Enhanced Research into Synthetic Biology

by Sean R. Watterson

Synthetic biology is a field of science that draws from methodologies found in engineering disciplines, such as computer engineering, electrical engineering, control engineering, and computer science, to construct new biological systems or modify existing ones.[1] The field has the potential to enable the creation of new and deadly biological pathogens without the need for specialized knowledge, large amounts of money, or sophisticated bioweapons programs. Since advances in synthetic biology are occurring rapidly, hostile actors with limited expertise and means may soon be able to design and employ biological weapons derived from these advances. To reduce the efficacy of a potential, synthetic, biological weapons attack on U.S. soil, the U.S. must identify domestic targets that are at risk for an attack, determine how a hostile actor would develop and employ a synthetically-developed bioweapon, and synthesize biological protections to prevent loss of life. In this article, I argue that to accomplish these goals, the U.S. interagency should, (1) identify vulnerabilities of U.S. citizens to biological weapons by conducting a "vulnerability assessment," (2) develop its own limited supply of synthetic pathogens for research purposes, bound by the constraints of biological weapons treaty obligations, and (3) harness the power of these new technologies to develop synthetic protections such as inoculations, vaccines, antibiotics, and immuno-boosters. Failure to do so could result in the U.S. being poorly prepared to handle a potential biological attack.

Background

The idea that synthetic biology could be used to create a deadly pathogen is already a reality. In 2016, virologist David Evans used synthetic biology to create *de novo* the horsepox virus at a cost of approximately $100,000 over the period of about six months.[2] In doing so, Evans was the first to publicly demonstrate the ability to create a pox virus. While he is an expert on viruses and understands viruses much better than an amateur biologist, there are many others with his level of skill.[3]

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In 2002, geneticists recreated the poliovirus using synthetic biology techniques developed in the 1980s.[4] At the time, the geneticists correctly predicted that the possibility to synthesize any virus would exist in the future.[5] Now, using techniques such as clustered regularly-interspaced short palindromic repeats,"(CRISPR), a procedure that rapidly and easily modifies genes at a low cost,[6] the ability to create the poliovirus is even more widespread than it was sixteen years ago, making the threat of polio more dire.

Beyond recreating known viruses, synthetic biology has the potential to enable the creation of novel viruses. In a *Science Magazine* article regarding the horsepox synthesis, bioethicist Nicholas Evans of the University of Massachusetts Lowell states that with synthetic biology "someone could create something as lethal as smallpox and as infectious as smallpox without ever creating smallpox."[7] Whereas a biological attack using the poliovirus or smallpox is a grave threat, an attack using a previously unknown virus with unique genetic properties, behaviors, symptoms, and lethality presents an even greater threat.

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The U.S. already has a robust biological defense program implemented across the interagency that includes the Department of Defense (DoD), the Department of Homeland Security (DHS), the Department of Justice (DOJ), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Department of Health and Human Services (HHS), the Department of Veterans Affairs (VA), and the Department of Agriculture (USDA).[8] It is the mission of these agencies to reduce the risk of a biological weapons attack on the U.S. and, to a certain extent, they are already undertaking measures to mitigate such a risk—but there is room for additional efforts.

U.S. Endeavors: Vulnerability Assessment

A vulnerability assessment is a process that identifies exploitable weaknesses in a system and suggests options to eliminate or mitigate those weaknesses.[9] One typically conducts this type of assessment to help inform planning and capability investments.[10] The DHS, for example, performs vulnerability assessments when it conducts a thorough risk analysis in order to gauge points of weaknesses alongside potential threats and their consequences for a scenario.[11] In conducting a vulnerability assessment, DHS identifies potential risks, categorizes the risks by likelihood and consequence, and then seeks to counter these risks via appropriate means.

Broadly, "vulnerability" is having exposure to the possibility of a harm or attack.[12] To assess U.S. vulnerability to biological weapons, one might profitably reference an analogous application of vulnerability from the climate change literature, which calculates the vulnerability of a given population to the effects of climate change as a function of that population's exposure to a particular climate threat or risk, sensitivity to the threat or risk, and ability to adapt do the threat or risk:

vulnerability =
f (exposure, sensitivity, adaptive capacity) [13]

For vulnerability to climate change, "exposure" represents factors such as a percentage of the population's roads that are exposed to flooding or a percentage of the population's buildings that are exposed to damage from wind or weather.[14] "Sensitivity" represents factors such as a population's access to critical infrastructure such as transportation terminals or the percentage of dependent demographic groups such as the very young or the very old.[15] "Adaptive

capacity" represents factors such as human and civic resources, such as the percentage of the population that is in the workforce, population wealth, the ability of a population to recover from natural disasters, or the percentage of the population that is educated.[16]

For biological weapons, a population's vulnerability must likewise include exposure, sensitivity and the ability to adapt. In this application, exposure to a biological weapon would represent the percentage of people infected by a pathogen in a geographic location; sensitivity would represent a population's access to critical infrastructure, such as hospitals, as well as a population's overall health and genetic susceptibility to ailments that may be associated with biological weapons; and adaptive capacity would represent civic resources, such as the percentage of the population that has been inoculated through vaccination.

The U.S. has previously recognized and assessed vulnerabilities to biological weapons as part of a 1996 study commissioned by Deputy Secretary of Defense John White to examine approaches and technologies that the U.S. armed forces could use for physical protection against chemical and biological agents in the battlefield.[17] The need for this study arose from concerns raised by Gulf War veterans who believed they were exposed to chemical and biological weapons during Operations Desert Shield and Desert Storm.[18] The DoD needed to assess that vulnerability in order to protect against potential future attacks that could exploit it. While the DoD was not able to identify specific causes of the veterans' symptoms, it did recognize that its armed forces had a vulnerability to biological and chemical agents/attacks.[19]

Because the 1996 DoD assessment did not address synthetic biological weapons specifically, and because DoD has not yet conducted a vulnerability assessment for synthetic biological weapons, it may be argued that it should assess the vulnerabilities of U.S. citizens today. This vulnerability assessment for synthetic biological weapons could follow the format of the DHS's vulnerability assessments, allowing assessments of entire populations (in contrast to DoD model, which assesses vulnerabilities of U.S. service members). Like previous assessments, it could first identify potential risks to U.S. populations, then categorize the risks by likelihood and consequence, and finally prepare to respond to any potential attack using the appropriate response action or set of actions.

Vulnerability assessments come with their own risks. If a state or nonstate actor with nefarious intentions became aware of the existence of the U.S. vulnerabilities, the actor could seek to exploit the vulnerabilities by crafting a biological weapon tailored to them. Additional risk comes from the potential for nefarious actors to steal this vulnerability information, as well as from the emergence of brokers that could widely proliferate the stolen vulnerability information.[20]

In any case, a comprehensive vulnerability assessment is an interagency task. In order to implement findings from assessments, the interagency should now coordinate to conduct vulnerability assessments and develop protections (including inoculations, vaccines, antibiotics, and immuno-boosters tailored to specific populations). This will help limit or nullify the potential effects of biological weapons based on their specific vulnerabilities.

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U.S. Endeavors: Recommendations for Science Research

Given that scientists have demonstrated the ability to reconstruct deadly viruses and have created *de novo* viruses, the U.S. interagency must invest in research identifying further

potential virus-causing pathogens before persons with malicious intent create and disperse them. The alternative would leave the U.S. unprepared to address a biological weapons attack by means of synthesized pathogens.

Since the U.S. is a party to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction—more commonly known as the Biological Weapons Convention (BWC)—development of synthetic pathogens must adhere to the provisions of the Convention. This means states must comply with Article I of the Convention prohibiting the development of biological agents or toxins that have no justification for prophylactic, protective, or other peaceful purposes. States must also refrain from developing any means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. Because the U.S. would produce synthetic pathogens solely for the purpose of preparing for and responding to a biological weapons attack, the production of synthetic pathogens for research purposes would not be in violation of the BWC.

To avoid any potential misperception of its research as offensive, the U.S. should take measures to comply with Article V of the Convention whereby states are directed to "consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention." Specifically, before undertaking the development of synthetic pathogens for purposes of conducting research, the U.S. should disclose the details of such an endeavor to states that are a party to the BWC. By disclosing the details of the endeavor before it begins, the U.S. would limit the potential for another state to invoke Article VI of the Convention that allows it to lodge a complaint with the Security Council of the United Nations.

The U.S. has precedent for developing weapons as a means of learning about weapon production and weapon effects.

This proposed research is speculative. There is no guarantee that novel synthetic pathogens would be any deadlier than pathogens that already occur naturally. Likewise, research and development efforts may only succeed at synthetically reproducing naturally occurring pathogens such as variola virus or polio. Either scenario would be a waste of resources since the U.S. would have expended funding, manpower, equipment, and facilities, with little in the way of usable results. However, although there is no guarantee that investment into developing synthetic pathogens will produce deadly pathogens that scientists can study and for which they can produce protections, the potential threat of synthetic pathogens may be sufficiently high to warrant the investment. Moreover, the U.S. can conduct a limited investigation into synthetic pathogens designed to be cost-effective. Since one of the main objectives of the research is to identify the method by which one could develop synthetic pathogens, the efforts should rely heavily on low-cost techniques for creating pathogens.

"Gaming" for Research

The U.S. has precedent for developing weapons as a means of learning about weapon production and weapon effects. In fact, it is done routinely for military conflicts and for the handling of explosives by U.S. service members. At the National Nuclear Security Administration's Nevada National Security Site, scientists and engineers have long been creating explosives that the U.S. military might encounter in conflict zones. They do so in order to better understand both how adversaries would develop something similar and how the U.S. could defend itself against the explosives.[21]

In 1921, the U.S. Congress gave approval to Army Brigadier General Billy Mitchell to conduct naval bombing tests against German ships captured by the U.S. during World War I in order to anticipate and prepare for a potential attack.[22] As part of this testing, Mitchell demonstrated that aircraft bombing runs could sink naval vessels, including a battleship, quickly—something the U.S. Navy had previously considered impossible. The testing also portended the change in naval warfare from the use of ever-growing ships with an increasing number of guns to aircraft carrier-based planes carrying ordnance to destroy ships faster and more efficiently than in ship-to-ship combat.[23]

Mitchell's test serves as an excellent early example of "red teaming." "Red teaming" is "a structured process that seeks to better understand the interests, intentions, and capabilities of an institution—or a potential competitor—through simulations, vulnerability probes, and alternative analyses."[24] The concept of red teaming has been applied to the use of biological weapons. In 1998, the Center for Counterproliferation Research at the National Defense University reported that common themes emerge when red teaming during a war game includes the potential use of biological weapons.[25] Findings from these war games reveal that the use of biological weapons is consistently valuable to an adversary in an attack against the U.S. They have also robustly shown that other states are likely to be hostile to the U.S. potentially using biological weapons. Hence, such gaming illustrates both the value of conducting red teaming in the context of biological weapons and the need to continue the concept of red teaming to synthetic biological weapons development. It follows that the U.S. ought to have a team of biologists/virologists working to employ the latest synthetic biology techniques to create new or modify existing biological weapons to identify future biological weapons and how an adversary might use these weapons, so that in the future, we could potentially recognize warning signs and be better equipped to prevent/mitigate such a situation.

U.S. Endeavors: Synthetic Protections

Whether one constructs DNA *de novo* or modifies existing DNA, the application of engineering principles to biology and new methods for rapidly and affordably modifying or creating DNA has further enabled rapid progress and near-instant success in this area. The ability of CRISPR, for example, to rapidly and affordably modify or create DNA has the potential to permit individuals with little training and limited funding to quickly and easily develop synthetic pathogens, as well as synthetic protections. Where the modification of pathogens and protections was once limited to a small number of individuals and organizations, these techniques are now becoming widely available.

Synthetically-made vaccines using synthetically-made bacteriophages (the viruses that infect them) have the potential to exceed the benefits of traditional vaccines and antibiotics. In comparison to traditional vaccines, a synthetic vaccine poses less risk to the health of a recipient of that vaccine.[26] Additionally, synthetic vaccine production is potentially faster and cheaper than traditional vaccine production.[27] Furthermore, bacteriophages have the potential to overcome antibiotic-resistance in bacteria.[28] Consequently, bacteriophages may eventually become the primary means, or potentially the only means, of eliminating anti-biotic resistant bacterial infections. Finally, synthetic protections have the potential to contribute to the effort to replace the "one-drug-for-one-bug" paradigm widely

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prevalent in today's medical practice.[29] Whereas today's one-drug-for-one-bug approach largely combats a single ailment, disease, or symptom with a single corresponding remedy—leading to the necessity for multiple drugs to treat multiple ailments, biologists could create synthetic protections that combat multiple ailments.

Because synthetic protections can be so effective against especially virulent and resistant infections, they have the potential to help counter biological weapons. Because the synthetic protections can be rapidly adapted to target the DNA of viruses, bacteria, and other pathogens, biologists could rapidly develop vaccines using this technology and could rapidly distribute the vaccines to counter the effects of biological weapons. This essentially represents the potential for a rapid-response biological weapons defense that could limit the number of casualties that a biological weapon could cause.

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In addition to the potential for CRISPR to provide a rapid-response capability, biologists could use CRISPR technology to develop inoculations and administer them before a biological attack. Such a preemptive capability could further reduce the number of casualties that a biological weapon could cause. To make the preemptive capability effective, biologists would have to administer the inoculations prior to a biological weapons attack. Biologists could do so either by leveraging early warning that may precede a biological weapons attack or by developing inoculations and administering them as part of routine medical care much like doctors do routinely for vaccinations such as the pneumococcal and meningococcal vaccines. In order for such a preemptive initiative to be successful, the U.S. must plan across agencies that have equities in defending against biological weapons. Proper dissemination of inoculations would include coordination among the DoD, DHS, DOJ, CDC, NIH, HHS, VA, and USDA.

While synthetic biology has the potential to increase the lethality of biological weapons, it also has the potential to enable powerful countermeasures to such weapons. The same technologies that are used to create more lethal biological weapons can also be used to create synthetic protections (inoculations, vaccines, antibiotics, immuno-boosters, etc.) that create protections from new DNA or genetically modify existing protections to produce new results.[30] Biologists may avail themselves of methods in order to create synthetic protections. One method involves reengineering viruses to attenuate the effects of a virus by reducing its virulence while still keeping them viable.[31] Biologists then administer the attenuated virus as a vaccine thereby allowing the vaccine recipient to develop an immunity to the virus without experiencing the effects of the un-attenuated virus. In attenuating the effects of the virus, the vaccine recipient's body identifies the virus as a foreign microbe and stimulates the immune system to attack the virus. Since the attenuated virus does not cause disease nor does it reproduce well, the vaccine recipient's body is able to develop an immunity to the un-attenuated virus.[32]

A second method involves synthesizing a bacteriophage—a virus that only infects specific bacteria—in order to combat bacterial infections. Such a method allows a biologist to inject the bacteriophage into a recipient's body, such that the bacteriophage does not cause any harmful effects to the recipient.[33] The bacteriophage attacks the bacterial infection in one of two ways: The first way is for the bacteriophage to infect the bacteria and, upon infection, rapidly reproduce to the point that the infected bacteria burst, further spreading the virus and repeating the process until the virus eliminates all of the

bacteria.[34] The second way is for the bacteriophage to produce an enzyme that breaks down part of the bacteria, exposing the bacteria to both antibiotics and the recipient's body's immune system.[35]

In either case, undertaking to develop synthetic protections that counter or protect against synthetic pathogens would serve as a mitigation to the risks that are associated with the development of synthetic pathogens by U.S. adversaries. Should either the U.S. or an adversary create a synthetic pathogen, a corresponding synthetic protection may be the only answer to preventing casualties that could result from a biological weapons attack that uses a synthetic pathogen.

Some might be concerned that the synthetic protections may be too expensive for the average citizen to obtain, and that only the financially secure would receive the necessary protections, while those of lesser means are left vulnerable. Indeed, ethical concerns that apply to existing medical treatments and pharmaceuticals may become more relevant for synthetic protections. Chief among those concerns is determining whether or not disadvantaged populations should have to forgo synthetic protections due to the potential cost or potential limited availability of those protections.[36] It may be argued, however, that these concerns could best be addressed by treating synthetic protections as a national security issue rather than as a public health or even individual healthcare issue. The U.S. could administer protections to populations that it has determined through analysis to be at the greatest risk for a biological weapons attack. The Strategic National Stockpile—the nation's largest supply of potentially, life-saving pharmaceuticals and medical supplies for use in a public health emergency[37]—is a prime candidate to house synthetic protections. Viewing the problem through a national security lens, the U.S. could subsidize the administration of the protections such that federal appropriations pay for the costs rather than individual citizens.

Conclusion

Synthetic biology is currently undergoing a revolution. Publications that announce some sort of new synthetic advancement by scientists seem to release almost weekly. As scientists make more discoveries that enable faster, cheaper, and more precise modifications of DNA, the world of synthetic biology will open up to the masses. People not specially trained in the fields of genetics or biology will likely be able to modify or create *de novo* DNA and, unfortunately, this could include states with hostile intentions, hostile nonstate actors, and even private companies that might work for the hostile state and nonstate actors. Because of this new potential for misuse of synthetic biology, the U.S. must quickly draw on these new capabilities, undertake research into identifying vulnerabilities of its population, and develop synthetic pathogens from which it can learn and develop synthetic protections to help thwart the efforts of those that would seek to use synthetic biology to cause harm. Only with close U.S. government interagency coordination can such initiatives be successful. ***IAJ***

The views expressed in this article are those of the authors and are not an official policy or position of the National Defense University, the Department of Defense or the U.S. government.

NOTES

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