advance global health security.

Additional U.S. investments should be used to seed a more effective, long- term global response to the shared challenge of global health security. Governments from around the world must also shoulder more of the responsibility for investing in the necessary R&D. While more sustained donor investment is necessary, it is unlikely to be sufficient to achieve the global health security agenda. Innovative financing mechanisms can create incentives to draw in private finance and returnable capital in this challenging just-in-time environment.

Lesson 2: Coordinate R&D around a roadmap of priority goals

The rush of companies and nonprofits to pursue drug, vaccines, and diagnostic candidates amid a global health crisis is laudable but unsustainable. Medical technology R&D costs increase greatly with later stage clinical development. The trials sites and researchers necessary to support that work are scarce. Companies and NGOs that devote significant resources to respond to one outbreak with nothing to show for it are unlikely to do so again.

The United States, working together with other governments, donors, and technical agencies, should set up an independent scientific advisory committee to develop a roadmap to accelerate development of vaccines and diagnostics to improve global health security. This roadmap should focus on pathogens where more market mechanisms for R&D have failed, and prioritize the development of platform technologies that can be used against multiple diseases. The WHO has **already developed** a preliminary list of target pathogens. The Scientific Committee should monitor compliance with the roadmap and be linked to the global fund or networks of funders established to support this work. The funding must be sufficient to cover the cost to private companies of foregoing commercially viable projects to work on drugs or vaccines against these high-priority pathogens.

Lesson 3: Engage and energize a network of geographically distributed multi-sector partners

Researchers and manufacturers in emerging economies play an increasingly central role in global health. For instance, the low per-dose cost and wide reach of MenAfriVac was possible only because of the engagement of the Serum Institute of India, the vaccine's manufacturer. Investments in global health security R&D should not disproportionately favor multinationals at the expense of innovators in emerging economies, who often have the cost structures and ability to respond to domestic markets in ways that global players may not.

Being prepared requires a plan that identifies and commits geographically distributed rapid development and manufacturing facilities to respond to epidemics, with negotiation of the necessary contractual arrangements in advance. Broad geographic engagement of private, public, and social sector partners will help diminish concerns that manufacturers may, in a crisis, prioritize national or commercial interests over global health needs. The **2011 agreement on pandemic influenza preparedness (PIP) framework** for sharing influenza viruses, access to vaccines, and other benefits may be a model for addressing these concerns.

Lesson 4: Remember that sustainability depends on adequate systems and equitable access

One important lesson of the last decade is that it is not enough to fund global health technologies without the corresponding investments in the regulatory and procurement systems needed to **develop** and **deliver** those technologies and ensure their **post-market safety**. There must be a framework in place that identifies the stringent regulatory authorities that will approve studies and experimental treatments. There must also be clear rules about decision-making processes for "permission to use" investigational medical products. Regional, cooperative approaches to clinical trial oversight and registration **offer a promising** approach for countries with nascent regulatory authorities.

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Product development partnerships such as the Medicines for Malaria Ventures and the Meningitis Vaccine Project have successfully used these principles to create a transparent framework for intellectual property management. This approach provides incentives for private investment in technology development while ensuring the resulting drugs, vaccines, and diagnostics are affordable and accessible, particularly in emergencies. Use of these access principles may be tied to participation in international global health security R&D funds.

Conclusion

Creating a sustainable and coordinated environment for supporting innovation is key to advancing the goal of improved global health security. This is true whether it is investing in "just-in-case" preparedness or a "just-in-time" response to an outbreak. Implementing the hard-learned lessons from the last decade in global health can help achieve this goal while ensuring that the assets, resources, and commitments of partners across various sectors all fully contribute to enhancing global security.