

Overview

The COVID-19 pandemic has underscored how vital the research and development (R&D) of medical countermeasures is to prevent and combat global health threats. The record-breaking speed at which vaccines, therapeutics, diagnostics, and other tools were developed proved a triumph of modern science. Yet systemic gaps in pandemic-related R&D supply chains, manufacturing, research and surveillance networks, regulatory systems, and delivery infrastructure continue to stymie the rollout of these technologies to all people, everywhere— perpetuating gross power imbalances between high- and low-income nations and exacerbating entrenched inequalities that have left significant portions of the world's population without access to these lifesaving tools. These gaps have also challenged our ability to stay ahead of emerging variants.

While the pandemic has pushed R&D into the spotlight and deepened consensus that R&D is a vital component of health preparedness, a global framework or process to assess and strengthen national and global R&D readiness is not included in *any* current governance and coordination mechanisms for health security. R&D is not formally addressed in the International Health Regulations (IHR), the Joint External Evaluation (JEE), or the Global Health Security Agenda's (GHSA) 2024 framework. In recognition of this gap and the urgent need to strengthen R&D capacities for health preparedness, in June 2021, the GHSA Steering Committee approved the launch of a one-year pilot R&D Task Force dedicated to improving R&D readiness. Given the crosscutting nature of R&D, and its relevance to several different GHSA action packages, a task force was deemed the most fitting model through which to advance this work.

R&D Task Force goals

The GHSA R&D Task Force was established with several clear goals and objectives:

- Galvanize acknowledgment of R&D as a critical component of health preparedness among policymakers and health decision-makers.
- Assess current barriers and bottlenecks for R&D of medical countermeasures, especially in low- and middle-income countries (LMICs).
- Define the scope of R&D to be addressed by GHSA and align countries on priority areas for R&D capacity strengthening. This includes determining on which research stages and capacities the task force will primarily focus.
- Develop a voluntary tool for countries to assess their R&D capacities and identify gaps, which aligns with and builds upon the IHR and JEE.
- Pilot, validate, refine, and encourage uptake of this R&D assessment tool by GHSA countries.
- **Cross-pollinate conversations with stakeholders of other GHSA action packages and task forces** to identify ways R&D intersects with and could be embedded into their existing work.
- Support countries in aligning their R&D capacity gaps with opportunities for financing health system improvements via existing and proposed new financing mechanisms.

Progress achieved

Since its launch in June 2021, the R&D Task Force has attracted the participation of 27 GHSA member countries (listed in appendix)—representing five continents and all four of the World Bank income groups—who regularly engage in the working group's bimonthly meetings and activities. This large cohort of participating GHSA members and their robust engagement signals both a strong acknowledgment by countries that R&D is a critical element of health preparedness and the high priority they place on closing gaps in their R&D readiness.

In its first year of operation, the task force has focused foremost on four areas of work:

Aligning around mission and scope

The task force kicked off its activities by working to align members around a shared mission and the scope of R&D on which the task force would concentrate. At its first meeting, members reflected on the key R&D challenges precipitating the task force's creation. Members also reviewed definitions of R&D and R&D capacity used by peer organizations, considered the different R&D stages that could be addressed as target areas to measure capacity, and conferred on a list of relevant national stakeholders that would be key to engage in the group's work.

Based on survey results solicited at this meeting, the task force determined it would focus on the capacity of countries to conduct biomedical R&D that results in products for health security threats that are safe, effective, appropriate, affordable, acceptable, and accessible. In its goal to build out an R&D capacity measurement tool, task force members agreed that all stages of R&D were relevant to address—including threat identification/surveillance, basic research, preclinical and translational research, clinical trials, regulatory review, advanced manufacturing capacity, post-approval surveillance, and implementation science. The group also coalesced around a vision of what ultimate success would look like: ensuring every country has a pathway to access the tools it needs when it needs them, and every region has ample medical countermeasures R&D capacities with ongoing utilization to tackle both emerging and enduring health threats.

Landscaping R&D indicators and methodologies for measuring capacity

To advance its objective of developing a tool for countries to assess R&D capacities, the task force began by landscaping what existing indicators on R&D capacity are already measured and publicly reported on and what accepted methodologies are in use to measure health preparedness more broadly. Over the course of several meetings, the task force heard presentations from and held dialogues with representatives from four groups:

- The ESSENCE on Health Research Initiative, which is an international collaboration between top research funders aimed at harmonizing funding efforts to enhance research capacity, presented on a framework its members created in 2020 that looks at four basic indicators to measure overall R&D capacity (not specific to health security).
- The <u>Global Health Security Index</u>, created in 2019 by the Nuclear Threat Initiative, Johns Hopkins Center for Health Security, and Economist Impact, presented on the methodology, indicators, and sub-indicators it uses for its index, which was created to assess and benchmark the health security–related capabilities of the 195 nations that are party to the IHR.
- The <u>World Health Organization's (WHO) Global Observatory on Health R&D</u>, which focuses on sharing information and analyses on health R&D to inform priority setting by policymakers, presented <u>on five</u> <u>national- and regional-level indicators</u> it tracks on health R&D that are linked to achievement of the Sustainable Development Goals.
- The <u>Global Preparedness Monitoring Board</u>, which was established as an independent monitoring and accountability body on preparedness, presented on a monitoring framework it is actively in the process of developing.

In addition, the Global Health Technologies Coalition (GHTC), as a member of the Global Health Security Agenda Consortium, provided technical assistance to the task force by landscaping additional R&D/health security– relevant indicators from sources including the SCImago Journal Rank, which measures national scholarly influence in scientific journals and academic institutions per country, and the JEE.

Building a draft tool to assess R&D capacities

From the above sources, GHTC compiled a list of 56 potentially relevant indicators, with data sources, that could be considered for measuring health security R&D capacity. GHTC then narrowed this into a proposed shortlist of 25 highest priority indicators—organized across four R&D stages: basic to preclinical research, clinical research, regulatory review, and post-approval—that will evolve into an easy-to-use-tool that countries can voluntarily employ to measure their R&D capacity. In May 2022, this shortlist of indicators was presented to the full R&D Task Force membership for comment and input. As the task force works to finalize the list, it is actively grappling with the challenge of finding the right balance between having the most robust assessment tool possible, with indicators that are specific enough to ascertain a country's actual R&D capacity, versus the work that will be required for countries to provide key data inputs into the tool. Throughout the development process, member states stressed their bandwidth constraints and the need to account for the volume of self-reporting required to complete the assessment.

Cross-pollinating with other action packages and task forces to identify intersections

In addition to working on an assessment tool, the task force has also begun to consult with other task forces and action package participants to identify opportunities to advance R&D through their work. Prior to the launch of the R&D Task Force, interested parties advocating for its founding held informal consultations in 2019 with stakeholders from the Antimicrobial Resistance, Zoonotic Disease, Laboratory Systems, and Biosecurity and Biosafety Action Packages to better understand the intersections of R&D in their workplans. Since the launch of the R&D Task Force, its representatives have coordinated with the Accountability and Results Task Force to provide input on their activities to measure country health preparedness capacity and strengthen linkages between GHSA and JEE and IHR implementation. They also held preliminary discussions with stakeholders in the Sustainable Financing Action Package regarding how domestic resource mobilization and a proposed pandemic preparedness financing mechanism could be leveraged to bolster national and regional R&D capacity.

The task force has also shared updates on its activities with the Advocacy and Communications Task Force to ensure broader global health security audiences are kept apprised of its progress and aims. In addition, the Action Package Coordination Task Force, which aims to align activities across all action packages, has invited the R&D Task Force to educate a broader group of stakeholders on its work by facilitating a webinar in June 2022.

Looking forward

Building on progress achieved in year one, the R&D Task Force now plans to pursue the following activities to realize its vision of a world better capacitated to develop and equitably deliver medical countermeasures.

Securing permanent mandate for task force

The R&D Task Force was approved by the GHSA Steering Committee as an initial one-year pilot program ending in June 2022. For it to continue its work, its members are requesting the Steering Committee vote to make it a permanent task force through the remainder of the current 2024 framework. This is a prerequisite for the task force to be able to complete the envisioned activities below.

Refine, pilot, validate, and encourage uptake of the R&D assessment tool

Applying feedback received from members, over the next few weeks, the task force will finalize the indicator shortlist and develop a weighting and scoring system for the tool that will ladder up to an overall R&D readiness score. It will then identify and work with a select group of task force countries, representing diverse regions and country income classifications, to pilot test a beta version of the tool by completing the self-assessment. Based on feedback from this pilot test, the task force may choose to further refine the tool and/or develop additional instructions and guidance to support users.

Once the tool is finalized, the task force then plans to roll it out to the full GHSA membership. It will encourage members to voluntarily complete the self-assessment and provide technical support to any countries that wish to do so. As countries complete the assessment and report back, the task force will explore the feasibility and potential options for coalescing results on a publicly accessible website. As individual country data is reported and trends begin to emerge illuminating where capacity gaps are most prominent, the R&D Task Force plans to reconnect with other action package participants and task forces to share findings and explore opportunities to address these gaps.

Influence JEE indicator reform process, drawing on assessment tool

While the GHSA R&D assessment tool will be a helpful independent means for countries to comprehensively selfassess their R&D capacities, the task force ultimately hopes a JEE R&D indicator will be adopted and the GHSA tool will be integrated to inform that indicator. This will create one streamlined WHO-endorsed process for countries to assess R&D readiness within a broader preparedness framework, as well as expand the number of countries measuring their R&D capacities—thereby elevating this issue on the agenda of global leaders and financing bodies. Given WHO has already kicked off a process to reform the JEE tool in the wake of COVID-19, the task force plans to share its R&D tool and learnings with relevant stakeholders and officials driving this reform process.

Connect capacity gaps with financing opportunities

The R&D Task Force will focus in particular on sharing results from the R&D assessment tool with the Sustainable Financing Action Package leads so they can support individual countries in identifying potential sources of domestic resource, donor, and development financing that could be secured to address identified R&D capacity gaps. This will be a long-term effort that could take several years to bear fruit. The task force can also be a platform that can help articulate the current bottlenecks and gaps and be a forum for LMIC voices and civil society to provide insights and recommendations for how to leverage sustainable financing mechanisms.

Appendix: List of R&D Task Force participating members

- 1. Argentina
- 2. Bangladesh
- 3. Canada
- 4. Ethiopia
- 5. Georgia
- 6. Germany
- 7. Ghana
- 8. Indonesia
- 9. Italy
- 10. Japan
- 11. Liberia

- 12. Malawi
- 13. Malaysia
- 14. Namibia
- 15. Netherlands
- 16. Nigeria
- 17. Pakistan
- 18. Rwanda
- 19. Saudi Arabia
- 20. Senegal
- 21. Sierra Leone
- 22. South Africa

- 23. Thailand
- 24. The Gambia
- 25. Togo
- 26. United Kingdom
- 27. United States
- 28. Global Health Security Agenda Consortium
- 29. Private Sector Roundtable