The Federal Research Enterprise and COVID-19

A Lesson in Unpreparedness

Daniel M. Gerstein
Good afternoon, Chairwoman Johnson and Ranking Member Lucas, and distinguished members of the committee. I thank you for the opportunity to discuss the federal research enterprise and COVID-19. I will focus my remarks on the federal response in general, with a particular focus on the role the Department of Homeland Security (DHS) has played.

Introduction

As we witness on a daily basis, we are still in the early stages of the COVID-19 pandemic. The global tally of confirmed cases and deaths from the novel coronavirus—the severe acute respiratory syndrome coronavirus 2 or SARS-CoV-2—continues to grow, and the disease continues to spread to previously uninfected parts of the globe. COVID-19 has spread to over 200 countries, causing over 3 million confirmed cases and more than 200,000 deaths worldwide, yet the progression of the disease shows little sign that the worst is over.

Early estimates from a study done by the Imperial College of London highlighted that the United States could suffer 2.2 million deaths, assuming no interventions. A report from the U.S. Centers for Disease Control and Prevention (CDC) estimated potential deaths of 200,000 to 1.7 million.

---

1 The opinions and conclusions expressed in this testimony are the author’s alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

2 The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

million Americans without intervention. These dire estimates will likely not come to pass, as social distancing; home quarantine; closures of schools universities, and businesses; and case isolation have flattened the curve of viral spread in the United States.

Despite these assessments, the federal response has been slow, inconsistent, and has deservedly become a target of criticism. One former senior emergency management coordinator for the City of Chicago summed up the federal response, stating, “Let’s be clear: the federal government has failed. If we maintain the status quo, the cavalry is not coming. Pandemic prevention efforts were ineffective. Pandemic preparedness efforts were ineffective. Pandemic coordination efforts were ineffective.”

Even now, there are many unanswered questions about COVID-19. What percentage of the population that is exposed becomes infected? What accounts for the variations in symptoms and the vast differences in outcomes, ranging from asymptomatic infections to death? Can people become reinfected? Will the virus mutate? Will COVID-19 be seasonal? What role did humans play in the disease spillover into humans? These, as well as many other questions surrounding COVID-19, will need to be addressed. Filling our knowledge gaps will be crucial to dealing with this pandemic and preparing for the next one.

There is much to be done to get through the current crisis, and it is too early to be developing a comprehensive “lessons learned” assessment. However, it is not too early to understand recent shortfalls and examine ways to steer the United States and international community through the current crisis.

Assessment

My assessment will focus on five issues: science, national biodefense strategies, the Strategic National Stockpile (SNS), governance issues, and emergency response doctrine.

Science

All decisions surrounding the response to a public health emergency must be grounded in science (and by extension technology). This includes decisions on establishing and relaxing or lifting mitigation measures. COVID-19 does not respond to the proclamations of world leaders, but to their actions, grounded in scientific effort.

Much about the virus remains unknown, and scientific discovery and technology development will be required to answer these questions. The disease, its various forms (e.g., respiratory, gastrointestinal, and systemic), and its range of outcomes from asymptomatic or mild in some people to death in others all need to be investigated. To address these issues, key

---


laboratories such as the CDC; the National Institutes of Health (NIH); the Department of Energy laboratories, such as Lawrence Livermore and Sandia National Labs; the Department of Defense’s U.S. Army Medical Research Institute of Infectious Diseases; and the DHS National Biodefense Analysis and Countermeasures Center (NBACC) are essential. Private industry, federally funded research and development centers (FFRDCs), and colleges and universities with specialized facilities and a wealth of talent will be needed as well. These institutions require proper funding and prioritization at the federal level to assist in answering these questions.

Scientific discovery and technology development that allows for more rapid development of diagnostics, therapeutics, and vaccines is also a necessity. For example, we need point-of-care diagnostics for use in a clinical setting to identify who is infected, and we need serological tests to determine who has antibodies to COVID-19. Without such diagnostics, we are flying blind in developing our mitigation and response efforts. Right now, testing lags behind requirements; the CDC-developed test has been recalled for inaccuracy, delaying our understanding of the spread of the disease in the United States. In addition to testing, we need to identify highly specific therapeutics that are effective against the virus, and we need to be able to mass produce these therapeutics at the speed of the disease. Vaccines must be developed and produced in weeks, not months or years.

International collaboration will continue to be important to understanding the spread of COVID-19 and developing key medical countermeasures. We need the World Health Organization to serve as a conduit for information and to coordinate with other nations as the disease spreads to other parts of the world. Global collaboration will also benefit medical countermeasures development. Disparate and competitive efforts are underway across the globe, where all would be better served through collaboration. Almost 90 COVID-19 vaccine projects are ongoing, with six currently in clinical trials and about two dozen more expected to enter into clinical trials by summer 2020. Given the time, expense, and regulatory requirements of vaccine development, global collaboration could speed up vaccine development, lead to more rapid approvals, and help determine priorities for vaccine administration. In addition, when nations share information on effectively controlling disease spread, it eliminates time wasted relearning lessons and solving already-solved problems, and it helps prevent future outbreaks.

COVID-19 also calls into question the U.S. government’s current approach to basic research, as explained by the President’s science adviser, Kelvin Droegemeier, in his 2019 American Association for the Advancement of Science speech, which calls for greater nongovernmental

---

6 RAND operates the Homeland Security Operational Analysis Center (HSOAC) for DHS. HSOAC is an FFRDC that conducts studies and analysis for federal sponsors.


entrepreneurship and funding. Droegemeier suggests that the private sector can deliver on the nation’s future basic research needs. Perhaps this is the case, but as this pandemic has demonstrated, government also has an important role in shaping the future research and development ecosystem. The private sector is naturally focused on commercialization, and the government’s role in providing early funding to technological discoveries that might not immediately be profitable remains important.

National Biodefense Strategies

Since the post–9/11 anthrax attacks, successive administrations have sought to develop biodefense strategies. These strategies contain detailed goals and objectives, but the resourcing has not followed, and many of the strategies’ stated outcomes remain aspirational.

Consider biosurveillance, which is essential for understanding the transmission of the disease within a population. Biosurveillance requires testing and diagnostics to determine who is and who has been infected, conducting contact tracing to identify who might have been exposed so that they can take mitigation protocols, and sharing information so that health officials can understand whether the disease has been contained or continues to spread. Armed with biosurveillance data, public health professionals can make analytically informed recommendations, and leaders can act on those recommendations. But despite strong pronouncements and good intentions, funding shortfalls, organizational dysfunction, and problems with information sharing have long confounded federal efforts.

DHS’s National Biosurveillance Integration Center has experienced these issues since its 2004 inception. The biosurveillance problem is magnified by having to knit together 56 state and territorial biosurveillance systems. As a result, by the time COVID-19 first appeared, three different presidential administrations had struggled to develop an effective national biosurveillance system.

Shortfalls in resourcing of state and local public health departments have also resulted in underperformance in the COVID-19 response. State and local public health departments have been under resourced for decades, with one analysis indicating that 52 health agencies (48 states, three territories, and the District of Columbia) had reported budget cuts from 2008 to 2014.

---


Trump Administration’s fiscal year 2020 budget proposal would have further exacerbated the issue, calling for significant reductions to the CDC and NIH; under that plan, they would receive a 12 and 10-percent reduction, respectively.\(^\text{14}\) Of note, these same state and local public health professionals are the ones charged with conducting contact tracing that is vital to biosurveillance, ultimately to halting the spread of the disease, and to getting people back to work and the economy restarted.

**Strategic National Stockpile**

The COVID-19 pandemic is highlighting the need to rethink the SNS, which was originally created in 1998 to provide critical medical supplies. In 2018, the stockpile was transferred from the CDC to the assistant secretary for preparedness and response within the Department of Health and Human Services. While the stockpile was designed to provide support during a pandemic response, the stockage levels and types of vaccines and therapeutics indicate a predisposition toward response to a bioterrorism event or a much smaller outbreak event such as the 2014 Ebola response. General equipment in the stockpile such as personal protective equipment (PPE) and ventilators would be useful regardless of whether it is a pandemic or bioterrorism event, but the stockpile was not envisioned to have enough for supplying a national crisis of this magnitude.\(^\text{15}\) The failure to replenish the SNS after previous biological incidents has exacerbated the issue and had left the stockpile with less-than-authorized stocks at the beginning of this pandemic.\(^\text{16}\) This has left governors having to search the open market to find needed supplies and the federal government changing its definition of the stockpile’s purpose midway through this pandemic.\(^\text{17}\)

In the COVID-19 response, we are witnessing an inability to scale at the national level to meet the demands of a public health emergency. The United States relies upon a “just in time” medical delivery system, which cannot provide necessary PPE and specialized equipment, such as ventilators, required for a widespread naturally occurring pandemic such as COVID-19. It is also demonstrating the interconnectedness of the global supply chains which source this PPE and supplies, such as reagents for testing. In previous exercises dealing with public health emergencies, the answer has consistently been to request support from the SNS, yet as COVID-19 demonstrates, this strategy might not be prudent.


**Governance Issues**

Organizational changes and personnel turnover have hindered the COVID-19 response. The decision by then–National Security Adviser John Bolton to dissolve the Global Health Security and Biodefense Office within the National Security Council (NSC) resulted in the realignment of the principal office responsible for pandemics. When the COVID-19 pandemic began, most of the office’s staff were no longer in the NSC.

The decision to stand up the DHS Countering Weapons of Mass Destruction office (CWMD) also disrupted offices that had previously been responsible for various aspects of biodefense, including the Science and Technology (S&T) Directorate and Office of Health Affairs (OHA). Some of the functions from these previous offices were not cleanly transferred to CWMD or were eliminated once the new office was formed. Examples include the S&T Directorate’s risk assessments and OHA’s biodefense exercises for state and local organizations.

DHS has also divested itself of the National Bio and Agro-Defense Facility. This new facility, which is meant to study diseases that threaten the U.S. animal agricultural industry and public health, \(^{18}\) will be transferred to the U.S. Department of Agriculture. The reduction to the DHS S&T budget also scaled back funding for biodefense, including for point-of-care diagnostics, which is relevant to pandemic response.

Some institutions and offices remain intact. The 2018 President’s Budget sought to defund the NBACC as part of cutting the DHS S&T budget by 28 percent, and DHS anticipated decommissioning the NBACC by September 30, 2018. However, DHS articulated the implications of this cut and Congress stepped in and restored the NBACC’s funding.\(^ {19}\) Today, the NBACC remains operational and is credited with “conducting ongoing research [to] help scientists better understand the coronavirus that causes the disease known as COVID-19, and methods to prevent its spread.”\(^ {20}\)

The personnel turbulence extends beyond the NSC issues discussed earlier. There have been five secretaries of DHS, only two of which were confirmed by the Senate. The Federal Emergency Management Agency (FEMA) has had three administrators. Both the S&T and CWMD organizations only have acting leadership. President Trump has also had three chiefs of staff. All of this is to say that there has been a great deal of turbulence and not much continuity, which can cause problems in times of crisis. As the adage goes, a crisis is not the time to be exchanging business cards; that is what training and exercises are for.

---


Emergency Response Doctrine

While it might seem like hyperbole, almost 220 years of U.S. emergency management experience going back to 1803 seems to be getting a make-over during the COVID-19 response. FEMA—established in 1979—traces its roots to the Congressional Act of 1803, which is considered the nation’s first piece of disaster legislation. With the 1988 Stafford Act, which describes the process for federal natural disaster assistance for state and local governments, the doctrine of national emergency management has been established and repeatedly exercised.21

Emergency management in the United States is based on the understanding that all initial response is local. When local authorities no longer have the capacity to mount an effective response, states provide necessary support. When the state capacity is exhausted, federal support is invoked through a Stafford Act declaration. The Stafford Act allows the President to declare a major disaster or emergency and provides access to the Disaster Relief Fund. The national emergency management system also has established doctrine for reporting information and making requests for support. The structure includes frameworks, critical functions, and training and exercises designed to test systems and ensure proficiency. An important part of the emergency management doctrine involves managing the logistics and supply chains that support the response. COVID-19 has exposed both the interconnectedness and the shortfalls of these global supply chains.

The Department of Health and Human Services is designated as the sector-specific lead agency for the healthcare and public health sector for all emergencies, including a pandemic. Initially, Secretary of Health and Human Services Alex Azar was in charge of the response. When the President put the Vice President in charge of the response, that was a change in doctrine. By standing up the White House Coronavirus Task Force on January 29, the President essentially disconnected some of the relationships that are needed to handle routine issues associated with disaster response and recovery. Many of these relationships ran down into state public health offices, which are in charge of the COVID-19 response in their respective states. Not relying on doctrine at the federal level has exacerbated the confusion at the state and local level as well. The effect has been to reduce emergency management professionals’ roles in the process and decisionmaking and hinder the ability of the normal information and supply chains to function. The national exercise programs that support crisis response are designed to exercise these communications chains.

Ironically, in 2016, the National Security Council, in coordination with other responsible government organizations, developed a playbook that provided a set of priorities and insights for managing a pandemic of this magnitude. It was developed based on the Obama administration’s concerns about response to the 2014-2015 Ebola outbreak. While the Trump administration was briefed about the playbook, it was not used for the COVID-19 response. The playbook covered many of the issues encountered in the COVID-19 response, such as early actions to credible threats, use of emergency funds and the SNS, and the Defense Production Act.22


Strategic communications, which is included in emergency response doctrine, has been inconsistent and troubling with regard to COVID-19. The inconsistencies in communication caused precious time to be wasted and created uncertainty that has likely resulted in greater human suffering and death. The federal failure to communicate clearly to the states and to the people of the United States throughout this crisis has led to poor—or at least uninformed—decisions at the lower levels of government: state, local, tribal, and territorial.

Recommendations

The response to COVID-19 has exposed key shortfalls in our nation’s preparedness and response capabilities. Going forward, the United States should undertake a fulsome accounting of the COVID-19 pandemic by a bipartisan commission. Basic assumptions—including regarding the role of the federal government in emergency management and disaster preparedness and response—should be on the table. Several DHS organizations should be part of this discussion.

COVID-19 will be with us at least until a safe and effective vaccine is available, which could be 12 to 18 months. While a vaccine is being developed, we should look to answer the earlier questions that were posed regarding COVID-19 to improve our understanding of the disease. Work should also continue on therapies for treating the disease.

Even now, testing capacity must be improved and made more available to determine who is infected (using polymerase chain reaction to detect the virus) and who has developed antibodies and potential immunity (using serological tests). Furthermore, questions remain about the accuracy of some of the tests that are being used and availability of supplies (e.g., nasal swabs, reagents) required to conduct the testing.

Risk-based social distancing, biosurveillance and contact tracing should continue to be promoted to allow us to sense if and when the coronavirus is active in communities. This will be essential as more of the economy is opened up and social distancing measures are relaxed.

Adequate funding for several key areas directly supporting COVID-19 will be required. This includes for medical countermeasures (therapeutics and vaccines), diagnostics capabilities, support to hospitals that remain on the front lines, and state and local public health offices, which are essential for monitoring the spread of disease and contact tracing.

We should also continue to engage internationally to examine what lessons can be learned from the experiences of other nations. The examination should assess where technologies and knowledge can be incorporated into our current efforts, as well as how they can be useful in preparing for and responding to a future biological event of national significance.

Conclusions

Some have called the novel coronavirus a black swan event—an event that is unforeseen. I reject that characterization; we have had ample evidence of the potential for a global pandemic, and indeed more than one national commission to advise on how to plan for one. However, competing priorities, inadequate funding, and a lack of national focus led us to ignore this potentially existential threat until it was too late.
Unfortunately, we should expect to see more pandemic events like COVID-19, given human activities that disrupt environmental habitats, promote the mixing of species, and allow humans and pathogens to crisscross the world along global supply chains. We can only hope to address these events more effectively in the future.

Thank you again for the opportunity to appear today and I look forward to your questions.