

# The Next Pandemic Won't Wait:

# What World Leaders Can Do to Strengthen Global Research and Development Architecture for Health Security

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## Introduction

The COVID-19 pandemic has made clear that there are severe gaps in global health security preparedness. Scientists around the globe are racing to <u>develop and deploy</u> new diagnostics, therapeutics, vaccines, and other tools in record time to flatten the curve and shore up overburdened and fragile health systems. And while it has never been more apparent that research and development (R&D) for health technologies and medical countermeasures is vital to enhance our capacity to prevent and combat threats as they emerge, the global approach to R&D for epidemic threats remains highly underfunded, fragmented, and dependent on market forces.

The global community has been slow to build—and adequately resource—coordinated international frameworks or mechanisms to advance the technologies needed to combat potential health emergencies. No global framework currently exists for assessing and strengthening the capacity of countries to conduct R&D, either as part of the World Health Organization's (WHO) International Health Regulations (IHR) or the Global Health Security Agenda (GHSA). Further, as noted in the 2020 Global Preparedness Monitoring Board (GPMB) report, the absence of a pre-established multilateral agreement or framework to develop and share medical countermeasures is threatening to prolong the pandemic and places the world at continued risk for future deadly outbreaks.

The lessons learned from this pandemic present an opportunity to rethink the global architecture for health preparedness to ensure that R&D for medical countermeasures is more explicitly included in global mechanisms and sustainably financed so we can develop and deliver safe, equitable, affordable access to innovations that are culturally appropriate and include community participation.

As world leaders consider key policy priorities to address the current pandemic and bolster our collective defenses against emerging epidemic or pandemic threats, the Pandemic Action Network has identified four areas for priority action for global health R&D:

- 1. Support upstream R&D activities and the development of medical countermeasures through the Access to COVID-19 Tools Accelerator (ACT-A).
- 2. Mobilize sustainable financing for global health security R&D capacity-building.
- 3. Strengthen GHSA through explicit inclusion of R&D in its Action Packages.
- 4. Formalize a forward-looking global architecture to strengthen R&D coordination and response.



## **Overview of key challenges in R&D for global health security**

# There are few readily deployable therapies, diagnostics, or vaccines for epidemic-risk diseases, particularly for low-resource contexts.

Today, the <u>world is still without essential tools</u> to combat many of the emerging and reemerging infectious diseases (EIDs) considered by the WHO most likely to cause widespread epidemics. Historically, the market potential for tools against EIDs has been too uncertain to drive commercial investment, and testing these products remains difficult—underscoring the need for strong government funding and well-coordinated and sustained international collaboration to drive development of these health technologies.

Even now, as unprecedented global investment in COVID-19 R&D is fueling a burgeoning pipeline of potential therapeutics, vaccines, and diagnostics, many of these tools present significant challenges for implementation in low- and middle-income countries (LMICs). For example, newly emerging antibody therapies must be administered intravenously in a hospital setting, while most of the advanced vaccine candidates now being tested in clinical trials are expected to require more than one dose and either consistent freezing or refrigeration, all barriers to achieving widespread distribution and access in low-resource settings. The need for suitable, adaptable tools for low-resource settings is not unique to COVID-19, but is a persistent challenge in product development for global health security that requires greater attention at the upstream R&D stage.

#### There is a lack of sustainable funding mechanisms for global health security R&D.

Funding for product development for epidemic-risk diseases has largely been subject to boom and bust cycles, driven by influxes of funding during crises and receding once the emergency subsides. These resources often come from a small group of donor countries, primarily through overseas development assistance (ODA) budgets vulnerable to political and economic swings. To date, this financing has not been at the scale or delivered within the timeframe necessary to accelerate R&D and guarantee maximum global access.

Likewise, funding for R&D capacity-building activities, such as strengthening laboratory, clinical trial, and quality-assured manufacturing capacity, has also come from a very limited pool of donors, primarily through bilateral aid programs. While International Financial Institutions (IFIs), including the World Bank and International Monetary Fund (IMF), could provide a new and more sustainable financing source, these institutions have historically been unable to finance the development of medical countermeasures and research capacity because of their internal structures and mandates. Much like traditional defense, health security R&D is a long game; it requires continual investment and enhancement in surveillance, readiness, and training, year in and year out.

#### There is no global framework for R&D capacity-building.

No global framework currently exists for assessing and strengthening the capacity of countries to develop, approve, manufacture, and deploy vaccines, therapeutics, diagnostics, and other medical countermeasures. This is not included as part of the WHO's <u>IHR</u>, the <u>Joint External</u> <u>Evaluations</u> (JEEs), or the <u>GHSA 2024 Framework and Action Packages</u>. In the absence of an agreed-upon global framework for R&D capacity strengthening, donors and implementing



countries have been slow to prioritize and mobilize this work that is essential to strengthening epidemic preparedness and laying the groundwork for equitable, affordable, ready, and safe access to lifesaving tools.

With the COVID-19 pandemic, this lack of a global R&D framework has led to a zero-sum approach by high-income countries to securing vaccines and medical products for their own citizens. Bidding wars for reagents, personal protective equipment, and other vital tools, coupled with a lack of manufacturing capacity in certain regions, led to many lower-income countries being unable to secure the health technologies they needed in the early days of the pandemic, and shortages continue to hamper effective response efforts. Voluntary initiatives like the <u>Developing Countries Vaccine Manufacturers Network</u>, an alliance of vaccine manufacturers from developing countries that aims to make a consistent supply of high quality, accessible vaccines, represent a welcome step in strengthening manufacturing capacity in LMICs, but more substantial efforts are needed. While not every country needs a full suite of R&D capabilities—such as advanced laboratories, clinical trials infrastructure, and quality-assured manufacturing—for the full spectrum of technology needs, including vaccines, diagnostics, therapeutics, and other technologies like personal protective equipment and oxygen therapies, **the global community must ensure that every country has a plan and pathway to gain access to these tools at an affordable price when needed**.

#### There is poor coordination of research across countries.

While humanity's reliance on scientific innovation has never been greater, the global approach to R&D for epidemic-risk diseases remains highly fragmented and uncoordinated. This has led to missed opportunities to align R&D efforts at the regional and global level to improve early outbreak detection and inform public health policies, as well as generate shared learnings to enhance knowledge on best clinical practice of different interventions and therapies. For example, the UK Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial, a large-scale trial comparing standard of care to six potential repurposed treatments for COVID-19, could have been scaled much earlier to be an international trial platform.

While in recent years, notable progress has been made in improving global coordination of R&D through the 2016 launch of the WHO's R&D Blueprint, and, in the midst of the COVID-19 pandemic, through the establishment of the Solidarity Trial and the ACT-A, this latter progress is both limited and fragile. These mechanisms have been temporarily stood up solely for COVID-19 and are being funded through emergency resource mobilization, dependent on time-consuming and unpredictable international donor appeals.

The world simply can't wait for the current pandemic to subside to establish more forwardlooking, sustainable mechanisms to coordinate and support the full range and scope of R&D needed to confront potential health threats.



## An agenda for international action

- 1. Support upstream R&D activities and development of medical countermeasures through the ACT-A.
  - Fully fund the US\$38 billion the ACT-A needs by March 2021 to advance product development and manufacturing. Only a small fraction of that money has been raised thus far, so a major resource mobilization push will be needed to meet the investment needs required by the ACT-A's R&D mechanisms – the Coalition for Epidemic Preparedness Innovations (CEPI), Foundation for Innovative New Diagnostics (FIND), and the Therapeutics Accelerator.
  - Ensure robust global participation and representation, including that of the Global South, in ACT-A governance and research mechanisms. For the ACT-A to be successful, it must be approached as a truly global endeavor. To ensure products are safe, effective, and globally accessible for diverse populations, it is important that LMICs are included in the Solidarity Trial and other clinical trials for COVID-19 products, and that diverse LMIC stakeholders are represented in the ACT-A's governance and decision-making processes.
  - Act now to reduce anticipated barriers to equitable product access, including the adaptability of tools for low-resource settings, data sharing, and manufacturing. Product development processes should from the outset reflect the perspectives and needs of end users and decision makers in LMICs to ensure resulting products are appropriate or adaptable for use in low-resource settings. Decision-makers must also ensure robust global data sharing of clinical trial results to accelerate scientific progress, as well as build in technology transfer mechanisms and strengthen regional manufacturing and distribution capacity to scale production to meet global demand.
  - Conduct an intra-action review of the ACT-A to capture lessons learned to strengthen preparedness against future health threats. As we gain more experience, ACT-A partners and the WHO should commission an independent analysis of ACT-A efforts in real time to assess what worked well, what didn't, and what kind of global mechanisms are needed moving forward to accelerate R&D to better prepare for and respond to the current pandemic and future health emergencies.
- 2. Mobilize sustainable financing for global health security R&D capacity-building.
  - Leverage the World Bank's Health Emergencies Preparedness and Response Multi-Donor Fund (HEPRF) to finance select short-term R&D capacity-building programs for COVID-19. This includes rapidly increasing regional diagnostics manufacturing capacity, expanding clinical trial capabilities in LMICs, and supporting regional regulatory processes to speed the uptake and use of these new technologies.
  - Establish a <u>Global Health Security Challenge Fund</u> and other sustainable financing mechanisms to fund the implementation of the GHSA framework, as well as other global and regional capacity-building activities, including laboratory and clinical trial strengthening, supporting manufacturing capacity, and research networks.



- Make R&D investments eligible for financing from the World Bank and other IFIs and develop mechanisms to provide financing for global R&D for health emergencies, as recommended by the GPMB report. The recent <u>\$12 billion funding commitment</u> by the World Bank to support LMICs to purchase and rollout COVID-19 vaccines and tools presents a near-term opportunity to leverage financing from the International Development Association and the International Bank for Reconstruction and Development to begin to bolster countries' own R&D capabilities and to prioritize R&D in future investments.
- 3. Strengthen GHSA through explicit inclusion of R&D in its Action Packages.
  - Expand the scope of the GHSA Workforce Development & Medical Countermeasures Action Package to incorporate R&D for medical countermeasures. This will serve as an important blueprint for countries to strengthen their capacity to develop, approve, manufacture, and deploy technologies for health threats.
- 4. Formalize a forward-looking global architecture to strengthen R&D coordination and response.
  - Activate and sustainably finance a global mechanism to proactively coordinate and advance biomedical product development for emerging epidemic-risk threats—addressing the full spectrum of technology needs including diagnostics, therapeutics, vaccines, medical devices, and platform technologies that can pivot to address the next "Disease X". This could be achieved by creating a new institution or by broadening the mission of an existing mechanism like CEPI whose initial mandate was more narrowly defined, but whose activities rapidly evolved to respond to the range of research, development, and manufacturing needs to quell the COVID-19 pandemic.
  - Establish a global governance framework for R&D for health emergencies to set shared priorities for capacity-building and product development and coordinate approaches to facilitate equitable and affordable access to lifesaving tools. This will ensure that every country has the ability to access and deploy vaccines, therapeutics, diagnostics, and other medical devices to respond to emerging epidemicrisk threats. This could be done through the WHO or a permanent structure coming out of the ACT-A partnership.
  - Prioritize R&D strengthening as part of the ongoing IHR implementation and expand the JEEs to include R&D capacity-building for medical countermeasures. Expanding these tools to include R&D metrics would help countries assess, prioritize, and better plan for strengthening their R&D capabilities.
  - Leverage the SDG3 Global Action Plan R&D Accelerator and the Independent Panel for Pandemic Preparedness and Response processes to advance global discussions around R&D bottlenecks and accelerate development of a standing global health R&D framework. These discussions should address a range of topics including regulatory harmonization, clinical trials, and product demand and should prioritize actions to strengthen R&D as part of the agenda for the UN Global Health Security Summit, as proposed by the GPMB and advocacy groups.



### Conclusion

The next pandemic won't wait, and neither can we. COVID-19 has underscored with devastating clarity the inadequacies of our current system for advancing and financing R&D for health security—a system that has too long left the development of lifesaving technologies to the whims of fluctuating national priorities, emergency response, and insufficient market forces and has turned a blind eye to the needs of the world's poorest and most vulnerable people.

As world leaders work together to address R&D, manufacturing, and access gaps to quell the COVID-19 pandemic, they must simultaneously take steps to strengthen multilateral coordinating frameworks and build country and regional R&D capacity to create a more resilient system to develop and deliver the tools needed to combat future pandemics. It's time to end the cycle of panic and neglect once and for all.

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This paper is one of a six-part Pandemic Action Agenda series urging world leaders to take action to strengthen pandemic preparedness. For other papers in this series, please visit <u>pandemicactionnetwork.org</u>.

For questions about the paper or the Working Group, please contact Carolyn Reynolds at <u>carolyn.reynolds@pandemicactionnetwork.org</u>.