Global Challenges in Focus

Urgent Innovation – Policies and Practices for Effective Response to Public Health Crises

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Introduction

Public health crises require urgent innovation, not only in research and development (R&D) but also in the delivery of therapies and diagnostics. What constitutes "urgency" and "innovation" in these contexts? How are priorities and targets determined? Who is best placed to deliver results? This edition of the *Global Challenges in Focus* series explores themes discussed at a recent Global Challenges Seminar on the policies and practices that facilitate effective responses to global health crises.

"Fortune favors the prepared"

John Reeder, Director, WHO Special Programme for Research and Training in Tropical Diseases – *paraphrasing Louis Pasteur to highlight preparedness as a key factor in responding to emergencies*

Building resilient and responsive health systems

In an increasingly interconnected world, public health emergencies no longer occur in geographical silos. With the movement of people, goods and services across borders, these crises are often defined and discussed in terms of global health security – and yet the greatest factor in preventing the spread of outbreaks is often a single country's preparedness to respond to initial incidences of a disease.

Thus, despite the seeming disparity in "urgency" between the two topics, global health security countermeasures and efforts to strengthen national health systems present two sides of the same coin. Recent emergencies such as the 2014 Ebola outbreak have demonstrated the ways in which weak health systems can significantly hamper response efforts – or even render them completely ineffective. Global, national, and local health systems are complex and, as a result, designing and implementing innovations that are effective within these contexts is an equally complex task. Designing successful interventions is further complicated by the lack of medical professionals, infrastructure, financing, information and delivery systems, and leadership and decision-making capacity that often affects public health emergencies in resource-poor settings.

Emergencies – from disease outbreaks to natural disasters – that occur within these fragile settings often mean limited resources are diverted away from other, more routine yet equally essential, public health interventions. Studies of the 2014 Ebola outbreak in Guinea and Sierra Leone have shown that vaccine administration for a variety of diseases dropped significantly during the outbreak – leading to an exponential increase in incidences of these diseases in the subsequent two years.

Therefore, the first step in formulating our response to future public health crises should be strengthening countries' health systems: increasing their capacity to absorb and implement innovation, both in terms of medical technologies and processes. In order to achieve that goal, we must first innovate our approach to global health dialogue around the intersection of these issues.

Want to learn more?

The World Health Organization's work on strengthening health systems relates to its work coordinating capacity and implementation related to the International Health Regulations (IHR), the agreement between WHO and countries which defines protocols and obligations in the event of an emergency. Kluge, Martín-Moreno, Emiroglu et al. make the case that these two workstreams cannot occur separately from one another, and draw lessons from H1N1 influenza (2009), Ebola (2014) and Zika (2016).

Kluge H., Martín-Moreno J.M., Emiroglu N., et al. *Strengthening global health security by embedding the International Health Regulations requirements into national health systems*. BMJ Global Health 2018; 3:e000656. Available online at: https://gh.bmj.com/content/3/Suppl_1/e000656

Investing in evidence-based decision making and priority setting

Infectious disease outbreaks arise from the interaction between pathogens (bacteria, viruses, or microorganisms that cause disease), hosts (humans or animals), and the environment. With a finite pool of global resources, understanding, predicting and prioritizing where innovation is urgently needed is an essential part of preparing for public health crises. This is even truer when it comes to the time-intensive process of R&D of new medicines, vaccines and diagnostics.

Further exacerbating the situation is that many infectious diseases, often related to conditions of poverty such as lack of access to safe water and sanitation, are considered "neglected." Neglected diseases, which afflict more than a billion of the world's most vulnerable, are so called because a lack of incentives leads to negligible investment in the development of new medicines, vaccines and diagnostics.

The figure above shows the results of a 2018 study on the R&D pipeline for 35 neglected diseases which looked at products likely to be launched by 2040. It found that HIV/AIDS, tuberculosis, and malaria represent a large majority of these innovation efforts, and that over 50% of all product candidates are vaccines, with diagnostics, repurposed drugs, and novel medicines far behind. This data indicates that huge gaps exist, with many high priority products completely missing – reflecting poorly on our preparedness for future infectious disease outbreaks.

Collecting and sharing this kind of data is a critical part of making sure available resources can be directed to the right tasks, and to avoid fractured and inefficient research and prioritization efforts. This means creating platforms to share scientific research and results, mapping on-going global R&D and financing efforts, empowering frontline health workers to gather information about

the impact of interventions, and developing common approaches for the identification and description of priorities. Organizations such as the WHO play a critical role in collecting data on global disease burden and developing target product profiles that inform researchers around the world of urgent, unmet needs for innovation in specific disease areas. This information further provides guidance to governments, informing the development of national strategies and priorities.
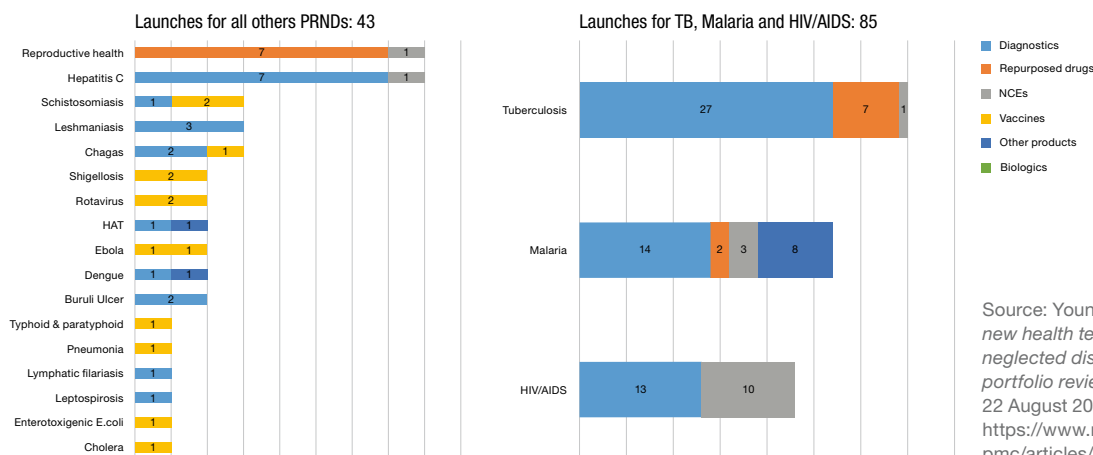
"We're fighting a forest fire with spray bottles"

Katy Athersuch, Senior Advisor, MSF Access Campaign – *recalling a comment from Ella Watson-Stryker, MSF health worker, on the Ebola outbreak in Sierra Leone (2014)*

With rapid advances being made in the field of information technology, the world has more tools than ever at its disposal. However, an important dimension to consider is privacy – creating inclusive, transparent, and neutral mechanisms for ensuring informed consent, good governance and the ethical collection, use and sharing of data. This is an even higher priority when data is being gathered from patient populations in situations of deep vulnerability and stress, and subject to significantly unequal power dynamics.

Sharing data to support innovation

Through initiatives such as WIPO Re:Search, Pat-INFORMED, PATENTSCOPE, and the Access to Research for Development Initiative, WIPO offers access to a broad array of health-related information and resources.

Expected product pipeline through 2040 for 35 neglected diseases

Launches for all others PRNDs: 43

Disease	
Reproductive health	7 / 1
Hepatitis C	7 / 1
Schistosomiasis	1 / 2
Leshmaniasis	3
Chagas	2 / 1
Shigellosis	2
Rotavirus	2
HAT	1 / 1
Ebola	1 / 1
Dengue	1 / 1
Buruli Ulcer	2
Typhoid & paratyphoid	1
Pneumonia	1
Lymphatic filariasis	1
Leptospirosis	1
Enterotoxigenic E.coli	1
Cholera	1

Launches for TB, Malaria and HIV/AIDS: 85

Disease	
Tuberculosis	27 / 7 / 1
Malaria	14 / 2 / 3 / 8
HIV/AIDS	13 / 10

Legend:
- Diagnostics
- Repurposed drugs
- NCEs
- Vaccines
- Other products
- Biologics

Source: Young et al. *Developing new health technologies for neglected diseases: a pipeline portfolio review and cost model.* 22 August 2018. Available online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6139384/

Implementing innovative R&D, financing and access models

In light of the significant gaps in the product pipeline and the limited financial investment in R&D for the diseases most likely to result in public health emergencies, identifying alternative models for innovation is critical. Product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi) and Medicines for Malaria Venture (MMV) function as "virtual" R&D organizations, coordinating and connecting capacities across the globe. Initiatives such as WIPO Re:Search and the NTD Drug Discovery Booster work to repurpose innovation from the private sector, screening compound libraries to test for effectiveness against infectious diseases. These organizations and initiatives often emphasize data sharing, capacity building, broad-based (bench-to-bedside) approaches and access as key components of effective innovation. Many have transparent intellectual property and access policies to signal expectations to partners before entering into collaborations.

Did you know?

"Innovation is not just about developing a product, but perfecting it over time"

Tomas Cihlar, Vice President of Virology, Gilead Sciences – *discussing his work developing antiretroviral therapies to combat HIV/AIDS*

The first **antiretroviral therapies to combat HIV**, developed in 1987, were repurposed anti-cancer compounds that were pushed to market thanks to unprecedented collaborations and shortened regulatory processes. They were far from perfect – patients developed numerous side effects and many developed drug resistance. A creative, concerted approach by scientists through the 1990s led to the development of new classes of drugs and combination therapies, leading to decreased resistance and higher survival rates. With these medicines available, the next stage of innovation was to develop convenient, durable, easily available drugs that could improve the quality of that survival – and were affordable to patients in the developing world. Today, after more than 20 years of innovation, most patients can follow a single tablet regimen and stay on it for years with minimal side effects and without developing resistance. However, with almost one million deaths from AIDS-related illnesses in 2017, lack of access to these therapies is still a major issue.

Others, like the Stop TB Alliance and Gavi, the Vaccine Alliance, further utilize innovative financing mechanisms such as country co-financing, social impact bonds, advanced market commitments, and advanced purchase commitments. The Médecins Sans Frontières (MSF) Access Campaign advocates for systemic changes to ensure patients have access to life-saving interventions.

All of these entities work closely with others to ensure rapid innovation in times of public health emergency. During the 2014-2016 West African Ebola outbreak, no viable medicines or vaccines existed on a large scale. The most healthcare workers on the frontline could do was offer basic care and attempt to suppress the spread of the highly contagious, often fatal disease. A promising vaccine candidate, developed by the Public Health Agency of Canada (PHAC) in 2003 and subsequently licensed to a company called New Link Genetics in 2010, existed but had never been tested in clinical trials. At the beginning of the outbreak, NewLink, PHAC, WHO and the United States National

Institutes for Health met to determine the way forward. The vaccine candidate was licensed to Merck in 2014, and two years later, in March 2016, the resulting vaccine – rVSV-ZEBOV – was tested in Guinea and found to be highly effective.

Although the vaccine is not yet registered for regulatory approval, experimental stockpiles funded by Gavi and permitted for use through WHO compassionate use exceptions, are being employed in the current outbreak in the Democratic Republic of Congo (DRC). This rapid progress represents an unprecedented collaboration between Merck, WHO, the United States, Canada, Guinea, DRC, Gavi and many others.

MSF medical team at MSF's treatment centre in Mangina, North Kivu, DRC, during the 2018 Ebola outbreak (Credit: Carl Theunis/MSF)

Acknowledging the centrality of communities

Health crises begin and end at the community level. Including patients and communities in the process of innovation and adoption is absolutely fundamental to building trust, scaling up and ensuring impact. Deficits in trust leading to community resistance in times of emergency can render response efforts futile. They can even – as seen in the current Ebola outbreak in the DRC – lead to violence against healthcare workers.

Innovations work best when aligned with the priorities of local communities, who may be far more concerned with food, water and other day-to-day realities; they may also have different belief systems about how and why disease occurs. Designing programs that take into account local priorities and beliefs can generate buy-in and create an enabling environment for further innovation, better suited to the realities on the ground.

Building models that listen to, understand, prioritize and co-innovate alongside communities requires emphasizing the importance of other social sciences in diffusing and delivering innovation. Health and risk communicators, anthropologists and sociologists, among others, all have a role to play in ensuring the successful implementation of emergency response programs.

Creating behavioral changes for the rational use of antibiotics

One of the complexities of developing new antibiotics to combat the rising threat of antimicrobial resistance is that the usual R&D and access models do not necessarily apply. While it is important to develop new antibiotics, rational use is a key component of ensuring the longevity of effective antibiotics. Factors such as over-prescription and misuse in both humans and animals lead to faster rates of resistance. Even if new interventions are developed, a great deal of work still needs to be done raising awareness – targeting the general public, medical professionals, policymakers, and the agriculture industry – to catalyze the behavioral changes necessary to ensure continued efficacy of those antibiotics.

Learn more: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

"The message from the communities was, 'You've come here to talk about *your* Ebola.' So, it was our priority, not theirs."

Jason Peat, Team Leader, Health in Complex Settings, IFRC – *on responses to IFRC leadership from communities in North Kivu, DRC where some viewed the outbreak as a foreign, versus local, priority.*

Creating effective collaboration frameworks

The common thread running through each of these themes is that innovation requires collaboration: among scientists, governments, companies, institutions, communities and patients. Prioritizing and putting into place enabling policies, practices, incentives and platforms ahead of time makes it easier to respond collectively and effectively to urgent crises. Whether this collaboration takes place online, in a conference room, over the phone or on the frontlines, pooling resources, expertise and buy-in is the most robust, sustainable way to identify and implement effective solutions to public health emergencies requiring urgent innovation.

"Innovation capacity exists everywhere"

Michelle Childs, Head of Policy & Advocacy, DNDi – *on why partnerships in all regions of the world are so critical within the global health space*

Participants at an April 2019 Global Challenges Seminar discuss urgent innovation in public health crises (Credit: WIPO/Berrod)

About Us

The WIPO Global Challenges Division is responsible for addressing innovation and IP at the nexus of interconnected global issues, with a particular focus on global health, climate change and food security. The Division's activities, including the two multi-stake-holder platforms it administers and trilateral cooperation with the World Health Organization and World Trade Organization, aim to harness the power of innovative partnerships to generate practical solutions for the benefit of all – especially developing countries.