Enhancing GHSA's role in supporting global health R&D to advance health security

GHSA's founding and core mission

Founded in 2014, the Global Health Security Agenda (GHSA) is a collaborative framework bringing together countries, civil society, and UN agencies to enhance countries' abilities to prevent, detect, and respond to infectious disease outbreaks by accelerating progress toward compliance with the International Health Regulations (IHR). The IHR is a legally-binding instrument endorsed by the World Health Organization's (WHO) 196 member states of that lays out requirements for capacities that each country must develop and maintain to respond to infectious disease outbreaks.

As of January, 2018, more than 60 countries have committed to GHSA. Prior to the 2014 West African Ebola outbreak, countries self-evaluated, which did not result in a full understanding of the gaps in national IHR compliance. As a result, as part of their commitment to GHSA, countries agreed to undergo a Joint External Evaluation (JEE), in which they voluntarily invite leading experts in the various IHR capacities to evaluate their actual national capabilities to identify gaps related to IHR compliance. Based on this, the country and its partners would then create a plan—including external support—to undertake steps to build capacity to meet the identified gaps.

GHSA's founding and core mission

To make the IHR requirements more operationalizable, GHSA countries have collectively agreed on 11 "action packages" which translate the IHR into concrete steps to be taken based on the outcome of the JEE. The 11 action packages are divided into three broad categories:

- Prevent:
  - Antimicrobial resistance
  - Zoonotic disease
  - Biosafety and biosecurity systems
  - Immunization
- Detect:
  - Laboratory systems
  - Real-time biosurveillance
  - Rapid reporting
  - Workforce development
- Respond:
  - Emergency operations centers
  - Multi-sectoral response
  - Medical countermeasures and personnel

Each of these action packages consist of target(s), indicator(s), a rationale for the importance of achieving the target, and countries/international organizations committed to helping other countries achieve the target.

Limitations of the current GHSA action packages

While GHSA has been successful in advancing global health security, a key component necessary for the world to be truly prepared to prevent, detect, and respond to emerging infectious diseases is notably missing; as currently structured, the GHSA action packages include no explicit commitment to enhance research and development (R&D) capacities for the broad range of health technologies necessary to

ensure that countries have the tools available within their health systems to respond to outbreaks.

The action package that does include robust, explicit commitments to R&D of new health technologies is Prevent: antimicrobial resistance (AMR), which includes "…collaboration to support the sustainable development of new antibiotics, alternative treatments, preventive measures, and rapid, point-of-care diagnostics…" in the target statement. It further commits countries to "…support initiatives to foster innovations in science and technology for the development of new antimicrobial agents."

While enhanced collaboration and support for R&D on AMR-relevant products is certainly a laudable goal, it does not capture the breadth of activities to support R&D that are necessary to ensure that the world has the proper tools to ensure health security. Collaboration, for example, will not address the fact that there are not functioning markets for novel antibiotics given stewardship imperatives. Similarly, as the world saw with the West African Ebola outbreak in 2014, there are currently very few incentives to develop technologies for emerging/re-emerging infectious diseases outside of AMR in advance of an outbreak, at which point the cost in lives and dollars is far higher than if an investment had been made in proactive R&D. In addition, overcoming the unique challenges to trials for health security products can require significant new capacities that many outbreak-prone countries lack. Building these laboratory, information systems, and oversight capacities is not only good for R&D, but also serves to strengthen the health system overall. Similarly, strengthening regulatory systems to allow for the speedy—but appropriate—uptake of new technologies during an outbreak can help countries increase access to needed products throughout the health system.

Ultimately, achieving health security requires new tools, and developing those tools requires a specialized, supportive environment given the unique characteristics of these tools and their markets (or lack thereof). As the leading global forum for collaborative action on health security, GHSA has a vital role to play in supporting R&D, must do so to achieve overall targets in health security.

The transition to GHSA 2019–2024 offers the GHSA member countries and partners the opportunity to accelerate progress toward health security by explicitly embedding support for global health R&D in a GHSA action package to ensure the world has the necessary medical technologies to prevent, detect, and respond to outbreaks. That action package should include provisions that enhance countries' capacities to:

1. **Conduct clinical trials on emerging/re-emerging infectious diseases.**

2. **Provide incentives to product developers to engage on products/diseases/technologies where there is no market.**

3. **Speed products through appropriate regulatory approvals to allow their quick uptake.**

4. **Collaborate regionally and globally on infectious disease research.**