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A SUMMIT ON ENDING BIOLOGICAL THREATS

EVENT SUMMARY

SEPTEMBER 26, 2022

Lillian Parr, Daniel P. Regan, and Jackson du Pont

Edited by Christine Parthemore
A Summit on Ending Biological Threats: Event Summary

February 2023

Lillian Parr, Fellow, Nolan Center
Dr. Daniel P. Regan, Fellow, Nolan Center
Jackson du Pont, Research Assistant, Nolan Center

Edited by Christine Parthemore, Chief Executive Officer, CSR;
Director, Nolan Center

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Participants and attendees at the CSR workshop on September 26, 2022.

Courtesy of the Author
Introduction

This report summarizes discussions held during a workshop hosted by the Council on Strategic Risks (CSR) on September 26, 2022, focused on ending extreme risks from biological threats. For several years, CSR has convened diverse experts who agree that it is more feasible than ever to halt the spread of infectious disease threats from all sources before they cause significant damage. After several years of virtual discussions during the heights of the COVID-19 pandemic, this in-person, invitation-only event brought together experts from government, academia, industry, and non-profit organizations to discuss how to use technological advances, policy, and other tools to gauge progress, identify open questions and ongoing challenges, and think strategically about what steps must be done next.

Conversations and panels held during “The Summit on Ending Biological Threats” were held under the Chatham House Rule. This report does not represent consensus among participants, nor does it assign specific perspectives to any individual participant. Though many topics were covered throughout the Summit, conversation centered around a few core subject areas: pathogen early warning, public-private collaboration, interagency efforts and collaboration, and strategic communications. This summary report will discuss these central topics and provide a general overview of discussions.
Key Takeaways

This summarizing section captures some of the most important themes, open questions, and opportunities that emerged from the Summit. While much of the material discussed during the Summit has previously been covered extensively by CSR, this section highlights some of the most novel and important ideas and questions that were discussed.

Themes

• Most policymakers and private actors now agree that creating an effective pathogen early warning and response system will enable the global community to prevent naturally emerging and deliberate biological threats from causing mass casualties. Experts have moved beyond debating this vision, and are now focusing more and more on key implementation issues, such as data integration, translating data into action, building political will for sustained funding, and international coordination.

• Pandemic prevention is increasingly seen as a national security issue, which is a promising trend. The presence of National Security Advisor Jake Sullivan at recent bio-related events suggests better integration and a clear recognition of the threat.

• Throughout the COVID-19 pandemic, there has been impressive innovation in biosurveillance efforts, including K-12 school testing, airport testing, and wastewater epidemiology. While continuing to advance technological solutions, it is important to continually improve routine elements of pandemic response—including developing better administrative tools, methods of shoring up the supply chain, and streamlining processes for clinical trials.

• The CDC is making progress in addressing some of the shortcomings that the COVID-19 pandemic exposed. For instance, the agency
has shared mpox virus data and technical reports far quicker than it shared similar information about COVID-19. Additionally, the current director has drawn attention to the need to expand CDC’s authorities to quickly deploy experts for on-the-ground responses. There has also been discussion of how to increase reporting of local data to the CDC to improve situational awareness and disease tracking.

• Currently, biodefense-oriented companies face unreasonable expectations to develop products with both national security and commercial utility, which is not the case for many other defense technologies (e.g., missile defense systems). Security leaders need to understand that this challenge can be addressed like it has with regard to other technology areas and adjust how defense agencies work with companies and academic labs to promote development of biodefense technologies.

• Building sufficient political will is going to be essential to enable continuous funding. For pathogen early warning, for example, it is very challenging to spin surveillance efforts up and down at will—systems must be kept up and running between threats, which necessitates sustained funding.

• Vaccine and medical countermeasure diplomacy will be key avenues to enhancing international trust, which in turn may make countries more likely to quickly report outbreaks without fear of blame.
Open Questions

- Some experts believe that advanced disease early warning coupled with rapid travel restrictions (i.e., shutting down travel and border crossings) can help quash outbreaks before they reach epidemic or pandemic scale. Others strongly disagree, and worry that this punishes nations for openly sharing outbreak-related data.

- To ease public-private cooperation, some participants suggested that there be a central location for coordinating the contracting of biosecurity work, though there was disagreement over whether this hub should be located within the Department of Defense (DoD) or the Department of Health and Human Services (HHS). Others suggested that centralizing contracting doesn’t make sense for an issue set as broad as biosecurity.

- There is currently no consensus on the point at which a warning signal in an early warning system would be sufficient to elicit a response, though this will differ based on specific disease threats and the locations and contexts in which they arise. The fear of a false positive from an early warning system setting off an unnecessary and expensive response is difficult to contend with—the political cost of restrictive lockdowns with few visible illnesses would be severe. Even if early warning systems are successfully developed, choosing benchmarks for action will be a major challenge.

- There was some disagreement among participants over whether to prioritize preventing the most likely biological threats or the most catastrophic biological threats. While there is much overlap, some types of early warning capabilities being developed may not be sufficient to fully protect against a catastrophic biological event. Some participants expressed concern that even leading experts in biosecurity have not fully recognized the scale of damage that a deliberate biological attack could cause.
Opportunities & Recommendations

• Creating a Congressional community of practice dedicated to biosecurity would help ensure more legislative commitment to combating biological threats. To start this process, think tanks, industry leaders, and academics should commit to educating Members of Congress and Congressional staffers on the urgency of biosecurity and work to build a bipartisan coalition.

• Building on the models created to address COVID-19, develop future school testing programs that test for many pathogens at once and potentially extend this to other types of organizations that serve as major collection points.

• UV-C lights—which kill airborne pathogens but are safe for humans—are a promising pathogen-agnostic technology to deploy over the coming years and an example of leveraging existing but less traditional tools for quelling outbreaks.

• Implementing International Classification of Diseases (ICD) codes for animal deaths would be useful for electronically tracking patterns and detecting anomalies, and could serve as a useful input for early warning systems. Additionally, expanding veterinary insurance may help incentivize reporting of deaths and illnesses in livestock.

• For some diseases (e.g., Zika), there are not enough infections to conduct traditional clinical trials despite the potential scale of effects. For these pathogens, human challenge trials may be a useful path. In these trials, healthy people who are not at serious risk volunteer to be deliberately infected and treated. The advancement of countermeasure options resulting from these trials has the potential to save lives and prevent serious illnesses.

• Governmental offices should prioritize hiring individuals who have private sector experience, and should consider implementing programs
in which private sector individuals can spend a year or two working on rotation in government.

- Communications experts should be present in the room throughout the policy-making process. Understanding how people will respond to and interpret policy is just as important as getting the science right.

- Non-governmental organizations (NGOs) should be leveraged as a source of innovative messaging techniques, as these methods may help advance public health communication goals.

- The U.S. government should focus more attention on leveraging technologies developed outside of the United States. By focusing solely on domestic technology, the United States is missing out on a great deal of innovation.
A view of white blood cells under a microscope in the Troop Medical Center in Contingency Operating Site Marez, Iraq, Oct. 26, 2010.

U.S. Army / Sgt. Brandon Bolick
Pathogen Early Warning

Overview

Pathogen early warning was a major subject covered at the Summit. In this context, pathogen early warning refers to systems that integrate a variety of data streams to rapidly detect outbreaks, allowing for an immediate response to prevent broader disease spread. While participants agreed that pathogen early warning capabilities have improved since the start of the COVID-19 pandemic, they also noted these advances are so far insufficient to enable us to head off the next pandemic.

Yet the critical importance of pathogen early warning was clear. Simply put, by creating an effective pathogen early warning system, as well as an effective early response system, outbreaks can be curbed before they become pandemics and deliberate biological threats can be robbed of their destructive power. This vision is realistic and feasible, but will require sustained funding and effort.

Policy makers and many private actors now agree fully with this concept. As early warning capabilities are being deployed, new questions are arising regarding implementation, and how to sustain and build upon the progress made to address the COVID-19 pandemic.
Key Data Inputs

Participants identified several key data inputs that are critical for existing and future early warning systems. In this aspect, COVID-19 clarified what has been useful throughout the pandemic and what information was clearly lacking.

Sampling at airports was commonly noted as an essential area of focus. The COVID-19 pandemic illustrated that airports were a significant site of disease transmission and that airport surveillance was crucial to understanding where COVID-19 was spreading. For example, a partnership among Ginkgo Bioworks, XpresCheck, and the Centers for Disease Control and Prevention (CDC) proved to be a valuable tool in tracking the spread and evolution of COVID-19: the program detected the first known cases of the BA.2 and BA.3 Omicron sub-variants in the United States.¹

The role of wastewater testing in disease detection is also clearly expanding. Because a wide range of pathogens are detectable in wastewater, wastewater testing can provide a wealth of information and can enable multiple outbreaks to be tracked simultaneously. Additionally, wastewater epidemiology can be conducted at a variety of scales, from individual buildings to entire communities, as Biobot Analytics has demonstrated throughout the pandemic.²

It is important to note, however, that wastewater epidemiology is not a comprehensive solution to all biological threats—it must be paired with other early warning tools. For some disease threats, waiting for a pathogen to show up in wastewater is too long—by that point, the disease is likely already spreading and the government is in reactionary mode. Another issue is that creating an assay for a new pathogen may take up to several weeks, slowing response time. Reducing this turn-around time will be an essential step in enhancing the utility of wastewater surveillance.

¹ Emily Anthes, “A C.D.C. airport surveillance program found the earliest known U.S. cases of Omicron subvariants,” New York Times, March 24, 2022
² Biobot Analytics, “The Biobot Network of Wastewater Treatment Plants.”
Another area of strong progress stemming from the COVID-19 pandemic is using testing in K-12 schools for early warning and disease monitoring (and ultimately supporting educational goals as well). Historically, absenteeism data from K-12 schools has been used to provide signals that a new infectious disease may be emerging. Throughout the pandemic, school testing has proven a useful additional data source to detect and track outbreaks of COVID-19, as well as see what variants are present in what locations. Concentric by Ginkgo conducts the largest COVID-19 testing program for K-12 students in the United States, and has provided crucial data to enable schools to make informed decisions about whether students need to stay home. This program could serve as a model for future school testing programs, and could potentially open the door for multiplexed testing efforts—that is, testing for multiple pathogens at once.

Several participants pointed out the critical need to further incorporate data from animal and livestock populations into early warning systems for two reasons. First, a deliberate attack on crops or livestock could cost billions and cause severe food insecurity. Second, detecting an uptick in diseases in animals can be an indication that disease may spill over into human populations. Expansion in veterinary insurance may help incentivize reporting of illnesses and deaths in livestock. Additionally, implementing International Classification of Diseases (ICD) codes for animal deaths would be useful for electronically tracking patterns and detecting anomalies.

Because infectious diseases are a global issue, international cooperation will be essential to achieve effective early warning. Where possible, strong partnerships and transparency will pave the way for a successful early warning system. However, when countries are unwilling to openly share data, intelligence and other tools will have to stand in for information sharing. Participants discussed some key signals to detect an emerging threat in a country that is attempting to conceal an outbreak. These include deaths of healthcare workers, deaths of healthy young people, spikes in medical supply purchases, and extraordinary, unusual government responses. When governments are not interested

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3 Concentric by Ginkgo, “Reclaim Learning and Enrichment.”
in official information sharing, relying on non-governmental information sources will be key: this includes social media and non-governmental channels like ProMED. Professional networks, particularly of healthcare workers, will be critical in raising alarms.

The Path Forward

It is a sign of strong progress that building effective pathogen early warning systems is a widespread, shared goal today. As the Summit showed, this means experts are focusing more and more on key implementation issues, such as data integration, translating data into action, building political will for sustained funding, international coordination, and responding to catastrophic threats.

Improving data collection and integration is one of the most essential tasks at hand to enable pathogen early warning. Throughout the COVID-19 pandemic, some federal agencies required time-intensive internal assessments before making their data public, meaning this data was often no longer relevant by the time it was shared. Moving forward, it will be important to prioritize timely data sharing and make efforts to shift the emphasis from publication to action—some efforts that CDC is making toward this goal will be described later in this report. Additionally, it will be essential to increase reporting of local data to the CDC. Developing data sharing agreements in advance of crises, and ensuring that data is interoperable amongst agencies, will also be key steps.

For effective pathogen early warning, collecting and analyzing data is only the first step. As the world applies early warning tools, questions surrounding how to best translate data into action are becoming more important. There is currently no consensus on the point at which a warning signal in an early warning system would be sufficient to elicit a response—though this point will differ based on specific disease threats and the locations and contexts in which they arise. Early warning systems still contain significant noise and
confounding variables, which further complicates this problem. The fear of a false positive from an early warning system setting off an unnecessary and expensive response is difficult to contend with—the political cost of restrictive lockdowns with few visible illnesses would be severe. While this problem does not have an easy or concrete solution yet, participants agreed that decision makers need to be biased toward taking action. Part of this will involve committing more resources to early detection technologies in order to lower the margin of error and to reduce noise. In this way, decision makers will be able to trust the information they receive to a greater extent, potentially making them more comfortable making decisions based on it.

Moving forward, one of the greatest needs is sufficient political will to build and sustain early warning systems. In order for monitoring to be effective, it must be continuous, which requires sustained funding. It is very challenging to spin surveillance efforts up and down at will—systems must be kept up and running between threats—akin to the continuity needed in weather monitoring and tracking potential disasters. Pandemic fatigue is a clear obstacle to achieving this sustained funding, as many policymakers would like to move on from the pandemic. In order to increase political will, efforts should be focused on building a Congressional community of practice that is willing and ready to advance biosecurity goals. Based on the impact to lives, the economy, and military readiness, think tanks, industry leaders, and academics should commit to educating Congressional staffers and Members of Congress on the urgency of biological threats and the need for greater engagement.

Furthermore, the international coordination and trust needed to effectively detect and respond to an emerging pathogen is lacking. Based on China’s early lack of transparency regarding COVID-19, there is concern that countries will attempt to conceal outbreaks rather than communicate what they are experiencing to enable a successful response. Growing geopolitical tensions are adding strains, making data-sharing and open communication more of a challenge. Making use of international fora, such as the Biological Weapons Convention, the World Health Organization, and future organizations that
may come online (such as the proposed International Bio Tech Organization)\(^4\) will be necessary to build relationships and confidence with international partners. By strengthening trust, countries will be more likely to quickly report outbreaks without fear of blame, and will be assured that they will receive international assistance for early disease response. Vaccine and medical countermeasure diplomacy will also play a central role in enhancing international trust.

Several participants raised the point that the type of early warning systems that are most commonly discussed would not be sufficient to fully protect against a catastrophic biological event. While there is much overlap, some types of early warning capabilities being developed may not be sufficient to fully protect against a catastrophic biological event. Some participants expressed concern that even leading experts in biosecurity have not fully recognized the scale of damage that a deliberate biological attack could cause.

The XpresCheck location at Salt Lake City Airport on its opening day, January 20, 2021.

SLC Airport Twitter
Public-Private Collaboration

Overview

The future of public-private collaboration in quelling infectious disease threats before they create widespread harm is one of the most vast and pressing questions emerging from the COVID-19 pandemic. Industry and government collaborations have led to tremendous innovations, including mRNA vaccines, novel diagnostics, and therapeutic antibodies. However, the scale of investments needed is growing at a time in which policy attention is waning. Creating a greater understanding of the various forms of public-private cooperation moving forward will be critical to keeping both sectors engaged and effective.

Recent Successes & Promising Models

Public-private collaboration has been the cornerstone of many of the successes during the COVID-19 response. Participants noted a few key examples of ways in which the private sector stepped up to support the federal government’s pandemic response.

There is wide consensus that NIH’s Rapid Acceleration of Diagnostics Program (RADx) has been an exceptionally useful effort. This program supported companies in developing, testing, and implementing diagnostics for SARS-CoV-2. RADx was particularly important in getting diagnostics through regulatory bottlenecks, providing invaluable assistance at a stage in
development in which products often flounder.⁵ Importantly, RADx used an ecosystem approach that allowed it to fluidly tap U.S. private sector biotech and engineering expertise.⁶

Additionally, public-private coordination has helped advance biosurveillance throughout the COVID-19 pandemic. Biobot Analytics’ partnerships with HHS and CDC have enabled Biobot to analyze wastewater from communities across the country, and Ginkgo Bioworks’ partnership with XpresCheck and CDC is facilitating voluntary COVID-19 testing at four major international airports.⁷

Operation Warp Speed is another important example of optimal public-private collaboration. The program brought together federal agencies and private industry to research, develop, test, and deliver COVID-19 vaccines, treatments, and diagnostics in record time, and was instrumental in protecting millions of people around the world from severe COVID-19. Its accomplishments relied on specific authorities for HHS and DoD, collaboration across key agencies, new models of operating with private companies, and deeply experienced personnel—all things that policy makers can ensure are replicated and expanded upon through policy changes and legislative action.

In the United States, healthcare is generally considered a personal problem until something of epidemic or pandemic scale comes around. This is an inherent challenge, as scaling up from zero to crisis mode is difficult. However, a “silver lining” of the COVID-19 pandemic was that the government made sure that private insurers covered vaccines and diagnostics despite the United States not having a nationalized healthcare system. This enabled greater access to these products, and helped keep people safe throughout the pandemic. The federal government’s ability to ensure coverage of diagnostics and vaccines for most Americans is a victory that should be built off of.

⁵ National Institutes of Health, “Rapid Acceleration of Diagnostics (RADx).”
These examples of successful partnerships, among others, should be further examined and distilled into specific recommendations for the various formats that public-private collaboration should take moving forward. By building upon the successes of these programs, the U.S. government can make lasting improvements in capabilities for addressing biological threats.

The Path Forward

Despite improvements made during the COVID-19 response, many challenges remain. Issues discussed at the Summit include long government decision-making cycles, a lack of demand at this stage for several important technologies, unclear processes for forming partnerships, a lack of trust between government and industry, convoluted approval processes, and the need for more collaboration with international companies. Though these issues are difficult to address, experts at the Summit shared an array of promising potential solutions.

In some cases, government priorities lie in the short-term, making it difficult for companies to build sustained relationships with the government and rely on continuous funding. This leads to a cycle in which companies are contracted to do short-term work, then dropped, and then contracted again for the next issue. Several participants noted that the federal government would be well served by working to address longer-term problems than it currently does.

A related issue is scaling—while interfacing with the government on smaller issues (tens of millions of dollars scale) is feasible, it is very difficult to interface on problems that are on a scale of billions of dollars. At the beginning of the pandemic, when trillions of dollars in funding were available, some Summit participants were hopeful that the federal government would be able to have more foresight and commit to longer-term solutions. It is clear that this was at least partially a missed opportunity and a key area of focus for the future.
Another obstacle to public-private cooperation lies in long government decision-making cycles. Prospective industry partners do not always have the ability to wait for government funding, especially when a private funder will be able to support them more quickly and reliably. Innovative programs with fast decision cycles, such as NIH’s Rapid Acceleration of Diagnostics program (RADx), have proven an efficient route to facilitate seamless contracting with the private sector. Expanding upon this success will be an important direction for easing public-private collaborations.

While the above issues have led many companies to prioritize partnerships with private funders, there are some areas for which private sector funding is scarce or nonexistent—a common pattern in the history of addressing infectious disease threats. Antimicrobial resistance (AMR) is one such area, with many companies seeking solutions for AMR ultimately facing bankruptcy. Additionally, there is no day-to-day market for some types of personal protective equipment beyond specific settings like medical facilities or military or industrial sites, making private funding scarce. It is important that the government directs funds to these and other issue sets that are important but unlikely to receive private funding. The newly-launched Advanced Research Projects Agency for Health (ARPA-H), which has great potential for combating infectious disease threats, appears to be taking this into account. By prioritizing innovative research that is currently underfunded, ARPA-H will be able to ensure essential technology is developed, and will also be able to limit duplication of philanthropic or commercial research efforts.

To further encourage private industry to work on technologies useful for pandemic response, the government needs to signal to industry that if they develop a useful technology, it will be bought. A signal of sustained demand will be an essential step in creating a thriving bioindustrial base. If there is not an immediate, emergency demand for products, purchases can be made to expand the Strategic National Stockpile—even if they are never put to use, it is important to have them on hand. Several agencies at HHS, including

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the Biomedical Advanced Research Authority (BARDA), already employ this ecosystem approach—they foster technology and countermeasure development in the private sector, and the private sector has assurance that their products will be bought and stockpiled. This type of relationship is a valuable way to ensure that the private sector is developing useful products, even if they may have no buyers outside of the government.

One important example of connectivity between the public and private sector is a 10-year venture investment partnership between BARDA and the Global Health Investment Corporation (GHIC). Through this partnership, which began in 2021, BARDA provides GHIC with funding and technical support, enabling GHIC to finance the development of technologies that will help prevent future pandemics.

In addition to enabling the development of useful products, another advantage of government funding is that it may grant companies enhanced flexibility. Some venture funders expect the company they fund to focus solely on one technology or subject, leaving little room for flexibility. Government funding may be able to provide companies the opportunity to explore alternative applications of their work, as well as the opportunity to pivot their work when an emergency calls for a new direction.

Government funders should commit to supporting biodefense-oriented companies without the expectation that these companies receive additional private funding. Biodefense-oriented companies tend to face unreasonable expectations to develop products with both national security and commercial utility. This is not the case for missile defense systems, for example, or many other defense technologies. Security leaders need to understand that this challenge can be addressed like it has with regard to other technology areas and adjust how defense agencies work with companies and academic labs to promote development of biodefense technologies.

Beyond developing specific technologies, it is also important to continually improve routine elements of pandemic response. For instance, developing
better administrative tools, methods of shoring up the supply chain, and streamlining processes for clinical trials will help improve preparedness. This is also financially efficient, as many steps can be taken that do not require substantial funding.

Several private sector participants noted that their companies wanted to work with government partners, but were unsure how to make this a reality. The decentralized nature of the biodefense/pandemic response enterprise makes it challenging for companies to identify the ideal branch or office to work with. This is a longstanding issue, but it created particular problems during COVID-19 responses: some private sector experts did not have the tools to effectively communicate with policymakers on how to best pivot manufacturing during the onset of the pandemic, while some government officials shared that they lacked channels to the private sector to build capacity during the early days of the pandemic. To help address this issue, some participants recommended that there be a central location for coordinating contracting work on biosecurity—either DoD or HHS. Other participants, however, felt that the issue set of biosecurity is too broad to be centralized in this manner.

Another issue that industry leaders have encountered while interfacing with government partners was a perceived lack of trust—technologists at the Summit often felt that the government viewed them as only being after money. To help overcome the disconnect between the government and the private sector, individuals who have moved between industry and government will be key. These individuals have a unique understanding of both sides, and can serve to demystify the private sector for the government and vice versa. To increase the exchange of talent between government and industry, governmental offices should prioritize hiring individuals who have private sector experience, and should consider implementing programs in which private sector individuals can spend a year or two working on rotation in government.

With regard to product development and implementation, opaque and convoluted government approval processes are a major roadblock in bringing life-saving technologies to market. One participant specifically mentioned
the confusion associated with the Emergency Use Authorization process for monkeypox countermeasures, noting that there seemed to be different standards for countermeasures that were very similar. Additionally, many participants agreed that the government could provide more assistance in supporting the translation of technology into the marketplace—the 2022 National Biotechnology and Biomanufacturing Initiative (NBBI) Executive Order may be able to help with this.9

The inefficiencies of clinical trials are another clear hurdle in effectively addressing future biological risks. Pharmaceutical companies are not incentivized to streamline their processes, given the minimal competition they face. Additionally, their priority is generally on completing clinical trials once they have begun, rather than starting new clinical trials. This means that it takes quite a while after the inception of an idea to begin a clinical trial, since ongoing clinical trials require significant human and material resources.

Furthermore, some participants noted that for some pathogens, clinical trials are not the most effective mechanism. For some diseases (e.g., Zika) there are not enough infections to conduct traditional clinical trials despite their potential scale of effects. For pathogens like Zika, some participants suggested that human challenge trials would be useful. In these trials, healthy young people who are not at serious risk are deliberately infected and treated (with their consent, of course). For pathogens of concern, some participants stated that it may be useful to do challenge trials for related pathogens that are less dangerous. By developing countermeasures for related pathogens, some participants argued, you will have a starting place if something more dangerous emerges from the same family. However, this type of approach raises ethical questions that must be accounted for.

It is clear that adjusting policy to improve incentive structures will be a crucial step in optimizing public-private interactions. One potentially useful model is that of Chief Incentives Officers (CIOs) at hospitals. These individuals are specifically tasked with developing ways to change behaviors to improve

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efficiency and cost-effectiveness. Using this model—tweaked so that government officers have CIOs dedicated to incentivizing industry to cooperate with the government—may be an innovative approach to strengthen and advance collaboration. The Orphan Drug Act of the 1980s and the incentivization of green buildings may also serve as potential inspiration.

While discussion on public-private cooperation mainly focused on those between the U.S. government and domestic companies, it is important to note that the federal government would be well served by taking a more international approach. There is a great deal of innovation and development occurring outside of the United States. Moving forward, the United States should ensure it can make use of the excellent tools produced around the world, not just those produced domestically.
The Centers for Disease Control and Prevention headquarters in Druid Hills, GA.

Brett Weinstein / CC BY-SA 2.5
Interagency Interactions and the Relationship between Biodefense and Public Health

Overview

Individuals from across the federal government attended the Summit and discussed some new and evolving government structures and agencies dedicated to tackling biological threats. The following section highlights a few key points that were discussed in detail at the Summit.

Centers for Disease Control and Prevention (CDC)

The CDC is a central player in pandemic response and has made several adjustments over the past year to account for shortcomings exposed during the COVID-19 pandemic. One important new program is the CDC’s Center for Forecasting and Outbreak Analytics (CFA), which was launched in early 2022.10 There has been a great deal of discussion of the CFA’s potential impact for addressing biological threats.

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10 Centers for Disease Control and Prevention, "Center for Forecasting and Outbreak Analytics."
At the Summit, three major goals of the CFA were outlined. First, the CFA aims to predict emerging infectious disease threats and to anticipate epidemic transmission patterns. The CFA is currently building a data science team to achieve this goal—and is actively recruiting talented data scientists to join the team. Second, the CFA seeks to inform the public and policymakers through interpreting data and communicating risk. This includes understanding the role of non-pharmaceutical interventions, particularly early on in the response before vaccines and therapeutics are available. Third, the CFA seeks to advance technology and innovation, focusing on improving data capture, analytics, and visualization tools, and building the architecture needed for an effective analytics response.

The CFA will also maintain a strong focus on collaborating and information sharing across the interagency, and intends to maintain a close relationship with the HHS’s Office of the Assistant Secretary of Preparedness and Response (ASPR) especially. Additionally, CFA aims to engage with industry partners to ensure their tools are as cutting edge as possible.

Discussion went beyond the CFA to address challenges and opportunities at CDC more broadly. The CDC has been criticized as having an overly academic outlook, incentivizing publications over rapid data sharing. As CDC Director Rochelle Walensky publicly stated, a cultural shift at CDC is needed, and the CDC is taking steps to ensure this happens.\footnote{Sharon LaFraniere and Noah Weiland, "Walensky, Citing Botched Pandemic Response, Calls for C.D.C. Reorganization," The New York Times, August 17, 2022.} There has been some progress on data sharing during the monkeypox outbreak—as of the Summit, the CDC had released three Technical Reports to more quickly get out data and analytics.

Another major challenge is that the CDC lacks some of the authorities necessary to enable rapid on-the-ground responses. To date this has included insufficient authority to deploy experts to help stop an outbreak—an issue to which the current director has drawn attention.
Some participants noted that the CDC does not optimally use its employees’ skill sets during public health emergencies. For example, subject matter experts may become program managers despite lacking experience in incident command scenarios. Moving forward, it is important to match skill sets with duties and training, and to ensure that managers have the background to understand how to drive government action in emergency situations.

Department of Energy (DOE)

The Department of Energy (DOE) has immense potential for conducting biosecurity research and technology development, and should have a central role in these areas going forward. DOE, though not traditionally thought of as an agency that focuses on human health, has been at the forefront of tackling big problems since the Manhattan Project, and has unique resources and multidisciplinary talent to contribute to addressing biological threats.

DOE has demonstrated its capabilities throughout the COVID-19 pandemic. A major success over the past few years has been the National Virtual Biotechnology Laboratory (NVBL), which was established with funding from the CARES Act.\(^\text{12}\) The NVBL brought together the broad expertise and resources of DOE’s national laboratories to address key challenges that arose during the COVID-19 pandemic. Some major successes include developing technologies for mass-manufacturing of PPE, screening antibodies to rapidly identify antiviral drug candidates, and epidemiological modeling of COVID-19 transmission. In 2022, DOE established the Bio-preparedness Research Virtual Environment (BRaVE) program, which will build off of the success of the NVBL and will focus on developing tools to enable real-world epidemiological data to be integrated into models.\(^\text{13}\)

\(^\text{12}\) Department of Energy, “National Virtual Biotechnology Laboratory.”

There are several other programs and offices at DOE of particular note. DOE’s Office of Intelligence and Counterintelligence has played a role in assessing the origins of COVID-19. The Office of Technology Transitions, as well as user facilities at the National Labs, are a useful tool for engaging the private sector and getting technologies to market. Finally, the National Nuclear Security Administration is currently leading a bio-assurance strategy development process that will help ensure that DOE’s assets can be effectively leveraged.

Unfortunately, once an emergency subsides, funding at DOE is often cut. In order for DOE to be able to contribute maximally, sustained funding appropriations for pandemic preparedness and biodefense work will be necessary. In this way, innovations can occur in between emergencies, leaving us better prepared to prevent the next crisis. Ensuring the DOE has a continued role in biosecurity will be key, given the talent, technology, and infrastructure housed at the National Labs. DOE was able to apply several of the advances made during COVID-19 to the interagency response effort on the mpox virus.

The Executive Office of the President & The American Pandemic Preparedness Plan

The American Pandemic Preparedness Plan (AP3), a strategy document released by the Executive Office of the President (EOP),\(^\text{14}\) was frequently discussed at the Summit. It is important to note that the AP3 is not intended to be a playbook for all biological threats, but rather a piece in the puzzle to build capacities for addressing vulnerabilities, upon which future work can be built. While the AP3 is a valuable base to build upon, more ambitious approaches will be necessary to address the full range of biological threats. For instance,

the AP3 presents the goal of having a vaccine available for use 100 days after an emerging threat is recognized. While some participants noted that 100 days is not fast enough, others felt that it was a valuable starting goal, and that the time frame can be reduced over time.

In addition to increasing the ambition of the U.S. government’s pandemic response plan, participants noted that a few key areas were missing. As the AP3 has a largely domestic focus, more attention to international engagement will likely be necessary to make real progress. Additionally, the AP3 does not include sufficient strategy for limiting disease spillover from animal populations, which will be critical to include in future iterations of the strategy.

Experts on the AP3 noted that the plan will not be useful unless there are new appropriations, and that these appropriations must be fortified over time. Along with creating sustained funding for addressing biological threats, there is an understanding within the Executive Branch that a more enduring system for pandemic response is needed. Currently, much of the community is built on individuals and their professional relationships, rather than formal, structured networks that can be sustained and easily launched into action.

Some participants suggested that the White House does not have the right structures to lead a pandemic response, noting that the National Security Council and the Office of Science and Technology Policy don’t have much authority. These participants largely suggested HHS or DoD as leads on pandemic response, given that these agencies are implementing bodies. Though the EOP is an important player in developing strategies and priorities, it is not going to be able to run pandemic responses alone.

15 Andrew Weber, Yong-Bee Lim, “10 + 10 Over 10: A Funding Vision for the U.S. Fight Against Biological Threats,” Council on Strategic Risks, April 1, 2021
Holistic Interagency Response

There were mixed opinions on how integrated preparedness for natural and deliberate threats should be, and some participants cautioned against regarding these two types of threats as identical. These participants noted that consolidating everything comes at the risk of losing some specialized aspects. For instance, solutions designed for naturally-emerging threats may not be sufficient for a truly catastrophic deliberate threat scenario. However, most participants agreed that siloing public health and biodefense has more disadvantages than advantages. Ultimately, the impact of deliberate and naturally-emerging threats may require similar responses, despite their disparate origins.

There was consensus that recognizing pandemic preparedness as a national security issue is essential to give it the resources needed. Several participants noted that they were pleased to see National Security Advisor Jake Sullivan play a prominent role at White House events launching the CFA and the NBBI. This suggests better integration and a clear recognition of the threat.

Biodefense and pandemic preparedness are incredibly broad issues, which translates to overlapping jurisdiction issues for Congress—some issues are so large and span so many agencies that they fall through the legislative cracks. This can drive a misperception that there are more redundancies than actually exist. Clarifying how agency programs, authorities, and funding work and complement each other can help in ensuring efficiency and also prevent federal agencies mistakenly believing that others are covering parts of this mission set that they are not.

The importance of educational opportunities and fellowships for growing the interagency biodefense workforce is clear. Specific fellowships that participants saw as valuable included the Science and Technology Policy Fellowship run by the American Association for the Advancement of Science, the Emerging Leaders in Biosecurity Fellowship run by the Center for Health Security, and
CSR’s Fellowship for Ending Bioweapons. Each of these programs helps to cultivate a dedicated workforce with the experience and expertise needed to address the national security threat posed by biological risks. Fellows from these programs have a solid understanding of the way that various government agencies fit together to address biological threats, and have the potential to increase connectivity across the interagency.
A user checks settings for COVID-19 exposure notifications on their cell phone, May 2020.

Mika Baumeister
Strategic Communications

Overview

Throughout the Summit, the importance of communication at all scales came up repeatedly. Though “strategic communications” means different things across different communities, the discussion at the Summit centered on public health messaging and broadly increasing messaging that biological threats are a serious and pressing issue. Overall, participants stressed that successful communications will rely on accurate information coming out of government and academic labs, coordination within the government, and targeted, concise messaging.

Public Health Messaging

Public health messaging and communication during the pandemic was a major issue. Oftentimes senior government officials learned of updates to public health guidance at the same time as the public, and there was little to no time committed to rollout or groundwork. Additionally, updated guidance from the CDC was rarely connected with an explanation for the changes, leaving the public confused and less likely to trust the information. COVID-19 has highlighted how essential it is to roll out public health guidance in a well-planned, well-explained manner, and the CDC appears committed to improving on these areas moving forward.

Siloed government efforts also hindered communication. There were multiple sources of information from across the interagency, and consolidating and communicating this information in a cohesive way was difficult—interagency communication will be key in addressing this problem in the future.
Another issue in public health messaging is that there are rarely communications experts in the room when policy decisions are being made. Communication strategies are written as bullet points by non-experts during these meetings, rather than integrating communications staff into the full process. This leaves communications staff little flexibility and limited resources to get their message out clearly. While public health officials are largely focused on getting the science right, it is just as important to understand how the message will be received and interpreted. As such, dedicated communications staff should be present throughout the policy-making process.

Moving forward, non-governmental organizations (NGOs) may be a valuable source of innovative messaging techniques—though throughout the past few years these resources have not been fully taken advantage of. Tapping into the unique skill sets of NGOs will be an important way to enhance government messaging.

In addition to harnessing the skills of NGOs, some Summit participants raised the idea of encouraging local public health departments to work with business schools on building business plans for communications and diagnostics. These plans could then be shared with local health departments. By having communities outside of scientists working on this issue, more outside-of-the-box thinking is possible, which can lead to innovative solutions that overcome groupthink.

With regard to specific improvements needed in communications, participants noted that communicators must think about how people take in information psychologically. Through employing effective storytelling and making information as simple as possible, communications are likely to be more impactful. Furthermore, developing a foundation of trust with the public is crucial, and is an endeavor that deserves its own dedicated resources.

It is also essential for communicators to tailor messages to specific communities. Targeted messaging may be best achieved by giving states authorities to experiment and develop their own health messaging that works well for their communities. The federal government can maintain overarching guidelines
and best practices while also allowing for small-scale and region-specific messaging from state and local governments. Furthermore, messaging for specific communities that are disproportionately affected by infectious disease threats is of utmost importance. For example, the federal response to the mpox virus lacked a specific outreach strategy to members of the LGBTQ+ community. It’s important to note that communication is a two-way street—the federal government should listen to local policymakers to best develop trust and communication channels to serve local communities.

There was consensus among many participants that exercises are an important way to flex communication skills, and to signal to adversarial groups that the United States is prepared for biological threats. While a great deal of money is spent on exercises, these exercises tend to be overly scripted, and communications are not considered as deeply as they should be. Exercises present an excellent opportunity to experiment with how to best incorporate messaging and communications into the policy planning strategy. Exercises should also incorporate the threat of misinformation and disinformation, as well as the potential for messages to be misconstrued or distorted. Overall, exercises can be more worthwhile if they are less scripted, if they include more diverse scenarios, and if executors have greater willingness to fail and see preparedness gaps.
Increasing Ambitions for Addressing Biological Threats

Though biological threats appear to be increasing in priority, it seems that the federal government still does not fully understand the scope of the threat. Driving home the seriousness of biological threats will be a necessary step to get the government to prioritize the biodefense enterprise. One participant noted that people don’t know or believe how many people have been killed by infectious disease threats. For instance, the 1918 flu killed more people (approximately 50 million) than the number of people who died in combat in World War I (approximately 40 million). This sentiment was echoed by other participants who noted that infectious disease threats are harder to visualize than a nuclear weapon going off, for example, which leads to people taking them less seriously.

Additionally, it appears that policymakers do not fully understand the odds of a deliberate or accidental threat occurring, nor do they understand how severe the outcome of such a threat could be. This is partially because the world has never seen a truly catastrophic biological event that was attributed to being deliberately or accidentally caused. Additionally, not all policymakers are familiar with advancing capabilities in the life sciences that lower the barrier to constructing a dangerous pathogen. Educating policymakers on this threat—including on the importance of synthetic DNA screening—will be essential to encourage that sufficient resources are dedicated to this threat.

To increase awareness of biological threats, several participants suggested that they should be covered early on in the education system, with a curriculum that provides more clarity on infectious diseases and the dangers that they pose. It is also important to recognize the changing character of warfare—it is necessary

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16 Centers for Disease Control and Prevention, “1918 Pandemic (H1N1 virus),” March 20, 2019.

for people to understand that this century will likely continue to include non-traditional and hybrid war methods. As discussed earlier in this report, building a bipartisan Congressional community of practice that understands the threat would also be a valuable direction—at present, neither political party is advocating for the investments necessary for effective biodefense.

Decision-makers need to be incentivized to take rapid action to get ahead of the curve of emerging threats, and government systems need to be recalibrated to be biased toward action over inaction. Unfortunately, the political environment has become divisive and distrustful which deters a forward leaning posture. However, through education and engagement, a more ambitious stance on combating biological threats is possible.
Conclusion

Throughout the Summit, participants agreed that there is strong potential for advancement in biodefense and pandemic preparedness. The COVID-19 pandemic provided a wealth of lessons and opportunities that, if applied, will ensure an improved response to the next biological event. Through supporting technological innovation, ensuring sustained funding, and clearly defining the roles and responsibilities of various government agencies, substantial progress can be made. In short: we have the necessary tools—the challenge is now to implement them.

The Council on Strategic Risks is grateful to our Summit participants for sharing their diverse perspectives and insights. The Summit served as an important reminder of the necessity to convene across disciplines and beyond everyday circles. By forging new connections and bringing in fresh voices, participants were able to develop creative and unique solutions to incredibly challenging issues.