GHTC
global health technologies coalition

Meeting the moment, fueling the future

Policy recommendations for a new era of US leadership in global health R&D

March 2021

Contents

About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) works to save and improve lives by encouraging the research and development of essential health technologies. We bring together more than 30 nonprofit organizations, academic institutions, and aligned businesses to advance policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people.

Acknowledgments

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Cover photo: World Bank/Henitsoa Rafalia

Abbreviations

AIDS	acquired immunodeficiency syndrome
AMD	Office of Advanced Molecular Detection
AMR	antimicrobial resistance
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CEPI	Coalition for Epidemic Preparedness Innovations
CGH	Center for Global Health
COVID-19	coronavirus disease 2019
DoD	Department of Defense
DPDM	Division of Parasitic Diseases and Malaria
DTBE	Division of Tuberculosis Elimination
DTRA	Defense Threat Reduction Agency
FDA	Food and Drug Administration
FIC	Fogarty International Center
GHB	Global Health Bureau
GHIA	Global Health Innovation Act of 2017
GHTC	Global Health Technologies Coalition
HIV	human immunodeficiency virus
JPEO-CBRND	Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NMRC	Naval Medical Research Center
OAR	Office of AIDS Research
R&D	research and development
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
STD	sexually transmitted disease
TB	tuberculosis
TBTC	Tuberculosis Trials Consortium
USAID	US Agency for International Development
USAMRDC	US Army Medical Research and Development Command
WHO	World Health Organization
WRAIR	Walter Reed Army Institute of Research

Introduction

The global health research and development (R&D) sector currently sits on a sharp fulcrum, precariously balanced between broad setbacks and inspiring possibility. Which way the sector tips will largely depend on the vision and leadership of the 117th Congress and the Biden-Harris administration.

In the last year, global health R&D has been thrown into disarray by the COVID-19 pandemic, which has redirected the attention of funders and experts typically focused on research for HIV/AIDS, tuberculosis (TB), malaria, and other neglected diseases. As a result, R&D programs for these persistent global health challenges have been delayed, indefinitely stalled, or canceled as resources, capacity, and expertise have been diverted to the pandemic.[1]

US leadership in global health has also been in limbo. In past global health emergencies, such as Ebola and Zika, the United States was quick to lend its expertise and resources to international efforts to combat these threats. In response to COVID-19, global aid and coordination were set aside for a near absolute focus on the national situation, leaving a conspicuous vacuum in global leadership. Across 2020, less than one-half of one percent of COVID-19 emergency supplemental funding appropriated by Congress supported global relief efforts.[2–6]

At the same time, the pandemic has revved up the global health R&D ecosystem, revealing what can be accomplished with clear direction and ample fuel. In the face of a global challenge, the sector has wielded its capacity to quickly develop new vaccines, therapeutics, diagnostics, and other tools under pressure. This progress suggests that, with proportionate attention and funding, the same rapid gains might be possible against other global health challenges.

In 2021, the Biden-Harris administration and new Congress have an opportunity to walk the United States back to the helm of global leadership: to reassert US scientific prowess and diplomacy through strong investment and smart policy developed with and facilitated by affected communities. This opportunity is about defeating COVID-19—with emerging variants, it is clearer than ever before that defeating this disease anywhere will require defeating it everywhere—and about continuing the fight against dozens of other global health challenges that have plagued humanity for generations, diseases that prior to the pandemic, the world was closer than ever to defeating, including HIV/AIDS, TB, malaria, Ebola, and neglected tropical diseases. COVID-19 has not only disrupted global programming against these diseases but also disrupted the development of new tools to fight them: the new and improved diagnostics, treatments, and vaccines that will be essential for bending the curve of these long-standing challenges.

Photo credit: PATH/Gabe Bienczycki

Photo credit: PATH/Gabe Bienczycki

This report is a collation of policy proposals to seize this opportunity: to end the COVID-19 pandemic; recover lost progress; learn from the lessons created by this crisis; and harness those lessons to launch a new, stronger era of research for neglected and emerging infectious diseases. These proposals represent a starting point for a larger-scale shift that is required for the field. We welcome the fresh energy, new perspectives, and visions that this new administration—and congressional champions for global health innovation—can bring to a fuller reevaluation of the global health R&D ecosystem and the role of US leadership in it. We encourage policymakers in the immediate term to consider these policy proposals as essential first steps toward that longer-term goal and vision.

Never has a single disease demonstrated what can be accomplished in so little time with the full resources and focus of the US government. Scientific milestones to defeat many of our world's toughest global health challenges are within sight, and with strong funding and smart policy, these milestones can be reached, protecting and improving the lives of billions of global citizens, including Americans.

These policy proposals are distributed across the seven US agencies and areas that are core to the US global health R&D enterprise:

US Agency for International Development

- Double funding for global health programs, including for innovation activities; establish voluntary minimum funding targets for R&D from these increases across global health funding lines.
- Report program-level spending on R&D more regularly and transparently.
- Establish a chief science and product development officer within the Global Health Bureau.
- Create and robustly fund a standing Grand Challenge for global health security.

Centers for Disease Control and Prevention

- Increase funding for the Center for Global Health, the National Center for Emerging and Zoonotic Infectious Diseases, and the Division of Tuberculosis Elimination and Tuberculosis Trials Consortium.

National Institutes of Health

- Expand focus on product development and translational research for health areas that lack a commercial market.
- Progressively increase funding for the Fogarty International Center by $10 million each fiscal year.
- Sustain funding growth for the National Institute of Allergy and Infectious Diseases and the Office of AIDS Research.
- Review impacts on global health research from COVID-19 and provide enhanced funding and grant flexibilities to mitigate those impacts.

Department of Defense

- Protect malaria and parasitic disease research programs within the Department of Defense, potentially through creation of a dedicated funding line.
- Retain malaria and TB on the list of eligible diseases for the Congressionally Directed Medical Research Programs.
- Increase funding for antimicrobial research programs.

Biomedical Advanced Research and Development Authority

- Establish a permanent funding line with an annual appropriation of at least $300 million to enable sustained work on emerging infectious diseases; antimicrobial resistance, including drug-resistant TB; and pandemic influenza.
- Prioritize development of products that are deployable in low-resource settings in the United States and around the world and require minimal infrastructure and medical expertise.
- Continue to report on work on emerging infectious diseases, antimicrobial resistance, and pandemic influenza in the five-year budget plan of the Office of the Assistant Secretary for Preparedness and Response, and provide regular, publicly available updates on both COVID-19 and non-COVID-19 funding.

Executive Office Leadership

- As the administration builds its leadership structure for responding to COVID-19 and evaluates options for improving the whole-of-government response to pandemics, ensure that the US Agency for International Development—the only US agency specifically charged with improving global health and development—is at the table.
- Hold global convenings that elevate global health research and principles of equity; the right to science; and needs-driven, country-led approaches in R&D.

Multilateral Leadership

- Authorize and support US participation in the Coalition for Epidemic Preparedness Innovations with annual appropriations of at least $200 million, and facilitate ongoing scientific collaboration with key US agencies.
- Push for the inclusion of R&D capacity strengthening in multilateral health preparedness frameworks.
- Advance commitment to innovative financing models and unlock investment from international financial institutions to strengthen R&D capacity in low- and middle-income countries.
- Promote collaboration between the Food and Drug Administration, the World Health Organization, and other international partners to improve regulatory coordination and harmonization to facilitate product approvals.

Background

What is global health R&D?

This report is squarely focused on the global health research and development (R&D) sector, which includes public, private, academic, and nonprofit scientists and organizations in the United States and around the world that are working on global health challenges. These challenges include neglected diseases—such as HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases—and emerging threats—such as Zika, coronaviruses, Ebola, and antimicrobial resistance. For the most part, these diseases disproportionately affect poor people living in low-resource settings, including in the United States; and as either diseases of poverty or health areas with little to no existing market demand (in the case of emerging diseases, for example), they do not offer commercial incentives for the private sector to develop medical products for them. In 2016, the global private pharmaceutical sector spent approximately $159.9 billion on R&D for health overall, but only $511 million, or less than one-third of one percent, on R&D for neglected diseases.[7] Unsurprisingly, most funding for R&D on neglected diseases comes from the public and nonprofit sectors, especially the US government. Total funding for neglected disease R&D across all sectors globally, however, still only amounts to $3 to $4 billion per year.[8] Combined with funds for research on emerging infectious diseases and sexual and reproductive health, total spending amounts to a mere $4 to $5 billion per year for health issues that affect more than a billion people.[8,9]

Why is global health R&D important?

Investment and support from US agencies have produced a rich garden of technologies that have saved millions of lives around the world: a low-cost meningitis A vaccine that has prevented at least 378,000 deaths and is estimated to have saved $9 billion dollars in treatment costs; new treatments for drug-resistant tuberculosis that have dramatically increased treatment success rates; antiretrovirals and pre-exposure prophylaxis, two global standards for treating and preventing HIV/AIDS that have saved millions of lives over the past 25 years; and nearly every Food and Drug Administration–approved malaria treatment and the world's first approved malaria vaccine.[10–15] As of 2016, the United States was supporting at least 128 global health products in late-stage development, including 103 for neglected diseases.[10]

Photo credit: PATH/Gabe Bienczycki

Even with these laudable achievements, a considerable list of innovation gaps remains: a vaccine and cure for HIV/AIDS, a single-dose cure for the deadliest form of malaria, shorter tuberculosis treatment regimens, better diagnostics for neglected tropical diseases, and many others. Defeating these global health challenges remains a distant goal, but if these gaps are bridged, the end game will at least be on the horizon.

In addition to delivering health benefits, investments in global health R&D boost the US economy. In 2015, approximately 89 cents of every US government dollar invested in global health research went to institutions in the United States, supporting local jobs and economies. Between 2007 and 2015, these investments are estimated to have generated an additional $33 billion in US economic output while creating approximately 200,000 new US jobs.[10]

Photo credit: USAID Maternal and Child Survival Program and Jhpiego/Karen Kasmauski

Finally, global health R&D is a small but essential cog within the greater health sciences research ecosystem. Discoveries in the global health R&D sector often translate to other sectors. Decades of research on global health challenges, including HIV/AIDS, severe acute respiratory syndrome, and other diseases, laid the groundwork for understanding the molecular biology and immunology of COVID-19, and many of the leading COVID-19 vaccine candidates were built using platforms originally developed for other global health challenges. The Johnson & Johnson vaccine is based on technology used in its investigational Ebola vaccine and its Zika, respiratory syncytial virus, and HIV/AIDS vaccine candidates; the Moderna-National Institute of Allergy and Infectious Diseases vaccine platform was previously used for vaccines against other respiratory viruses and the chikungunya virus; and the Oxford University-AstraZeneca vaccine was based on technology for malaria vaccine research.[16–19] Without past, robust investments in global health R&D, the world would have been less prepared for COVID-19, and these investments must continue, to better prepare us for the next pandemic and other global health security threats.

A vision for the future of global health R&D

Ultimately, how the global health R&D sector emerges from COVID-19 will be determined by the choices of policymakers. In this report, we outline policies to strengthen and build toward a global health R&D ecosystem in which products are developed through global collaborations and brought to market through public-private partnerships; the perspectives, needs, and demands of end-users and communities are incorporated at every phase of research; and over time, R&D is conducted and led closer to the communities that most need it. Such a system would strengthen local R&D capacity and international collaboration—building local and global resilience to meet the challenges of today and tomorrow.

Policy Recommendations

Photo credit: Architect of the Capitol

US Agency for International Development

Photo credit: USAID/Morgana Wingard

As the only US agency with a mandate to focus on global health and development, the US Agency for International Development (USAID) is exceptionally well positioned to advance new global health products. USAID has a broad international footprint and deep understanding of the needs and cultures of local communities; with this expertise, the agency is able to advance tools that are appropriate, affordable, and accessible for widespread uptake in low-resource settings. Over its 60-year history, USAID has supported a range of game-changing innovations, including a sticker that indicates whether a vaccine vial has been unsafely exposed to heat; new rapid diagnostic tests that can be delivered at the point of care without electricity or laboratory equipment; and fruit-flavored, dissolvable tuberculosis medicines designed for children.[20–23]

Photo credit: USAID Maternal and Child Survival Program/Fernando Fidélis

USAID specializes in supporting promising innovations through late-stage clinical and implementation research. It has several mechanisms for identifying, developing, introducing, and scaling these innovations, which often involve partnerships with nonprofits and private-sector organizations. For example, USAID directed more than three-quarters of its research and development (R&D) funding over the last decade ($699 million) to product development partnerships, a type of public-private partnership that combines the public, philanthropic, and private sectors to share resources, expertise, and investment.[8] USAID investments in health R&D also strengthen local health systems and scientific capacity, equipping communities to contribute to research that benefits themselves, to advance their health goals, and creating a more equitable and inclusive research ecosystem.

As of late 2020, USAID had not been appropriated sufficient emergency supplemental COVID-19 funding to advance and roll out new tools designed to address COVID-19 in low-resource settings, despite its laudable success in advancing innovations during the West African Ebola epidemic and Zika outbreak. USAID has used funding from its regular accounts, including the Emergency Reserve Fund, the International Disaster Assistance account, and the Economic Support Fund, to provide upward of $1.335 billion in bilateral relief to countries in need of COVID-19 assistance as of September 2020, far too little given the scale of the crisis faced by these nations.[24]

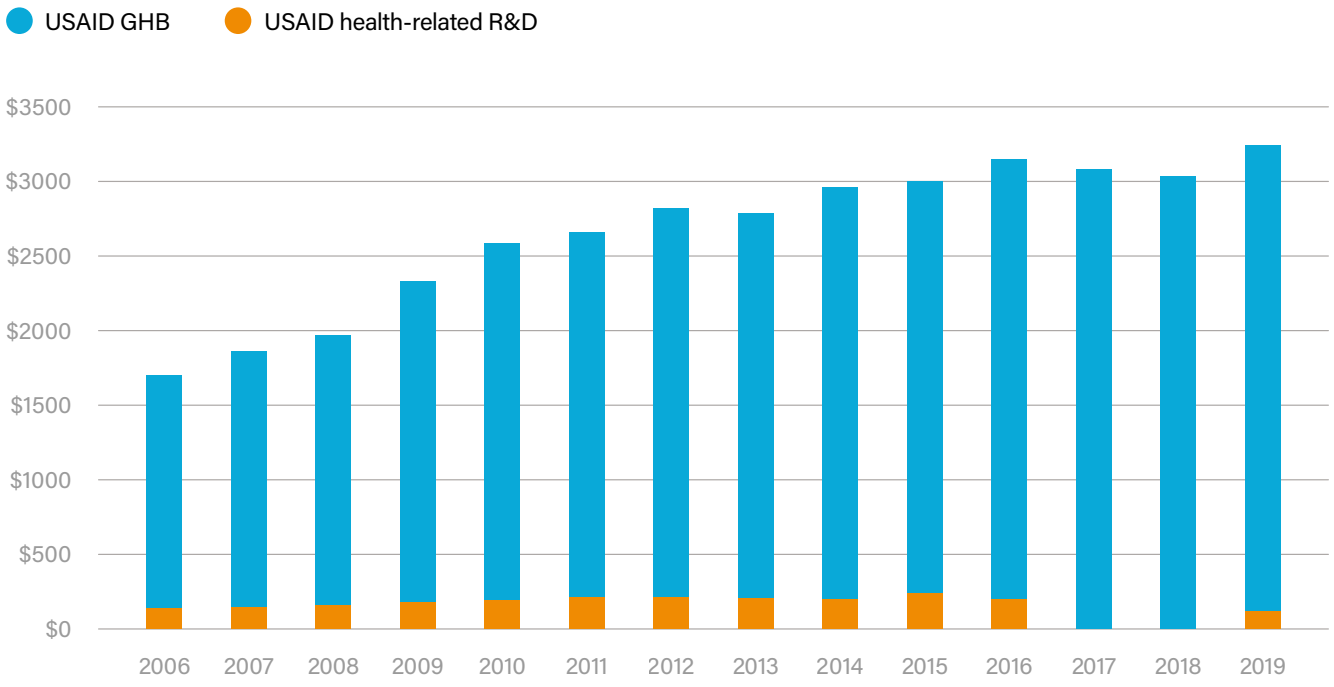
Policy recommendations

In the next four years, double funding for global health programs to meet the full spectrum of global health needs and allow for funding increases to innovation; establish voluntary minimum funding targets for R&D from these increases across global health funding lines.

Funding for global health programs at USAID grew significantly between 2006 and 2016, but in recent years it has leveled off. The need for global health funding has continued to grow, however, and has been further exacerbated by COVID-19. In concert with the global health community, the Global Health Technologies Coalition (GHTC) urges Congress to make bold investments in global health by committing to doubling appropriations for USAID's Global Health Bureau (GHB) by 2025.[25]

In tandem with this funding increase, GHB leadership should establish voluntary minimum funding targets for R&D within each of its disease-area offices and programs. Though funding for GHB has increased since 2006, funding for product development and implementation research within GHB has remained relatively flat, even decreasing from fiscal years 2015 to 2019, according to GHTC's analysis of the agency's health-related R&D progress reports.[26,27] Nevertheless, despite this relative decline in R&D spending, USAID has used this limited funding to advance dozens of successful global health products. Without USAID funding, many of these crucial but unprofitable products would not have received funding from elsewhere, stalling in the research pipeline. If R&D funding were increased proportionately with overall funding increases for global health, USAID could multiply the impact of its health programming, accelerating progress toward its long-standing global health goals.

Figure 1. USAID GHB health-related R&D funding as a proportion of total GHB funding.



Source: GHTC analysis based on 2006 to 2019 federal appropriations and available USAID R&D reports. USAID did not publicly disclose R&D spending in its 2017 report and did not publicly release a 2018 report.

Report program-level spending on R&D more regularly and transparently.

For fiscal years 2006 to 2016, USAID consistently published an annual public report on its health-related R&D strategy with comprehensive details on priorities, partnerships, and funding flows. In recent years, USAID has not consistently followed the 2017 congressional directive that its annual progress report on its health R&D strategy be made public. In addition, the overall length and level of detail in the reports has been progressively scaled back, often lacking details of funding by disease area, which greatly limits the transparency and accountability the report is designed to facilitate.[26,27]

In 2019, the Global Health Innovation Act of 2017 (GHIA) was signed into law, requiring USAID to report annually to Congress on the development and use of global health innovations.[28] Since then, USAID has produced only two GHIA-related reports, neither of which have been made public, reducing the utility and impact of such reporting. In the fiscal year 2021 appropriations joint explanatory statement, Congress reiterated its request that the USAID administrator produce a report on USAID's health-related R&D strategy, in line with the GHIA requirements.[29,30] Regular and transparent reporting on USAID's global health R&D investments is needed to track how the agency is funding global health product development, to prevent unnecessary duplication of research across agencies, and to publicly demonstrate USAID's strength in health innovation for low-resource settings.

Establish a chief science and product development officer within the Global Health Bureau.

Global health R&D at USAID lacks high-level leadership and a clear focal point for external stakeholder engagement. With the exception of dedicated funding appropriated by Congress for microbicides and HIV vaccine research, the agency's R&D investment decisions are made independently across different programs and offices within GHB. This decentralization, in combination with limited public reporting, makes it difficult for external stakeholders to identify how to engage with the agency and leads to missed opportunities for shared learning.[31] To establish a clear focal point for intra- and interagency coordination, USAID should create a chief science and product development officer position at the deputy assistant administrator level. The officeholder should engage with external stakeholders, ensure USAID is delivering on the agency's vision and strategy for R&D, and have direct oversight over the Center for Innovation and Impact, which sits within GHB and serves as a center of excellence for global health innovation.

Photo credit: USAID/Morgana Wingard

Photo credit: PATH/Gabe Bienczycki

Create and robustly fund a standing Grand Challenge for global health security.

COVID-19 has again underscored differences between the health technology needs of low- and high-resource settings. During the Ebola and Zika emergencies, USAID funded the development of technologies designed specifically for low-resource communities to confront these threats through Grand Challenges, a prize-competition model pioneered by USAID and since replicated for other global health priorities, including maternal and child health and health supply chains. USAID typically works with external partners to co-finance and operate Grand Challenges, which to date have attracted thousands of ideas from innovators based around the world and built a robust pipeline of more than 150 new tools for global health problems.[32]

Both the Ebola and Zika Grand Challenges yielded innovations that have been redeployed for COVID-19, demonstrating that global health innovations can translate to new disease areas.[33] Still, new funding is needed to develop health technologies to combat COVID-19 and other emerging infectious diseases in low-resource settings; Congress should establish a standing global health security Grand Challenge program administered by USAID to source new innovative ideas and develop technologies needed for future health security threats. This program could follow the model of the multiyear Saving Lives at Birth Grand Challenge that developed innovations for maternal and child health.[34]

Centers for Disease Control and Prevention

Photo credit: CDC

The Centers for Disease Control and Prevention (CDC) protects people at home and abroad through global disease surveillance; rapid outbreak response; training of epidemiologists; and the research and development (R&D) of diagnostics, drugs, and other prevention and surveillance technologies to combat infectious diseases. Within the global health R&D ecosystem, CDC is distinguished by its scientific and technical capacity, which equips it to help other nations build laboratory systems, bolster public health workforces, and create knowledge-sharing networks—each of which helps in the monitoring of neglected and emerging diseases and provides the infrastructure within which research can happen.[35,36] This capacity makes CDC an integral part of the global health R&D ecosystem.

Several centers and divisions at CDC share responsibility for the agency's global health R&D work. Each of these centers, and CDC overall, has historically been underfunded, operating on tight and relatively stagnant budgets—a trend that has only worsened over the past decade. These challenges have become especially acute during COVID-19, which has set back some CDC global health programming and diverted core expertise. In addition, though CDC is a world leading institution in global health expertise, the agency was politicized and undermined in the national and international response to COVID-19 in 2020. With new leadership and fresh, sustainable increases in funding, CDC and its centers could fulfill their potential for global health R&D.

Photo credit: Thailand Ministry of Public Health

Policy recommendations

Increase funding for the Center for Global Health, particularly for divisions with the largest funding gaps.

The CDC Center for Global Health (CGH) provides expertise on immunizations, disease eradication, and public health capacity-building around the globe. Among the far-reaching and high-impact work of CGH, one of its main priorities is to "research, develop, and evaluate new tools and approaches to combat global health threats."[37] As a global hub for infectious disease research, CGH is uniquely equipped to develop and validate tools for disease surveillance and diagnosis.[37,38] These tools are critical not only for tracking events of public health importance, such as emerging infectious diseases, but also for monitoring the impact of US global health programs in settings that might otherwise have limited data collection capacity. CGH also operates in some countries where the US Agency for International Development (USAID) does not have a presence, extending the reach of US global health programming.

Photo credit: CDC

As a division of CGH, the Division of Parasitic Diseases and Malaria (DPDM) works to protect Americans and those living abroad from malaria and other parasitic diseases that can cause blindness, malnutrition, and disfigurement. One of DPDM's priorities is to develop tools for detecting, preventing, and eliminating parasitic diseases, with an emphasis on curtailing drug and insecticide resistance.[39] CGH and DPDM specifically are at the vanguard of global health scientific expertise, and, with additional funding, can multiply opportunities for global health R&D.

Photo credit: CDC/Emily Jentes

DPDM's budget remained virtually unchanged between fiscal years 2004 and 2020, with a modest increase in fiscal year 2018 to $26 million—resulting in at least a 20 percent drop in real purchasing power from its budget since fiscal year 2004. Strong funding increases are needed at CGH, with an emphasis on DPDM, to restore CDC's role as a global health R&D leader.

Increase funding for the National Center for Emerging and Zoonotic Infectious Diseases, particularly for divisions with the largest funding gaps.

The CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) and its Office of Advanced Molecular Detection (AMD) provide advanced laboratory services and molecular detection techniques that enable researchers to understand and monitor infectious diseases, identify new infectious diseases of unknown origin, and develop new diagnostic tests and other tools to combat global health challenges. AMD uses DNA sequencing and advanced computing technologies to study infectious diseases, revealing knowledge about their basic biology that is critical to developing diagnostics, drugs, and vaccines against them. For instance, AMD played a vital role in first revealing the genetics of Ebola and Zika.[40,41]

AMD's genetic sequencing capabilities also support the public health response to infectious diseases by increasing scientific understanding of how they evolve and spread. For example, in response to COVID-19, AMD has led the SPHERES (SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance) Initiative, a national consortium collecting genetic data on SARS-CoV-2, the virus responsible for COVID-19, so that public health experts can better understand how the virus is evolving and transmitting to inform diagnostic development and public health policy and guidance.[42,43]

Another core strength of NCEZID is diagnostic development.[44–48] For example, NCEZID developed Trioplex, a diagnostic that can differentiate Zika, dengue, and chikungunya viruses.[49] NCEZID also supports early-stage R&D of vaccines for infectious diseases such as Nipah virus infection and dengue, Lassa, and Rift Valley fevers.[50]

Despite its essential role in studying the biology of infectious diseases and developing new tools to combat them, appropriations for NCEZID between fiscal years 2016 and 2020 increased only 7 percent.[51,52] In comparison, appropriations for the National Institutes of Health increased by 29 percent over that same period.[53] At the same time, scientific developments have expanded AMD's technical and analytical potential—provided it is able to strengthen its computing and laboratory infrastructure. Increased funding and capacity strengthening can keep AMD, NCEZID, and CDC at the scientific frontier.

Photo credit: CDC/Victor Balaban

Increase funding for the Division of Tuberculosis Elimination and the Tuberculosis Trials Consortium.

Prior to the spread of COVID-19 in 2020, tuberculosis (TB) was the world's leading infectious disease killer, impacting individuals and families around the world—including in all 50 states of the United States. The Tuberculosis Trials Consortium (TBTC) is a collaboration of researchers from CDC and other domestic and international partners that conduct research on the diagnosis, clinical management, and prevention of TB infection and disease relevant to improving TB programming, such as that led by USAID. TBTC has a strong record of research success; its clinical trials—which have enrolled more than 14,000 patients and volunteers around the world over the last 20 years—have supported the development and implementation of new lifesaving TB technologies and significantly improved global TB treatment and prevention guidelines, including by developing precision medicine approaches that reduce costs to patients and health care systems.[54–56] TBTC is operated by the Division of Tuberculosis Elimination (DTBE) within the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Funding to DTBE has been flat for 20 years, resulting in a 49 percent loss in real funding between fiscal years 1994 and 2016.[54,57] Further, between fiscal years 2005 and 2016, DTBE reduced its share of spending on TB research from 20 percent to 10 percent.[54] Congress needs to sustainably increase funding to DTBE to continue and build on its progress in TB research. This is especially critical now because COVID-19 research, which has benefited from past investments in TB R&D, has redirected respiratory disease control resources and expertise from DTBE and its ongoing TB research.[58,59] Funding for TB R&D at CDC, in addition to other US agencies, including the National Institutes of Health and USAID, should be increased to reach the United States' fair share funding target as identified at the recent United Nations High-Level Meeting on TB, which would amount to just 0.1 percent of US gross domestic expenditure on R&D.[60]

Photo credit: CDC/Tom Maguire

National Institutes of Health

Photo credit: NIH/David Sone

The National Institutes of Health (NIH) excels at basic and early-stage biomedical research, unlocking scientific discoveries that can later be translated into lifesaving global health technologies by the private sector, nonprofits, and other US agencies. While NIH primarily facilitates basic research on global health challenges through intramural programs and external grants to universities, nonprofits, and other organizations across the United States, its ongoing investment in clinical trials for HIV/AIDS and, increasingly, trials for malaria and tuberculosis products, also makes it one of the biggest global funders of clinical development in each of these disease areas.[8]

NIH is the leading US medical research institution; a respected, world-class scientific powerhouse; and the world's largest single public funder of both biomedical research at large and research focused on neglected diseases.[8] Its work to advance research for global infectious diseases, through the National Institute of Allergy and Infectious Diseases (NIAID); to coordinate crosscutting HIV/AIDS research, through the Office of AIDS Research (OAR); and to strengthen international research capacity, through the Fogarty International Center (FIC), forms the building blocks of future drugs, vaccines, and diagnostics that save and improve lives around the world.

NIH has led the US scientific response against COVID-19, convening public-private partnerships, setting research agendas, and coordinating major clinical trials.[61–63] Much NIH-funded research that is not related to COVID-19, however, has been stalled or set back as resources and expertise have been diverted to addressing the pandemic, leading to urgent requests for research relief funding from Congress.[64] Beyond COVID-19, additional policy changes and funding are necessary to meet longer-term needs and emerging priorities.

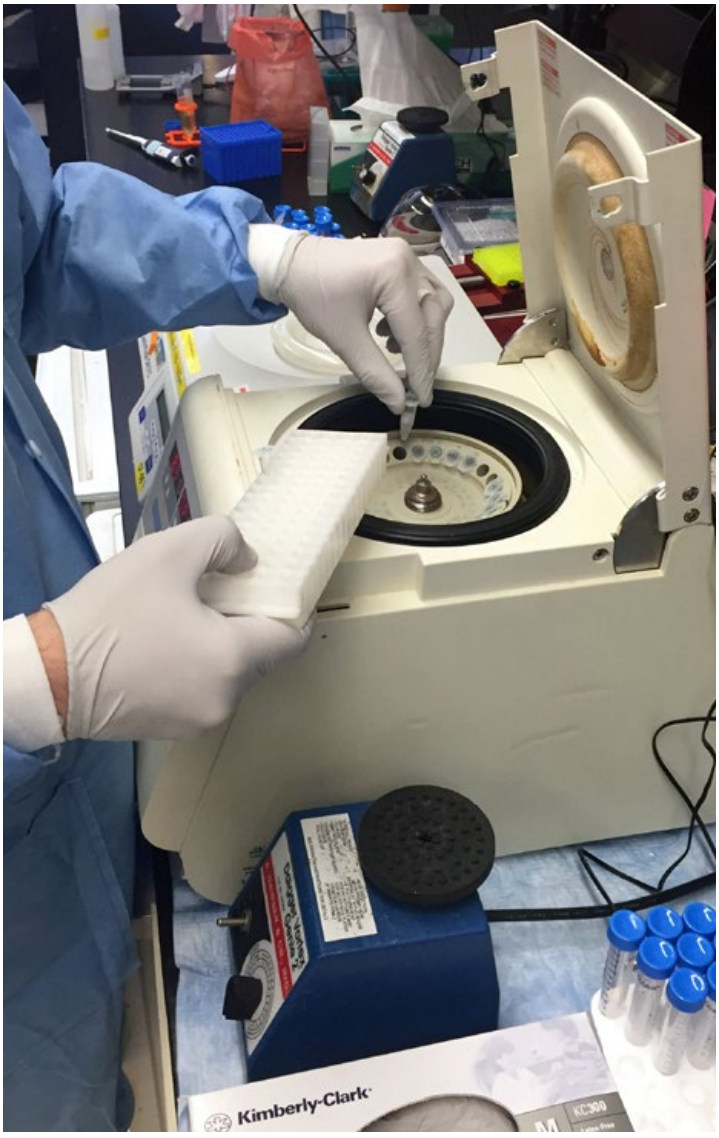


Photo credit: NIH NIAID

Policy recommendations

Expand focus on product development and translational research for health areas that lack a commercial market.

Neglected diseases are so named because their disproportionate impact on the world's poorest leads to a lack of commercial incentives strong enough to attract private-sector investment in research and development (R&D). The challenge is similar for emerging infectious diseases with epidemic potential; there is no market of patients until the disease spreads and becomes an epidemic. Developing new tools to address these diseases is unfeasible without initial government funding. NIH typically funds basic research of new medical products, which works well for disease areas where private-sector companies will eagerly invest to bring nascent discoveries from NIH-funded laboratories to market. For neglected and epidemic-risk diseases, though, fewer companies are willing to take the risk of funding the late-stage development of new products. NIH should build on its existing funding of late-stage research for emerging infectious diseases, like COVID-19 and Ebola, and select neglected diseases like HIV/AIDS, malaria, and tuberculosis. By expanding funding or co-funding of late-stage development of new products for the full spectrum of neglected diseases, NIH could provide the final push required to get these innovations across the finish line.

Progressively increase funding for the Fogarty International Center by $10 million each fiscal year.

FIC is a critical conduit between researchers in the United States and their colleagues around the world. The center strengthens international research and laboratory capacity, facilitates global research partnerships, improves surveillance of emerging infectious diseases, and trains the scientists who make critical contributions to long-standing global public health challenges such as HIV/AIDS and emerging threats like antimicrobial resistance, Zika, Ebola, and COVID-19. FIC accomplishes this work with less than one-quarter of one percent of the NIH budget.[65]

While funding for NIH increased by 38 percent between fiscal years 2015 and 2020, funding for FIC increased by only 19 percent.[53,66] In fiscal year 2021, FIC was appropriated $84 million.[65] An additional $10 million should be appropriated to FIC in each of the next five fiscal years to support sustainable growth and long-term planning in pursuit of its mission to build research capacity in partner countries.

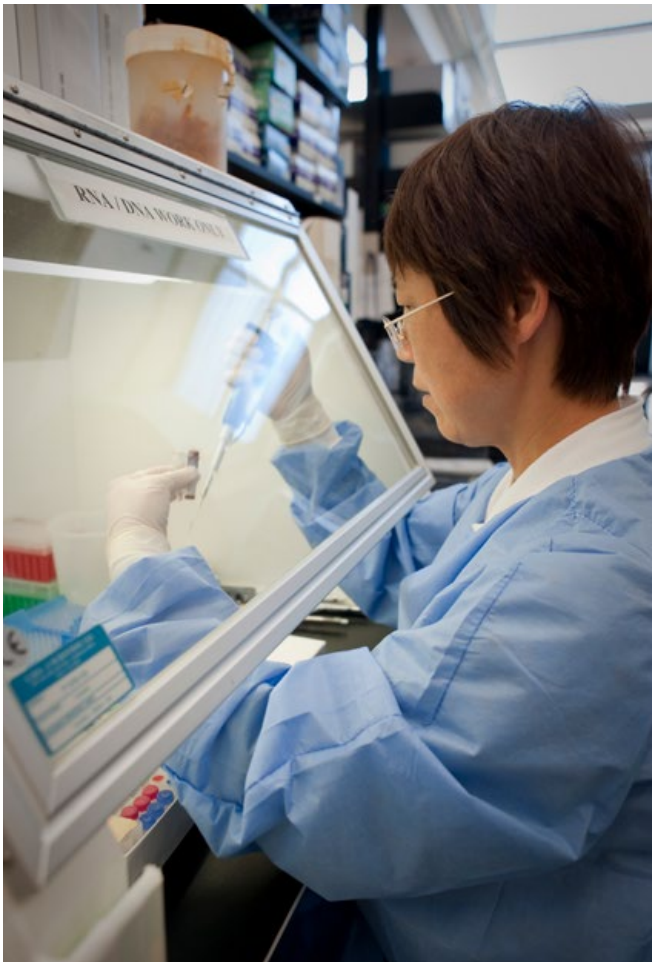


Photo credit: NIH NIAID

Sustain funding growth for the National Institute of Allergy and Infectious Diseases and the Office of AIDS Research.

Most NIH funding for neglected disease R&D is routed through NIAID, which conducts research across a range of global infectious disease threats, including HIV/AIDS, malaria, tuberculosis, neglected tropical diseases, and influenza, and epidemic diseases like Zika, Ebola, and COVID-19. Appropriations for NIAID have historically increased at approximately the same rate as those for NIH. Congress must continue to robustly fund NIAID to ensure continued progress in neglected disease R&D. Most funding for HIV/AIDS R&D is overseen by OAR, which coordinates HIV/AIDS-related research taking place across all centers at NIH, including NIAID. OAR submits an annual professional judgment budget estimating the funding needed to fulfill the scientific potential of HIV/AIDS research.[67] OAR should receive appropriations at or exceeding the levels outlined in its annual professional judgment budgets.

Review impacts on global health research from COVID-19 and provide enhanced funding and grant flexibilities to mitigate those impacts.

All life sciences R&D has been impacted by the COVID-19 pandemic, but R&D for neglected diseases has been particularly disrupted, as COVID-19 has siphoned off a significant amount of expertise and attention, challenged international collaborations, and diverted the sector's already limited and tenuous funding, while raising the costs of doing research.[1] Both the NIH Office of the Director and Congress should investigate these impacts and the policy and funding changes needed to mitigate them.

Photo credit: NIH NIAID

Department of Defense

Photo credit: U.S. Army/Staff Sgt. V. Michelle Woods

Historically, the Department of Defense (DoD) has focused on developing vaccines, drugs, and other tools for conditions that pose a risk to US national security and service members stationed abroad. American warfighters are often deployed to austere environments with limited health infrastructure and exposure to prominent global health challenges, such as malaria and leishmaniasis, a parasitic disease spread through sandflies. At peak incidence, at least 1 in 20 service members stationed in Eastern Afghanistan from 2001 to 2013 was diagnosed with malaria. Of service members stationed in Afghanistan in 2004, at least 2.1 percent were estimated to have been infected with leishmaniasis. In 2003, during Operation Sheltering Sky, one in five marines deployed to Liberia was diagnosed with malaria within ten days of arrival.[68]

DoD is the only US agency that supports every stage of research and development for health products, from basic research to late-stage clinical development and manufacturing. DoD has a strong record of developing or codeveloping new drugs, vaccines, and diagnostics for infectious diseases, including the development of at least seven Food and Drug Administration (FDA)–approved vaccines; nearly every FDA-approved malaria treatment; and diagnostics for typhus, malaria, and West Nile virus for low-resource settings.[69] The agency also has a rich history of supporting research against antimicrobial-resistant threats, which can complicate the ability to conduct safe surgeries and to treat infections impacting service members.

During COVID-19, DoD, especially via the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), has been an instrumental partner with the Department of Health and Human Services, especially with the Biomedical Advanced Research and Development Authority, in co-funding medical countermeasures against the pandemic. Early in the pandemic, JPEO-CBRND supported research into COVID-19 medical countermeasures suitable for low-resource settings, including a single-use COVID-19 rapid diagnostic test and a temperature-stable, needleless vaccine.[70,71] These contributions demonstrate the potential for DoD to play a more consistent role in global health innovation.

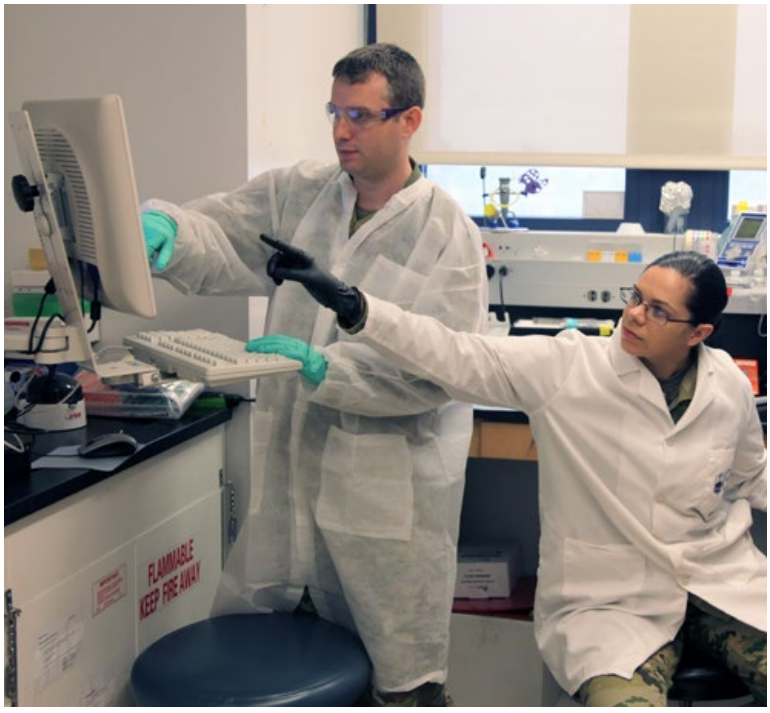


Photo credit: Walter Reed Army Institute of Research

Policy recommendations

Protect malaria and parasitic disease research programs within DoD, potentially through creation of a dedicated funding line.

DoD is perhaps the most influential malaria research institution in the world. It has contributed to the development of nearly every FDA-approved malaria drug, was a key partner in the early development of the first approved malaria vaccine for children, and pioneered seminal research methods that enabled the development of antimalarial drugs and vaccines around the world.[69,72–74] DoD's continued leadership and expertise in malaria research is essential for developing the next generation of tools that are needed to protect troop health and defeat malaria globally, including more efficacious malaria vaccines that work in adult populations and new treatments to combat growing antimalarial resistance.[75]

In recent years, however, DoD has reduced funding for its malaria work, particularly its vaccine research conducted through the Walter Reed Army Institute of Research (WRAIR) and Naval Medical Research Center (NMRC). Programs have been shifted and, in some cases, eliminated from funding lines and program elements. In 2019 and 2020, internal, closed-door deliberations at DoD targeted malaria research for elimination. Shuttering these programs completely would halt decades of DoD's progress in developing new tools for malaria and other parasitic diseases and would ultimately harm troop readiness and protection. Even the threat of closure could forestall scientists from launching or maintaining programs that require sustained, multiyear investment. Internal DoD funding decisions should continue to support research on malaria and other parasitic diseases in line with the military threat assessments that identify malaria as a top-tier infectious disease risk.[76,77] Congress could consider creating a dedicated funding line for malaria and parasitic disease research at DoD to secure the reliable funding that ambitious scientific projects require.

Retain malaria and tuberculosis on the list of eligible diseases for the Congressionally Directed Medical Research Programs.

The Congressionally Directed Medical Research Programs (CDMRP) within DoD funds high-impact research on a list of priority diseases identified by Congress that affect service members and the American public.[78] What distinguishes CDMRP from other federal programs is that it works with advocates and scientists to identify areas of disease research that have high potential for impact, while ensuring minimal redundancy with research funded by the National Institutes of Health.[79] This includes funding along the full range of research and development, from basic research to clinical development. Historically, malaria and tuberculosis have both been included on the CDMRP-eligible diseases list but have cycled on and off in recent years. Congress should annually include malaria and tuberculosis on the CDMRP list so that research against those diseases can be funded sustainably.

Photo credit: U.S. Army/Staff Sgt. V. Michelle Woods

Increase funding for antimicrobial research programs.

DoD has a long history of supporting the development of new antibiotics through the Defense Threat Reduction Agency (DTRA), the US Army Medical Research and Development Command (USAMRDC), WRAIR, NMRC, and the Defense Advanced Research Projects Agency. Since 2012, DoD has spent at least $271 million, mostly through DTRA and USAMRDC, on developing traditional antibiotics as well as bacteriophages, peptides, and vaccines—products at the vanguard of antimicrobial resistance (AMR) science.[80] Even with DoD's contributions, the global research pipeline remains inadequate for meeting a challenge described by the Infectious Diseases Society of America as "one of the greatest threats to human health worldwide."[81,82] This research pipeline is thin because there is little commercial incentive for companies to invest. When new antimicrobial products are developed, providers seek to limit their use to prevent AMR from growing and can be reluctant to prescribe a premium drug when an older generic is available.[83,84] This lack of demand keeps the private sector from investing and warrants public investment. Congress and administration officials should increase DoD's funding for AMR research to boost the antimicrobial pipeline. Such investment would protect the health of troops while strengthening global health security by preventing a post-antibiotic era that threatens to reverse modern medical advances that depend on working antibiotics, such as cancer chemotherapy, organ transplants, and routine surgeries.

Photo credit: US Army

Photo credit: IAVI

Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services, supports the advanced development of vaccines, drugs, and other medical countermeasures to protect Americans against threats to public health, including emerging infectious diseases, antimicrobial resistance (AMR), and pandemic influenza. BARDA is perhaps the world's leading institution for developing medical countermeasures against global health security threats through public-private partnerships. BARDA works with industry to bridge the "valley of death" between basic research and product development, so-called because many potential medical innovations stall after public funding for basic research drops off but before other public, private, or nonprofit research and development (R&D) funders pick up later-stage product development efforts. Through unique contracting and incentive mechanisms, BARDA's partnerships ensure promising research is translated into urgently needed medical products by creating commercial incentives for private-sector partners.

BARDA has been the primary US funder of new medical countermeasures against COVID-19, distributing billions of dollars in supplemental funding from Congress to advance and procure new vaccines, therapeutics, diagnostics, and other technologies for use against the pandemic. In 2020, BARDA received an influx of more than $25 billion in emergency supplemental funding, an amount 43 times the size of its annual appropriations and 16 times the size of its annual budget.[85–90]

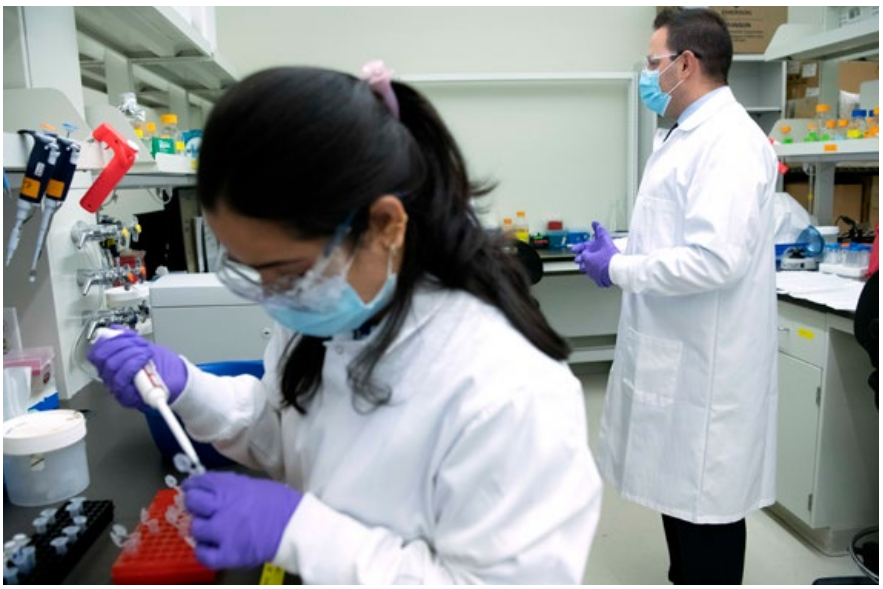


Photo credit: Government of Alberta/Chris Schwarz

Policy recommendations

Establish a permanent funding line with an annual appropriation of at least $300 million to enable sustained work on emerging infectious diseases; antimicrobial resistance, including drug-resistant tuberculosis; and pandemic influenza.

Since its founding in 2006, BARDA has been authorized to engage in the development of medical countermeasures for naturally occurring health threats. This work was bolstered by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, which specifically authorized BARDA to implement "strategic initiatives" to develop medical countermeasures against emerging infectious diseases, pandemic influenza, and AMR. BARDA, however, was established in response to the anthrax attacks, and this historical legacy has bent the agency toward developing medical countermeasures against man-made threats over naturally occurring ones.

While BARDA has responded to emerging infectious diseases, including Ebola, Zika, and COVID-19, this work has been advanced largely through one-off emergency supplemental appropriations—a trend accelerated in the COVID-19 emergency supplemental bills. Instead of relying on reactive funding that cannot keep pace with emerging threats and stalls science as public health emergencies unfold, Congress should establish a permanent funding line with an annual appropriation of $300 million to sustain BARDA's work on emerging infectious diseases, pandemic influenza, and AMR, including drug-resistant tuberculosis (TB).

Such an increase in funding would bolster BARDA's capacity to support development of medical countermeasures for the full range of priority infectious disease threats identified by health experts as most likely to cause the next pandemic and to expand its work on pandemic influenza and AMR.[91] The latter should include support for pediatric indications; multidrug-resistant sexually transmitted infections; the Centers for Disease Control and Prevention's (CDC) full list of antimicrobial-resistant threats, as detailed in its *Antibiotic Resistance Threats in the United States, 2019* report; and continued support for the CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) program, a major public-private partnership to develop new products that support the government-wide National Action Plan for Combating Antibiotic-Resistant Bacteria.[92] This work is critical to preventing a post-antibiotic era that would threaten global health security and reverse antibiotic-dependent medical advances. In particular, BARDA's work on AMR should be expanded to include drug-resistant TB, the leading cause of death globally from AMR. Our progress against TB is at great risk as drug resistance intensifies. BARDA currently conducts *no* research on drug-resistant TB despite its repeated identification as a global health security threat by experts and as a "leading health security threat" to the United States in congressional testimony provided by CDC.[93–95]

Photo credit: Penn State

Prioritize development of products that are deployable in low-resource settings in the United States and around the world and require minimal infrastructure and medical expertise.

COVID-19 has cast a harsh light on how first-to-market medical technologies are rarely appropriate for all geographies, and BARDA should explicitly recognize this reality in its grant-making process. Tools developed for well-resourced health care settings often do not meet the needs of low-resource settings, and COVID-19 has reaffirmed that many low-resource settings—including rural communities in the United States—will face challenges implementing technologies that require robust health infrastructure, such as vaccines that require ultra-cold chain storage and multiple doses.[96,97] Limited health infrastructure creates challenges for implementing treatments that require intravenous delivery, such as monoclonal antibodies, and diagnostics that require expensive laboratory equipment. With focused funding, first-line tools could be designed for implementation in low-resource settings, obviating the challenges commonly faced in those regions. In other fields, this is typically called "designing to the edges," or designing products that will work for the most extreme cases, which leads to better products for everyone.[98]

Continue to report work on emerging infectious diseases, antimicrobial resistance, and pandemic influenza in the five-year budget plan of the Assistant Secretary for Preparedness and Response, and provide regular, publicly available updates on both COVID-19 and non-COVID-19 funding.

BARDA/ASPR is the primary coordinating agency for the Public Health Emergency Countermeasures Enterprise, which coordinates the development of medical countermeasures across many federal agencies, including BARDA, the National Institutes of Health, CDC, the Department of Defense, and others. ASPR is required to annually produce a five-year budget report that includes projected costs for development of medical countermeasures. In the last completed budget (2018 to 2022), this spending was delineated by disease area, which is important for providing insight into how the agency is applying its strategy and contributing to the global health R&D ecosystem.[99]

To allow stakeholders to properly identify BARDA's contributions to public health R&D, including changes to its funding priorities in response to emerging epidemics, forward-looking budgetary information should be supplemented by regularly updating pathogen, product, and project-level data. BARDA has provided this kind of detailed information in relation to its COVID-19 funding via medicalcountermeasures.gov since early 2020.[100] We urge BARDA to broaden the coverage provided by the medical countermeasures portal to include all its funding—not limited to investments funded under the COVID-19 emergency supplements—in a similar format to the existing COVID-19 data, to provide access to the underlying data in tabular form, and to continue to provide regular updates even after the current crisis has passed.

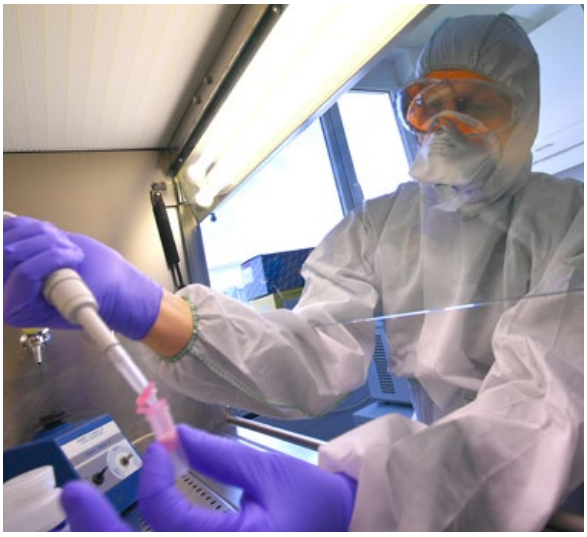


Photo credit: International Atomic Energy Agency/Dean Calma

Executive Office Leadership

Photo credit: World Bank/Henitsoa Rafalia

The White House can play a powerful role in fostering interagency coordination and leadership on global health research and development (R&D). The Biden-Harris administration has been quick to take actions toward several goals supported by the Global Health Technologies Coalition: reinstating the National Security Council Directorate on Global Health Security and Biodefense and elevating the role of the US Agency for International Development (USAID) administrator to the National Security Council; directing the national security advisor to complete a review and recommend actions on global biological risks and national biopreparedness policies, including on the development of medical countermeasures; reaffirming global health as a top national security priority; and directing the secretaries of the Department of State and Department of Health and Human Services to coordinate with the heads of relevant agencies to create a plan for engaging and supporting the development of COVID-19 tools through multilateral institutions.[101,102]

Policy recommendations

As the administration builds its leadership structure for responding to COVID-19 and evaluates options for improving the whole-of-government response to pandemics, ensure that USAID is at the table.

In 2020, USAID—the only US agency with a mandate to focus on global health and development—was largely excluded from high-level strategic planning for the COVID-19 response. The agency was not included in either the White House Coronavirus Task Force or Operation Warp Speed, creating a disconnect between the tools and efforts needed to confront the pandemic domestically and globally. USAID's deep expertise in global health and development is essential for engineering a US global response to COVID-19. As the Biden-Harris administration looks at the global situation, USAID should be included in high-level planning for the COVID-19 R&D response.

Photo credit: USAID/Morgana Wingard

Photo credit: Government of Alberta/Chris Schwarz

Hold convenings that elevate global health research and principles of equity; the right to science; and needs-driven, country-led approaches in R&D.

Global health and life sciences research, generally, is at a turning point. COVID-19 has further exposed a deficit of equitable funding for health research that meets the actual needs of affected communities, as they themselves define them, rather than the perceived needs of patients and communities as determined by scientists and policymakers from afar. The United States is recognized for its expertise in R&D and can underscore that expertise by actively demonstrating an ethical and needs-based approach to that work. The Biden-Harris administration should spearhead global convenings that work to decentralize and redistribute power within the global health sector and promote a global health research ecosystem whose agenda and priorities are set by communities that experience a disproportionate burden of disease. These convenings should be established through a health equity lens that critically examines how US scientific resources can equitably and ethically support the most marginalized communities around the world.

Multilateral Leadership

Photo credit: United Nations/Mark Garten

In the last four years, the Trump administration withdrew US leadership from the global stage, initiating a withdrawal from the World Health Organization (WHO) and generally abdicating the US role as a global leader. The Biden-Harris administration, however, has taken early steps to resume the mantle of global leadership. In its first week in office, the administration ended US withdrawal from WHO and publicly committed the United States to join ACT-A, the Access to COVID-19 Tools Accelerator—a multilateral research and development (R&D) partnership for developing and equitably delivering COVID-19 therapeutics, diagnostics, and vaccines—and COVAX, its COVID-19 Vaccine Global Access Facility—focused on vaccine distribution. Despite these promising movements, gaps remain for the US Congress and administration to address.

Policy recommendations

Authorize and support US participation in the Coalition for Epidemic Preparedness Innovations with annual appropriations of at least $200 million, and facilitate ongoing scientific collaboration with key US agencies.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international organization created to co-finance and coordinate the development of vaccines against emerging infectious disease threats. US government scientists at the National Institutes of Health and the Biomedical Advanced Research and Development Authority have collaborated with CEPI to align vaccine research and reduce duplication, but to date the US government's only commitment to CEPI is $20 million, spread over five years, delivered through the US Agency for International Development—subject to annual appropriation. Congress should permanently authorize US participation in CEPI and commit to providing it with at least $200 million annually. By investing in CEPI, the US government can leverage funding from other global funders to support promising vaccine candidates, while not bearing the full cost of development. It would also significantly accelerate global access, by funding the development of vaccines that are being designed with global access in mind—a modest investment in preparedness that pales in comparison to the cost of responding to a pandemic.

Photo credit: USAID

Push for the inclusion of R&D capacity strengthening in multilateral health preparedness frameworks.

No global framework currently exists for assessing and strengthening the capacity of every country to develop, approve, manufacture, and deploy vaccines, treatments, diagnostics, and other medical countermeasures—despite the importance of these tools in preparing for and responding to global health challenges. In the absence of an agreed-upon global framework for R&D capacity strengthening, donors and implementing countries have been slow to prioritize, finance, and mobilize this work. The Biden-Harris administration should leverage US global leadership to push for the inclusion of R&D capacity strengthening in multilateral frameworks, including the implementation of WHO's International Health Regulations, which govern the obligations of countries to international public health preparedness, and the Global Health Security Agenda, an international partnership to strengthen the capacity of participating countries to detect, prevent, and respond to infectious disease threats in compliance with the International Health Regulations.

Advance commitment to innovative financing models and unlock investment from international financial institutions to strengthen R&D capacity in low- and middle-income countries.

A largely untapped source of new sustainable financing for global health R&D is international financial institutions, including the World Bank. Health R&D has the potential to both multiply the outcomes of development investments and foster new hubs of health innovation. The Biden-Harris administration should push the World Bank and other regional development banks to support mechanisms to provide financing for global R&D capacity-building, particularly in low- and middle-income countries. Building this capacity could improve both global and local resilience to persistent and emerging global health challenges.

Promote collaboration between the Food and Drug Administration, the World Health Organization, and other international partners to improve regulatory coordination and harmonization to facilitate product approvals.

Strong regulatory systems play a critical role in global health R&D. As new global health innovations move further through the pipeline, regulatory bodies are required to ensure they are safe and effective and ultimately approve them for use in a timely manner to ensure populations have access to new tools as soon as possible. The Food and Drug Administration (FDA) is a global leader in the safety, efficacy, and security review of biomedical products and regulates products marketed in the United States—and it could play a stronger role in providing more technical support to under-capacitated national and regional regulatory authorities.

The Global Health Technologies Coalition encourages legislative provisions or administrative actions that support FDA in deploying its expertise to strengthen global regulatory pathways in low- and middle-income countries, such as by providing technical support and work product sharing with international partners through improved global clinical data interoperability, evidence sharing, mutual recognition agreements, and increased coordination and harmonization, especially with WHO.

Conclusion

COVID-19 has been a landmark event for global health research and development (R&D). The pandemic has simultaneously demonstrated the power and value of this sector while also challenging its progress against enduring health challenges, including neglected and emerging infectious diseases.

There is a clear opportunity for policymakers to enact new funding and policies that would allow the sector to learn from the pandemic, recover ground lost on research projects that were delayed or canceled, and emerge on the other end more impactful, efficient, and resilient.

With time, focused response efforts, strengthened health systems, and new tools, global society may finally overcome COVID-19, or at least subdue it to a slow-burning threat. This will be an achievement—and only so because of the billions of dollars that the world was willing to direct toward solving the scientific puzzles of the disease and developing the health innovations needed to outwit it.

Tragically, for many of the world's most enduring global health challenges, without new innovations, the end game will likely remain beyond view.

While COVID-19 is an urgent global health challenge that deserves urgent attention, it is one of many health priorities for communities around the globe and should be addressed contextually. Diseases that challenge communities the most are not always the ones prioritized for R&D because they are not globally profitable. Ambitious support for the policies in this paper is needed from Congress and the Biden-Harris administration—and soon, with sustained investment and focused R&D, the ends of many neglected diseases might be within reach, eventually leading to better health for all.

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