COUNCIL ON STRATEGIC RISKS
THE NOLAN CENTER

BRIEFER

No. 24 | August 23, 2021

Key U.S. Initiatives for Addressing Biological Threats Part 4: The Department of State

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INTRODUCTION

The COVID-19 pandemic is a microcosm of both the risks and opportunities that the life sciences represent for the modern, globalized world. On the one hand, COVID-19 continues to devastate the world. On the other hand, the pandemic has galvanized the international community to leverage cutting-edge life sciences tools and knowledge into the highly-effective vaccines, therapeutics, and diagnostics the world has today.[1]

In terms of biological threats, the COVID-19 pandemic struck at a time when geopolitical, sociocultural, economic, and environmental factors were already drastically changing the security landscape. Nations such as Russia, China, and North Korea are suspected of possessing biological weapons capabilities and have shown a willingness and ability to engage in gray-zone warfare (i.e., competitive activities between states that are characterized by "intense political, economic, informational, and military competition" that is short of conventional war).[2] The perceived erosion of the norm against the use of chemical weapons has also raised concerns at the highest levels of the United Nations on how this may be a harbinger for the decay of norms against the use of other lethal agents, including biological weapons.[3]

[1] Government Accountability Office, *Science and Tech Spotlight: COVID-19 Vaccine Development*, June 2021.
[2] See Matthew R. Crouch and Ronald C. Fairbanks, "How Should the Next National Defense Strategy Balance Terrorism, Rogue Regimes, and Great-Power Competition?" Atlantic Council, March 1, 2021; Joseph L. Votel, Charles T. Cleveland, Charles T. Connett, and Will Irwin, "Unconventional Warfare in the Gray Zone," *Joint Force Quarterly*, Vol. 80, No. 1, 2016; and U.S. State Department, *2021 Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament and Commitments*. April, 15, 2021.
[3] United Nations General Assembly, "Amid Reports of Continued Chemical Weapon Use, First Committee Delegates Debate How Best to Effectively Eliminate Banned Lethal Agents," October 23, 2018.

As a result of these trends, the United States will have to expand its efforts to maximize benefits and minimize risks from advances in synthetic biology, bioinformatics, and additive bio-manufacturing.[4] Hopefully, one of the results of the pandemic will be a surge toward greater international cooperation in this regard. The U.S. Department of State (State) will be pivotal in realizing this vision.

THE ROLE OF THE U.S. DEPARTMENT OF STATE

Addressing biological threats depends heavily on relationships. Progress for the United States and the world in this area requires strong human and intergovernmental connections to encourage communication, maintain situational awareness, share best practices, and build capacity around the world for finding and stopping biological threats before they cause mass destruction.[5] The Department of State's critical activities include:

- Leading U.S. engagement in fora like the Biological Weapons Convention (BWC) and promoting norms against biological weapons.
- Building capacity with partner nations via the Biosecurity Engagement Program, which engages life scientists, government officials, non-governmental organizations, and other stakeholders to provide assistance in improving biosecurity, biosafety, and pathogen surveillance and response in partner nations.[6]
- Working through more than 270 embassies, consulates, and missions worldwide to lead and support arms control and counterproliferation efforts around the world, for example via the Proliferation Security Initiative (PSI) that aims to stymie weapons of mass destruction (WMD) proliferation efforts.[7]
- Collaborating with other U.S. agencies, including via the Biodefense Coordination Team (which identifies gaps, shortfalls, redundancies, and opportunities for better activity and resource alignment) and the National Science Advisory Board on Biosecurity.[8]

The flipside to State's operational strength highlights a significant challenge it must also navigate: operating effectively in regions where relationships are weak or non-existent, including with regard to sanctioned nations like Russia, North Korea, and Iran.

The aim of this briefer is not to be comprehensive regarding State's roles and responsibilities in addressing biological threats. Rather, it identifies critical gaps that the department can fill in the years ahead. In this context, the briefer promotes four critical recommendations that State should prioritize immediately:

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[4] National Academy of Sciences, *Biodefense in the Age of Synthetic Biology*, 2018.

[5] David R. Franz, "With the Changing Biological Threat...Smart International Engagement Policy Would Lower Cost and Increase National Security," *Virtual Biosecurity Center*, November 13, 2012.

[6] U.S. Department of State, "Biosafety and Biosecurity," accessed July 15, 2021; Kenneth Yeh, Jeanne Fair, Helen Cui, Carl Newman, Gavin Braunstein, Gvantsa Chanturia, Sapana Vora, Kendra Chittenden, Ashley Tseng, Corina Monagin, and Jacqueline Fletcher, "Achieving Health Security and Threat Reduction through Sharing Sequence Data," *Tropical Medicine and Infectious Disease*, *Vol. 4*, No. 2, 2019, p. 78; and U.S. Department of State Biological Engagement Program, "About Us" accessed July 15, 2021.

[7] United States Department of State, "Diplomacy: The U.S. Department of State at Work," accessed July 15, 2021; Susan J. Koch, *Occasional Paper 9 - Proliferation Security Initiative: Origins and Evolution* (2012), National Defense University, Center for the Study of Weapons of Mass Destruction; and "Proliferation Initiative (PSI)," *Nuclear Threat Initiative*, May 31, 2020.

[8] U.S. Government Accountability Office, "National Biodefense Strategy: Opportunities and Challenges with Early Implementation," March 11, 2020.

- Enhance multilateralism via tailored bio cooperation mechanisms
- Leverage existing and emerging technologies to assist in detection, attribution, and verification of treaty compliance
- Expand diplomacy and programs for pathogen early warning
- Appoint a special envoy and increase biorisk expertise

ENHANCE MULTILATERALISM VIA TAILORED BIO COOPERATION MECHANISMS

COVID-19 displays the acute need for enhancing multilateral cooperation in addressing biological threats. State should help advance creative mechanisms in this regard that complement, but are not constrained by, existing international structures. As one of the co-authors of this briefer wrote in 2019:

> "[A] significant strength to global governance of WMD has been the rise of ad hoc efforts to bolster the primary treaty systems and accelerate progress toward their goals. Many of these mechanisms have been in multilateral and minilateral formats, welcoming small- to medium-sized groups of countries (and often other actors) to join together in committing resources, driving action, and communicating their political commitment to reducing well-defined WMD risks."[9]

In the coming years, State should work with other nations and nongovernmental entities to advance such mechanisms that complement the Biological Weapons Convention (BWC) and help improve the world's capabilities to address biological threats. In the near term, the International Agency for Biological Safety (IABS) proposed by the President of Kazakhstan to the UN General Assembly in 2020 is an ideal target. Though nations wishing to advance the IABS have yet to detail its operations and roles, Kazakhstan has indicated an interest in it becoming a hub for data exchange, aiding countries in responsible governance of their bio economies, and supporting investigative efforts to rapidly understand and address outbreaks.[10]

Additionally, Ambassador Ahmet Üzümcü, former director general of the Organization for the Prohibition of Chemical Weapons (OPCW) and a Senior Advisor to CSR, has proposed that countries unite to establish a new institution. This institution would operate an "epidemic early warning center" and "rapid response teams" that deploy to investigate and characterize the threat when a potentially-serious outbreak emerges.[11] Further, this effort could utilize promising technologies like metagenomic sequencing in the labs, which can rapidly and effectively analyze samples for all known pathogens. Metagenomic sequencing would also be promising in addressing novel pathogens, including those from natural sources with future pandemic potential as well as synthesized biological weapons.[12]

Modeled from OPCW functions, this could help confer neutrality on work to understand outbreaks and promote science-led decision making. This proposition may be part of the IABS put forth by Kazakhstan or promoted along separate diplomatic lines.

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[9] Christine Parthemore, "Weapons of Mass Destruction: The State of Global Governance Amid Rising Threats & Emerging Opportunities," The Council on Strategic Risks, October 2019, p. 12.

[10] Dmitry Babich, "President Tokayev Addresses the SCO Summit: Emphasizes Collective Responses to Common Threats," *The Astana Times*, November 13, 2020.

[11] Ambassador Ahmet Üzümcü, "International Response to Pandemics: Is there a need for a new international institution?" The Council on Strategic Risks, April 27, 2020; and "Preparing for the Next Pandemic: A Scenario Exercise," The Council on Strategic Risks, June 24, 2020.

[12] One example of metagenomic sequencing that could be put to use as part of multilateral labs and cooperative mechanisms is an open platform called IDseq, accessed July 28, 2021.

LEVERAGE EXISTING AND EMERGING TECHNOLOGIES TO ASSIST IN DETECTION, ATTRIBUTION, AND VERIFICATION OF TREATY COMPLIANCE

Detection, attribution, and verification of anthropogenically-derived pathogen events have been perennial problems for State and other institutions. Three main factors contribute to these issues. First, variations in capabilities and infrastructure, as well as data collection, logging and sharing, pose significant challenges to accurate and timely pathogen detection.[13] Second, the life sciences exemplify the dual-use dilemma: the phenomenon where research, development, deployment, and advances in the life sciences can produce both legitimate and illicit applications which, thus, makes it "inherently difficult to control one [application] without inhibiting the other."[14] Third, even if the preponderance of a biological event points to the deliberate use of a biological weapon by a state actor, attribution and verification attempts are muddied by both politics and the difficulty in separating treaty-prohibited from treaty-permitted activities due to the dual-use dilemma. Therefore, intent becomes a key factor that State and other actors need to ascertain in suspected cases of biological weapons use.[15]

Assessing intent continues to be a major challenge due to the difficulties in fully understanding something that is inherently socio-political. However, there are significant advances in technologies and methodologies that State can take advantage of to make impactful strides in addressing detection, attribution, and verification gaps both for on-site and off-site verification.

On-site verification inherently requires access to a facility for inspection. With access, advances in DNA sequencing and data collection have dramatically reduced the cost of sequencing collection as well as novel modalities for inspection. This has led to sequences that are more accurate and detailed with real-time turnaround for results. Once such data is collected, there is greater baseline data on the use of biotechnology with the expansion of the modern biotechnology industry and scientific domains. This has also led to a greater repository of publicly available data on hazardous biological agents through numerous private and public investments such as the Intelligence Advanced Research Projects Activity's (IARPA's) programs FELIX and FunGCAT, which are instrumental in developing next-generation computational and bioinformatics tools to "improve DNA sequence screening, augment biodefense capabilities through the characterization of threat based on function, and to advance our understanding of the relative risks posed by unknown acid sequences."[16]

Advances in technologies for the inspection of biological agents and a rapidly-expanding body of public and private biological data creates the right conditions to take advantage of modern big data analysis and high-power computing. In one example, the artificial intelligence company DeepMind recently publicly released the direct sequence to 3D protein structure prediction algorithm AlphaFold[17] along with structural predictions of every known protein in the human proteome.[18] The combination of structural and functional predictions of a sequence in the geopolitical context of where a sample was collected can provide inspectors with a faster understanding of the biological nature of a sequence of concern.

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[13] Natasha E. Bajema, William Beaver, and Christine Parthemore, "Toward a Global Pathogen Early Warning System: Building on the Landscape of Biosurveillance Today," The Council on Strategic Risks, 2021.
[14] Gerald L. Epstein, "Preventing Biological Weapons Development Through the Governance of Life Science Research," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, *Vol. 10*, No. 1, 2012, p. 17 - 37.
[15] Jonathan B. Tucker, "Biological Weapons Proliferation: Reasons for Concern, Courses of Action," Stimson Center, January 13, 1998.
[16] See Intelligence Advanced Research Projects Activity, "Finding Engineered Linked Indicators,"accessed July 23, 2021; and "Functional Genomics and Computational Assessment of Threats," accessed July 23, 2021..
[17] "Putting the power of AlphaFold into the world's hands," DeepMind.
[18] "AlphaFold Protein Structure Database," DeepMind.

With the growing dependence on commercial DNA synthesis companies, there are emerging modalities to enhance off-site verification. While many commercial synthesis companies already screen both customers and the sequences being ordered, there is additional opportunity for multilateral cooperation to strengthen these screening methods. A combination of enhanced cooperation combined with advances in modern computing can provide additional context for sequences of concern.[19]

In addition, the proliferation of web-based content provides opportunities to leverage big data analysis of academic literature, news, and media - both social and reporting - to identify indicators of concern. In the context of both novel modalities of screening sequences and online content, identification of intent still remains a primary challenge of verification. However, both tools can provide information to enhance negotiations and multilateral cooperation. In this context, State should promote the development and deployment of such tools, potentially through new cooperative, multilateral mechanisms like those mentioned above.

EXPAND DIPLOMACY AND PROGRAMS FOR PATHOGEN EARLY WARNING

Across the international community, there is a growing movement toward creating a global pathogen early warning system.[20] Such a system would go beyond today's biosurveillance systems, which are fragmented and often do not convey information quickly enough to stop infectious diseases before they become outbreaks or worse. The world has the technologies and tools today to transform this landscape into a global early warning system that can identify disease threats in real time and cover their full spectrum effectively---including pathogens that may be engineered or otherwise targeted for use as biological weapons.[21] A global early warning system could advance as a component of the operations center and rapid response concepts noted above, or developed in ways that ensure collaboration across these initiatives.

As these capabilities are being expanded, it is clear that meeting the vision of a global pathogen early warning system will entail significant diplomacy across all nations. The data-sharing it will require necessitates far greater trust and confidence among nations than the world has today---and may require updates to international law or existing cooperative mechanisms. The diplomatic corps of the United States and other countries will need to ramp up training in infectious diseases, the technologies that can help prevent future pandemics, and other related issues. If it has not yet done so, the White House should lead an interagency planning process to guide U.S. diplomacy for advancing pathogen early warning capacity, complemented by a significant ramp-up in cooperative biological engagement activities to ensure the United States leads the world in providing the needed tools and training.[22]

APPOINT A SPECIAL ENVOY AND INCREASE BIORISK EXPERTISE

The Department of State's work on biological issues crosses many offices and functions. Many key roles are coupled with nuclear arms control, chemical security, environmental, and other issues, which hold benefits but can limit diplomatic capacity for working on bio issues.

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[19] Piers Millet, Tessa Alexanian, Evan Appleton, James Diggans, Michael Montague, and Alexander J. Titus, "Feasibility of Onsite Verification," *Untitled Book*, forthcoming Fall/Month 2021.

[20] Dr. Natasha E. Bajema, William Beaver, and Christine Parthemore, "Toward a Global Pathogen Early Warning System: Building on the Landscape of Biosurveillance Today," The Council on Strategic Risks, July 2021.

[21] Dr. Natasha E. Bajema, William Beaver, and Christine Parthemore, "Toward a Global Pathogen Early Warning System: Building on the Landscape of Biosurveillance Today," The Council on Strategic Risks, July 2021.

[22] Bill Beaver, Christine Parthemore, and Dr. Nikki Teran, "Key U.S. Initiatives for Addressing Biological Threats Part 3: The Biological Threat Reduction Program," The Council on Strategic Risks, August 9, 2021.

One way to address this gap would be to create a position akin to similar special positions created for transnational issues like climate change. This should be an elevation and continuation past the current pandemic of the current Coordinator for Global COVID-19 Response and Health Security position, and incorporate lessons from the special envoy office State established in 2014 to curate international cooperation to stop the West Africa Ebola crisis. This special envoy and supporting staff should focus on preventing future pandemics, addressing deliberate and accidental biological threats, and advancing biotechnology cooperation with partners around the world, a remit that is slightly broader than traditional health security roles. This should be a highly-empowered position to lead on the initiatives outlined above---and to promote the United States as the partner of choice in advancing bio economies around the world in ways that respect high biosecurity, safety, and nonproliferation standards. The envoy's office would conduct this work alongside counterparts whose responsibilities overlap as part of broader arms control and threat reduction portfolios. This may be done with a specific time horizon, such as five years, followed by a reassessment of the international landscape and national needs.

Further, State should increase the number of biosecurity experts to support both the policy development and implementation aspects of addressing biological threats. These experts could serve three main purposes. First, they could provide much-needed expertise on the intricacies and nuances of addressing biological threats — threats which significantly differ from other threat agent categories such as chemical, nuclear, and radiological. Second, these experts would be exceptionally helpful toward the formulation, implementation, evaluation, and course-correction of actions taken by State to address biological threats. Finally, these experts can serve as leaders who can highlight and advocate for the importance of addressing biological threats as the security environment changes domestically, regionally, and internationally.

The effectiveness of international cooperation on biological threats is shaped by whether State has willing partners in embassies around the world. In general, biological threats should be widely accepted as a core strategic priority given how dramatically the ongoing pandemic has affected the world. Yet staffing and competing priorities may interfere with advancing work to address biological threats.

Foreign service officer capacity has declined precipitously for these and other science, technology, and environmental roles---by one assessment, a decline of more than ⅔ to just 50 such embassy positions from 2004 to 2013.[23] Second, embassy teams in many countries simply juggle many other issues that will compete for their time, from internal instability to conflict to the conduct of highest-level negotiations that all require significant diplomatic action. In addition, the increasing complexity and transnational nature of biological threats means diplomats with deep expertise in science and technology matters are more important than ever.[24] Therefore, augmenting diplomatic staff with more experts with biorisk-specific knowledge and experiences, including in embassies, can provide critical technical and policy expertise. This expertise, in turn, can improve the U.S. ability to understand how biological threats evolve and succeed in cooperative solutions like those proposed in this briefer.

Finally, and perhaps most importantly, State has to find a way to ensure that biological threat prevention remains a high priority, resources are increased to a level commensurate with the scale of the risks, and awareness of biological issues survives after the specter of COVID-19 eventually fades. The Office of Policy Planning at State, whose storied history includes the creation of George Kennan's Long Telegram, researches and creates long-term foreign policy visions and objectives for the department. Recognizing

[23] Justine F. Chen, "Reinstituting the ESTH Cone Within the US Foreign Service," *Journal of Science Policy & Governance*, August 2015.
[24] "The United States Needs a Modern Foreign Service with Science at the Forefront," *National Science Policy Network*, March 2021.

the emerging threats posed by science, the Policy Planning staff should include civil servants with a deep knowledge of scientific issues, not limited to biology, to generate the forward-thinking policy needed to address future threats.

CONCLUSION

The role of the U.S. Department of State is a quintessential one in addressing all manner of risks, threats, and opportunities. As Richard Haass, the President of the Council on Foreign Relations pointed out in an interview in 2017, "we have got to understand that what we do in the world is not only good for the world; it's good for us. It's not a form of philanthropy; it's a form of national security."[25] Through its vast influence in the international community and its engagement in both policy and implementation, State has a wide variety of capabilities to draw from to address biological threats in a way that's both good for the world, and good for the United States.

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ACKNOWLEDGEMENTS

The authors and the Council on Strategic Risks would like to thank the team of government, academic, and private sector experts who convened (virtually) to help us define and explore these recommendations on a non-attribution basis.

[25] "How a Former Diplomat Makes Sense of 'A World in Disarray," *PBS News Hour*, April 17, 2017.