Strategic Multilayer Assessment Special Topics Paper

The COVID Crisis: Implications for United States – and Global – Biosecurity

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COVID-19 and Vulnerabilities in US Biosecurity

The United States' (US) engagement of public health resources to meet the current SARS-CoV-2 (COVID-19) crisis has revealed vulnerabilities in testing and treatment components of biosecurity. Facing a severe shortage of available testing kits, the US Centers for Disease Control (CDC) attempted to develop its own test for COVID-19, rather than following World Health Organization (WHO) recommendations for testing methods[1]. The lack of tests has made it difficult to track exactly how many people within each state, as well as the US at-large have been affected, which has implications both for the extent of public health response, and considerations for approaches to stabilize and sustain the national economy.

Currently, COVID-19 testing utilizes a polymerase chain reaction (PCR) method to analyze genetic material found within bodily fluids, to identify the presence of SARS-CoV-2 viral genetic material[2]. However, PCR testing has incurred a number of problems: there have been considerable delays in making test results available to healthcare professionals and patients; the test may provide false negative results if administered soon after initial infection[3]; and PCR methods only assess the presence of a current viral infection, but do not afford information about whether the test recipient has recovered from prior COVID-19 infection.

This latter issue is important. Following infection, the immune system produces antibodies that are specific to the virus, and which remain functional after recovery[4]. This antibody response also occurs in individuals who have been infected, but do not develop signs or symptoms of disease[5]. Serological testing can assess the presence of viral-specific antibodies in a person's

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[1] Chen, Caroline, Marshall Allen, Lexi Churchill, and Isaac Arnsdorf. 2020. "Key Missteps at the CDC Have Set Back Its Ability to Detect the Potential Spread of Coronavirus." ProPublica. February 28, 2020. https://www.propublica.org/article/cdc-coronavirus-covid-19-test.

[2] Australian Government Department of Health. 2020. "How Testing Works for COVID-19." Therapeutic Goods Administration (TGA). Australian Government Department of Health. March 27, 2020. https://www.tga.gov.au/how-testing-works-covid-19.

[3] "Testing for COVID-19." 2020. Centers for Disease Control and Prevention. Centers for Disease Control and Prevention. April 15, 2020. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.

[4] Dowd, Scot E., Marilyn J. Halonen, and Raina M. Maier. 2009. "Chapter 12 - Immunological Methods." In *Environmental Microbiology (Second Edition)*, 2nd ed., 225–41. https://doi.org/10.1016/B978-0-12-370519-8.00012-2

[5] Rogers, Adam. 2020. "Blood From Covid-19 Survivors May Point the Way to a Cure." Wired. Conde Nast. March 24, 2020. https://www.wired.com/story/an-old-source-for-potential-new-covid-19-drugs-blood-serum/.

blood, and in this way detect presence of an immune response (rather than the virus itself), thus identifying those individuals who will likely possess subsequent immunity – at least in the short-term[6]. This makes serological testing extremely useful to enable more precise evaluation of viral spread, how many individuals are likely to be immune, and how many people remain vulnerable to infection. Such assessments would facilitate more accurate predictions about the trajectory of COVID-19, and could also be used to identify those individuals who are immune and could provide the human resources necessary to stabilize and sustain the economy[7].

Importance of Awareness and Preparedness to Biosecurity Response

To be sure, COVID-19 is a novel virus. However, corona viruses, and other viral species capable of producing rapid and broad epidemic, if not pandemic effects are well-known, and the risk and threat of such a viral pandemic to US and global biosecurity were previously identified and communicated[8]. The lack of available treatments – coupled to insufficiency of critical care resources (e.g.-mechanical ventilators) - has placed enormous pressure on healthcare systems and personnel, and is prompting consideration of worst-case scenarios that necessitate difficult decisions[9] about triage and prioritization of care[10] in public, military, and political domains.

An important step toward treating COVID-19 is the development and use of safe and effective antiviral agents. Antiviral therapy to COVID-19 could be aimed at targeting a number of different stages in viral infection, replication and dissemination processes. Another useful approach to COVID-19 therapeutics is antibody treatment that may take the form of drugs[11], or the use of "convalescent plasma" taken from infected individuals who have recovered from COVID-19 and possess neutralizing antibodies[12]. Certainly, there are limitations that must be acknowledged and addressed when considering the use of antibody-based treatment methods. For example, at present it remains uncertain if and to what extent such treatments are effective in practice, and even if shown to be efficacious and effective in real-world settings, it is likely that

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[6] Hahn, Stephen M. 2020. "Coronavirus (COVID-19) Update: Serological Tests." U.S. Food and Drug Administration. FDA. April 7, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests.

[7] Gerstein, Daniel M., and James Giordano. 2020. "How to Reopen America." CNN. Cable News Network. March 27, 2020. https://www.cnn.com/2020/03/27/opinions/reopen-america-coronavirus-gerstein-giordano/index.html.

[8] Walcott, John. 2020. "The Trump Administration Is Stalling an Intel Report That Warns the U.S. Isn't Ready for a Global Pandemic." Time. Time USA. March 9, 2020. https://time.com/5799765/intelligence-report-pandemic-dangers/.

[9] Cha, Ariana Eunjung, and Laurie McGinley. 2020. "Who Gets a Shot at Life If Hospitals Run Short of Ventilators?" The Washington Post. WP Company. April 7, 2020. https://www.washingtonpost.com/health/2020/04/07/ventilators-rationing-coronavirus-hospitals/.

[10] Fink, Sheri. 2020. "The Hardest Questions Doctors May Face: Who Will Be Saved? Who Won't?" The New York Times. The New York Times Company. March 21, 2020. https://www.nytimes.com/2020/03/21/us/coronavirus-medical-rationing.html.

[11] Hynds, Margaret. 2020. "4 Things to Know about Possible Antibody Treatments for COVID-19." CBS News. CBS Interactive. April 7, 2020. https://www.cbsnews.com/news/four-things-to-know-about-possible-antibody-treatments-for-covid-19/.

[12] "Recommendations for Investigational COVID-19 Convalescent Plasma." 2020. U.S. Food and Drug Administration. FDA. April 13, 2020. https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma.

antibody-rich plasma will not be easily identifiable or copiously available, at least in the near-term. Still such treatments are promising, both as potential "stand-alone" measures, and to serve as a stop-gap while time and resources are committed to developing antiviral therapeutics and/or a viable vaccine.

Yet here too, increased availability and accessibility of serological tests will be essential to reveal who has been infected, and therefore who may be potential plasma donors. Improving the ability to quickly produce these resources, and creating them with accessible supply will be vital to rectify the US' ability to effectively respond to pandemics - and other biological threats –at present and in the years to come. The COVID-19 pandemic has demonstrated that the US is currently ill-equipped in biosecurity preparedness and response. The rapid spread of the disease has forced citizens to drastically change their behavior[13], dramatically impacted domestic and global dimensions of the national economy[14], prompted concerns about[15] readiness of the military in times of crisis[16], and in these ways, fostered genuine manifest risks to US national security.

The Current Crisis' Implications – and Lessons to be Learned - for the Future

There is no evidence to indicate or support that COVID-19 was an intentionally developed or delivered biological weapon[17]. It is a naturally-occurring virus that spread zoonotically (from horseshoe bats[18], via pangolins as an intermediate species, to humans) in pandemic proportion. Yet, the impact and effects that the COVID crisis has had upon the US is illustrative of inherent weaknesses, flaws, and vulnerabilities in domestic biosecurity that could be targeted and kinetically or non-kinetically leveraged by adversaries in the future. Therefore, it is clear that the US must improve its biosecurity preparedness and responsiveness in order to effectively and efficiently provide protection from both natural and man-made threats. We have previously

[13] Miller, Jenesse. 2020. "Bracing for Coronavirus, U.S. Residents Are Changing Their Behavior." USC News. University of Southern California. March 13, 2020. https://news.usc.edu/166834/coronavirus-survey-usc-behavior-changes-health-economic-fallout/.
[14] Menickella, Brian. 2020. "COVID-19 Worldwide: The Pandemic's Impact on The Economy And Markets." Forbes. Forbes Magazine. April 8, 2020. https://www.forbes.com/sites/brianmenickella/2020/04/08/covid-19-worldwide-the-pandemics-impact-on-the-economy-and-markets/#668ce0c428c3.
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[17] Lee, Bruce Y. 2020. "No, COVID-19 Coronavirus Was Not Bioengineered. Here's the Research That Debunks That Idea." Forbes. Forbes Magazine. March 17, 2020. https://www.forbes.com/sites/brucelee/2020/03/17/covid-19-coronavirus-did-not-come-from-a-lab-study-shows-natural-origins/#602176ef3728.
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stated, and re-iterate here that ongoing advancements in gene-editing[19], the use of drones[20], and increasing diversion[21] of information[22] all serve to force-multiply the risks to US – and global – biosafety and security. The current situation brings into stark relief that it is not an issue of absent or insufficient intelligence: pandemic risks and threats to US biosecurity were identified and noted[23].

But awareness is only one component of preparedness. Any genuine stance of readiness must entail assessment, development, and availability of resources, services, and personnel that can be readily operationalized toward prompt, actionable response. And, as the COVID crisis is revealing, both readiness and response will require a whole-of-nation approach[24], not merely coordinated whole-of-government activity (although such coordination and collaboration is surely necessary). We further opine that any such whole-of-nation engagement must be multi-nationally cooperative to enable effective surveillance, prompt notification, tactical flexibility of resource utilization and response, and fixity in strategic planning to ensure the success of outcomes. Our opinion is both predicated upon – and evocative of – our hope that lessons learned from the current crisis can be leveraged to foster more capable biosecurity in the future.

Disclaimer.

The views and opinions expressed in this commentary are those of the authors, and do not necessarily represent those of the US Department of Defense, the Strategic Multilayer Assessment Branch, Joint Staff, Pentagon, and/or the institutions and organizations that support the authors' ongoing work.

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[20] DeFranco, Joseph. 2020. "Dark Side of Delivery: The Growing Threat of Bioweapon Dissemination by Drones." Defence IQ. Defence IQ. January 24, 2020. https://www.defenceiq.com/cyber-defence-and-security/articles/the-dark-side-of-delivery-the-growing-threat-of-bioweapon-dissemination-by-drones.

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Vikram Venkatram is a student at Georgetown University's School of Foreign Service, where his studies focus on Science, Technology, and International Affairs, with a concentration in Science, Technology, and Security, and a minor in Biology, and is pursuing graduate work through the accelerated BSFS/Security Studies M.A. program. He is a scholar of the O'Neill-Pellegrino Program in Science and Global Health Law and Policy of the Georgetown University Medical Center. His ongoing work addresses biosecurity and biohazard response, dual-use neuroscience and technology and global surveillance and policy. His work has been featured by the Strategic Multi-Layer Assessment group, Joint Staff, Pentagon, and the Mad Scientist Network of US Army Training and Doctrine Command (TRADOC).

Senior author **James Giordano, PhD** is Professor in the Departments of Neurology and Biochemistry, Chief of the Neuroethics Studies Program, Co-director of the O'Neill-Pellegrino Program in Science and Global Law and Policy, and Special Projects' Advisor to the Brain Bank at Georgetown University Medical Center. He is Scientific Advisory Fellow of the Defense Operations Cognitive Science section, SMA Branch, Joint Staff, Pentagon; Senior Fellow of the Project on Biosecurity and Ethics at the US Naval War College, Newport, RI; and consulting bioethicist to the US Defense Medical Ethics Committee, currently addressing biosecurity and biomedical response capabilities to mitigate the COVID-19 crisis. As well, he chairs the Neuroethics Subprogram of the IEEE Brain Initiative; and is an appointed member of the Neuroethics, Legal and Social Issues Advisory Panel of the Defense Advanced Research Projects Agency (DARPA). He has previously served as Donovan Senior Fellow for Biowarfare and Biosecurity at US Special Operations Command (USSOCOM); as Research Fellow and Task Leader of the EU-Human Brain Project Sub-Program on Dual-Use Brain Science; as an appointed member of the Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections (SACHRP); and as senior consultant to the Organisation for Economic Cooperation and Development Working Group on Dual-Use of International Neurotechnology.

A Fulbright scholar, Dr. Giordano was awarded the JW Fulbright Visiting Professorship of Neuroscience and Neuroethics at the Ludwig-Maximilians University, Munich, GER, and currently is Distinguished Visiting Professor of Brain Science, Health Promotions, and Ethics at the Coburg University of Applied Sciences, Coburg, GER. He was previously an International Fellow of the Centre for Neuroethics at the University of Oxford, UK.

Prof. Giordano is the author of over 300 papers, 7 books, 21 book chapters, and 20 government white papers on brain science, national defense and ethics. His book, *Neurotechnology in National Security and Defense: Practical Considerations, Neuroethical Concerns* (2015, CRC Press) is widely regarded and used as a definitive work on the topic. In recognition of his achievements he was elected to the European Academy of Science and Arts, and named an Overseas Fellow of the Royal Society of Medicine (UK). A former US Naval officer, Prof. Giordano was designated as an aerospace physiologist, research physiologist, and research psychologist, and served with the US Navy and US Marine Corps.