# Preparing for the Next Pandemic

MOBILIZING AND INTEGRATING RESPONSES ACROSS THE GOVERNMENT AND THE PRIVATE SECTOR

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## **EXECUTIVE SUMMARY**

By October 2020, COVID-19, the disease caused by the novel coronavirus, had infected more than seven million Americans and killed more than 200,000. Unemployment skyrocketed, and the toll that shutdowns took on physical and mental health mounted. People in government agencies, state governors' offices, local authorities, hospital systems, and other health care providers worked overtime to care for the sick and fight the disease. Obstacles to effective coordination across federal agencies; between local, state, and federal governments; and among critical public- and private-sector organizations hampered the speed and the effectiveness of the medical response and implementation of measures necessary to reduce the spread and effect of the virus. The purpose of this report is to describe those obstacles and recommend policies and actions to help overcome them and improve our nation's response to this pandemic as well as future biomedical crises.

This report considers lessons learned in pandemic response under the framework that the 2017 National Security Strategy (NSS) outlined for such response. The NSS identified three pillars of priority actions: (1) detect and contain biothreats at their source, (2) support biomedical innovations, and (3) improve emergency response. Due to the Chinese Communist Party's (CCP) deliberate suppression of early novel coronavirus case reports, the virus spread rapidly around the world and to the United States. Although the United States stopped flights from China to the United States, the virus managed to reach US shores by means of globalized travel through other points of entry such as major European travel hubs. The CCP's deceit, delayed travel restrictions, and easy airborne transmission of a novel virus in a hyperconnected world rapidly overcame efforts to contain it at the source, effectively rendering the United States unable to act on NSS Pillar 1. By the time that the severity of the pandemic was known, the virus was already in the United States and spreading. While the need to improve global surveillance to detect and contain biothreats early is a vital lesson of the COVID-19 pandemic, this report focuses on how to improve biomedical innovations and emergency response.

The first step is to clear away obfuscation associated with vitriolic political partisanship. This report is grounded in facts and assumptions with which the vast majority of Americans



across the political spectrum can agree. To screen out misleading assessments and unrealistic recommendations, the research team recognized the following realities at the outset of its work:

- The United States has a federal system of government. Recommendations should be consistent with that form of government.
- The United States has a free-market economic system and is a free and open society. Recommendations must mobilize social and economic strength while adhering to democratic principles and protecting those most vulnerable to the pandemic. For the purposes of this report, the private sector includes health care systems, businesses, the hospitality industry, the transportation sector, the financial services sector, and private education entities.
- Large segments of US society are highly polarized and will remain so, regardless of who wins the election in November. Recommendations must be grounded in facts and reliable statistics rather than in conjecture and inference.
- Early information on the virus and data sets was incomplete and misleading in the United States and around the world. Analysis and recommendations must allow for the uncertainty that remains.
- Pandemics are inherently international problems; the United States can neither
  defeat the virus alone nor isolate itself from the effects of other countries' efforts.
   Recommendations must consider the international dimension of the problem.

## **Key Findings**

- 1. All states experienced issues in data collection and reporting—including sampling bias, incomplete data recording, inconsistent definitions, delays, and poor reporting infrastructure—that complicated surveillance efforts, modeling attempts, and the development of testing strategies. Public health institutions should provide a clearly defined protocol to identify and address errors in reported data as well as reconcile inconsistencies between federal and state governments' statistics.
- 2. Care facilities faced differing levels of medical professional availability, equipment, and resources as they attempted to treat the sick and protect the elderly (who experienced the highest rates of mortality from COVID-19). Many states and local communities were quick to adapt to protect the elderly, but funding structures and building layouts of long-term-care facilities made mitigation of spread difficult. Governments at all levels should tailor emergency response plans to facility and staff type; maintain a stockpile of essential medical supplies at the facility level;

maintain assured access to an infection-control expert in every nursing home; standardize facility communication with state departments of public health during a crisis; and emphasize local community support and involvement.

- 3. Military forces, such as the Army Reserve and Army Corps of Engineers, and acquisition shops, such as the Air Force's AFWERX, moved swiftly to surge personnel and resources to areas where they were most needed and adapted to rapidly changing situations as the disease spread. The federal government and states can learn from the processes our military forces leveraged to move fast, but they must put in place new policies, procedures, and structures to supplement the military's rapid response.
- 4. The initial mobilization of critical medical supplies was compromised by information asymmetry between buyers and sellers in the personal protective equipment (PPE) market as well as by inconsistent understanding of PPE regulatory standards, particularly at the state and private-hospital levels. With other countries' governments fully backing PPE supply purchases, US buyers were frequently at a disadvantage early on due to lack of public-private cooperation. Greater collaboration between the government and private sector could help ensure all personnel assisting with procurement are sufficiently versed in the PPE regulatory framework. Furthermore, the federal government should help identify trusted intermediaries and verify a marketplace focused on connecting legitimate buyers and sellers that is conducive to bridging the information asymmetry on both sides of the market.
- 5. Care facilities, government organizations, and the private sector actively bid against each other for critical medical supplies and personnel. **States should reform** government acquisition systems and contracting and manage the workforce to surge furloughed people to areas of need and alleviate the competition.
- 6. Issues of scale and cultural incompatibility suggest that contact tracing's role in mitigating the spread of COVID-19 was initially overemphasized. Local government should recommend that businesses and schools operate their own contact tracing efforts where it is necessary to increase confidence in opening or to protect against large-scale transmission in work environments that require employees to be in close proximity to one another. When the use of contact tracing is appropriate, contact tracers must be paid in order to create a professional workforce that is of sufficient size and not reliant on volunteers.
- 7. Frontline health care workers did not receive systematic stress-management and mental health support and treatment, which jeopardized the resilience of the skilled workforce needed to face future waves of the pandemic. **Hospitals should provide**



psychological first aid and critical incident stress-management training to frontline health care workers; mobilize in-house medical facility resources—social workers, psychologists, chaplains—to conduct mental health webinars on handling stress and burnout; be available for on-site screening and counseling; and help refer frontline health care workers to more resources if needed.

- 8. Regulations impeded the early development of a variety of tests. Scientific-research exemption must be made more broadly available to private-sector organizations under established legal boundaries.
- 9. There are insufficient economic incentives for US companies to produce critical medical supplies domestically. The United States must establish and maintain a minimum level of domestic sourcing capacity for raw materials and for manufacturing capacity as well. Efforts to establish such capacity could be modeled after programs designed to maintain a minimum size of the US Merchant Marine or the annual acquisition of Tomahawk missiles for national security purposes. In addition, it is imperative that the United States strengthen cooperative manufacturing and distribution networks with American allies.

Sources for this report consisted of interviews with practitioners, open-source research on reporting, and other lessons-learned efforts. As of October 1, 2020, the research team conducted more than forty-five interviews with leaders at multiple levels of state, local, and federal government, as well as with medical professionals and epidemiologists. The researchers have created an archive at the Hoover Institution, where the interviews and primary-source materials will be available for future researchers to study and learn from the COVID-19 experience.

#### PART 1: MOBILIZING THE MEDICAL RESPONSE

Successful mobilization of the medical response is key to combating the spread of a novel biothreat. Early responses to the COVID-19 pandemic were conducted under vast uncertainty. Our understanding of the virus and awareness about remaining "known unknowns" has increased. Better yet, still-imperfect information has inspired myriad opinions on which efforts and metrics compose a "successful" approach to combating the virus. A successful approach to combating a biothreat shares the following elements:

- Early and accurate **surveillance** of disease spread;
- Reliable and widespread **testing** for both clinical diagnosis and population screening;

- Containment of symptomatic cases within US borders through strategic and widespread testing and encouragement of contagion-reducing actions by those who may be asymptomatic; and
- Safe and effective **treatment** of the sick to decrease morbidity and mortality and protect the most vulnerable.

The key to a timely and effective medical response is the ability to adapt, to have available the requisite resources and personnel to mobilize and arrive at points of need ahead of hot spots as they appear, to integrate government and private-sector responses such that surge resources are unnecessary, and to sustain those efforts through multiple and unpredictable waves. The ability to adapt depends on care providers sharing accurate data quickly with governmental organizations to inform policy decisions aimed at mitigating the spread of the virus. It is also important that authoritative data seamlessly transfer into models that predict the spread so that surge medical supplies and personnel can be mobilized and deployed to anticipated hot spots in advance of the need.

## Early Data Coding, Reporting, and Modeling

Inconsistencies in data collection and reporting prevented the surveillance necessary to mobilize the medical response rapidly and adopt a strategy for widespread testing. Data is essential to an effective pandemic response. Fast, accurate, and complete case-surveillance data allows authorities to:

- Identify and isolate infected individuals, preempting further spread of disease;
- Understand the epidemiology of a virus (e.g., how it spreads, who is vulnerable), facilitating a more efficient, targeted policy response and improving assumptions in epidemic-forecasting models;
- Identify hot spots and high-risk areas and allocate finite resources (e.g., hospital staff, critical medical supplies) efficiently;
- Detect evolving trends in a pandemic, and shift policy responses accordingly;
- Improve public understanding of the situation and, in turn, public trust in and engagement with government directives; and
- Aid hindsight examination of pandemic response, learning lessons to improve future pandemic responses.



As of the writing of this report, the United States' patchwork of data collection is hindering a coherent, efficient response. Each state had different processes and capabilities for handling data at every stage of the data supply chain. States started testing at different dates and employed different testing strategies that were largely a reflection of their varying capacities for testing. In some states anyone who wanted a test could have one, whereas in others a doctor's order was required, or patients had to satisfy other specified criteria. States also implemented different data and reporting procedures. For instance, eleven states and the Centers for Disease Control and Prevention (CDC) had mixed case-reporting results from antibody tests (which can indicate previous infection) and viral tests (which can identify current infection) in the same metric. This conflation potentially double counts individuals who took both types of tests and obfuscates the data.<sup>2</sup> Furthermore, whereas twenty states reported over 75 percent of total deaths in a timely manner (within ten days of patient mortality), three others took far longer to report less than 1 percent of deaths within ten days of mortality.<sup>3</sup> States also provided different levels of contextual information for each case. For instance, early in the pandemic, several states only reported positive COVID-19 test results from private labs. 4 By not reporting negative results or the total number of tests conducted, states skew the percentage-positivity rate. Moreover, many states counted all tests as individual cases, even when the same individual took multiple tests. Such errors have reduced the reliability and usefulness of the data reported.

The inconsistencies in protocols across states also complicated cross-state comparisons necessary to surveil the spread of the virus and surge critical supplies and medical personnel to areas of need. While severity varied, all states experienced some degree of challenge with data collection, including the following:

**Nonrepresentative data** Sampling bias complicated derivations of key statistics. Generally, there was an underestimation of the number of cases (as asymptomatic carriers often were not tested), but an overestimation of the severity of cases (as those with severe outcomes were more likely to be reported). Initially, stringent rationing of tests to travelers from Wuhan, China, with severe symptoms meant that cases from community spread went undetected. Reserving tests for severe cases also contributed to an upward bias in COVID-19 severity; there is a higher mortality rate among hospitalized and severely symptomatic individuals. Even as the criteria for testing were expanded, testing shortages meant that many infected individuals could still not get tested. Meanwhile, asymptomatic or mildly symptomatic individuals did not seek health care and testing, contributing to the undercount of cases. Such access to testing and willingness to test also varied across demographics. Lower-income persons and individuals of color were more likely to be infected and to experience severe symptoms (e.g., as many are frontline workers less able to physically distance, and have higher rates of comorbidities). However, they were less likely to get tested, due either to a dearth of stocked testing centers in their vicinity or to distrust.5

#### **CFR versus IFR**

The use of certain metrics, namely the Case Fatality Rate (CFR), in data models did not take into account this sampling bias in the data-collection process. Data models, including those used by policy makers, often used the CFR, which is the ratio of number of deaths from disease divided by number of diagnosed cases. The CFR's denominator—number of diagnosed cases—varies with different populations' health-seeking behaviors and states' testing capacities and strategies, and excludes many with asymptomatic or mildly symptomatic cases who do not seek health care or testing. The Infection Fatality Rate (IFR), on the other hand, is the ratio of the number of deaths from the disease divided by the number of actual infections in the population. The IFR is a more consistent measure of fatality; it is stable regardless of health-seeking behavior or testing capacity, though it is unknown early in a pandemic and does not include full or representative random-sample testing of the population. For an accurate estimate of the fatality rate, the denominator must be representative of the population, including asymptomatic and mildly symptomatic carriers. Testing the entire population or testing the population through robust representative random sampling would reveal an accurate and much lower fatality rate than has been reported at the time of this report (though this Infection Fatality Rate may differ across states depending on factors such as the underlying health of the populations).

**Incomplete data recording** Not only were certain demographics (e.g., minorities, asymptomatic carriers) less likely to get tested, but the demographic characteristics (e.g., race/ethnicity) and underlying medical conditions (e.g., hypertension, diabetes) of those tested were less uniformly or accurately recorded. This incompleteness in data records perpetuated blind spots and inaccurate generalizations from the nonrepresentative data.<sup>6</sup>

Inconsistent definitions Inaccurate or inconsistent labeling of measured aspects compounded the data-collection problem. The definitions of measured figures such as "COVID-19 hospitalizations" or "recoveries" are not only ambiguous, but they also change across state and time. For instance, on April 14 the state of New York saw a sharp rise in its death toll due to revised reporting that included individuals presumed to have died from COVID-19 but who were never tested (i.e., probable COVID-19 deaths). This artifactually altered reported figures and contributed to public distrust of the data, believed by some Americans to be manipulated for political reasons.

**Delays** The nature of the virus's lengthy incubation period/symptomatic period meant that those infected did not elect to get tested until days or weeks after initial infection. Due to shortages in testing components and backlogs of patient swabs, subsequent lab results were often delayed up to weeks. Delayed test results reduce the utility of testing; patients with COVID-19 could not quarantine in a timely manner. States' and labs' initial low testing capacity resulted in a backlog of patient swabs. By the time labs processed these swabs, many individuals had already recovered from the disease. Delayed test results and subsequent reporting practices contributed to weekly oscillations of the infection death



rate.<sup>8</sup> The time frames for each of these delays varied by factors such as type of test taken, laboratory performing the test, health care provider or public-health agency reporting, and state. Hence, case-surveillance data was not only not in "real time," it was also inconsistent across states and time in the degree of its untimeliness. This complicated policy decisions based on case trends.

Poor data-reporting infrastructure Underfunding of the American public health infrastructure exacerbated the data lags witnessed in the COVID-19 response. Hospitals and care centers across the country differ in their reporting mechanisms. Some centers manually fax handwritten forms to the national data-reporting agencies—the CDC and the Department of Health and Human Services (HHS)—while others send in electronic forms. The dissimilarities in all the forms complicate data centralization for the CDC and HHS. The use of antiquated technologies like fax machines is not only more time-consuming and error prone, it is also administratively burdensome; more personnel were required to manage the inefficient data system at a time when the centers were already facing a personnel shortage that contributed to severe data-reporting delays of one to eight weeks. While the CDC had experience in combating less infectious diseases, COVID-19's rapid transmission and long incubation properties provided new challenges to which the organization was unable to adapt. Forced to lead proper data-modeling efforts, the CDC resorted to retroactively filling in data, and even having to write in 30 percent of missing data in some cases.9

### **Recommendations**

Provide a clearly defined protocol to identify and address errors in reported data and reconcile inconsistencies in statistics When adopting data-reporting changes during the pandemic as case numbers continue to rapidly change, the federal government should provide sufficient forewarning, stress explicitly the interim nature of the transition, and, if possible, reduce repetitive work for hospitals, such as submitting data to both HHS and state governments. With changes in data-receiving entities, HHS should offer clarity in nuanced definitions for data points to explain statistical differences. In preparation for future pandemics, institutions should clarify the responsibilities of each agency well in advance of a crisis, to avoid midpandemic reorganization or temporary committees with vague functions.

**Modernize reporting systems** Reporting systems should be updated to be electronic, consistent (to the degree possible) across all hospital types, and streamlined so hospital staff can easily and quickly report data.

**Establish dedicated staff for data extraction** Hospitals should establish or designate dedicated staff, or the government should provide funding for additional emergency nonmedical personnel, to regularly centralize patient data so hospitals do not become overwhelmed by reporting requirements in the event of a surge of patients caused by another pandemic or COVID-19 wave.

## **Application of Models**

The consistency and accuracy of data modeling is crucial in combating the COVID-19 pandemic because models assist in developing sound policy decisions. Models were misapplied early and often in this pandemic, which resulted in an inability to understand its true scope and respond effectively. Decisions about whether to lock down, the doses of therapeutics to be delivered to each state, and where and how to prioritize distribution of personal protective equipment (PPE) all affect each community's local economy, citizens' livelihoods, and an individual's ability to recover from the novel coronavirus. Unfortunately, both early and current models offer inaccurate depictions of the status of coronavirus in the United States and continue to result in ill-informed policy outcomes.

Models aim to simplify the current public health environment for their audience but contain limitations as a result of fewer input parameters to keep them useful. Parameters make models more nuanced and therefore more realistic, but also complicate the model and risk making it less relevant to specific case scenarios. Policy makers often prefer enough input parameters to achieve a degree of accuracy, but not so many that the model remains generalizable to the majority of scenarios. Examples of parameters include population size, basic reproduction number, and symptomatic period length. These parameters can change as the scientific community learns more about the target virus. The audience viewing the models must understand the degrees of error that result from the model's chosen input parameters.

Thresholds derived from models are helpful to trigger action, even though they are imperfect. With all models and thresholds, "it is not a question of whether models are flawed but in which ways are they flawed, and models can still be enormously valuable if their shortcomings are appreciated." Models should not be used in a vacuum, but rather as a tool to inform policy decisions.

#### Recommendation

When reporting models, emphasize assumptions and uncertainties up front The media provides necessary transparency of governmental pandemic-related policies and COVID-19 infection cases to the public, but often fails to report key limitations of the models it references. Emergency response best practice should be for the media and government to clearly list the assumptions of the models they promote to better inform the public of the reasoning behind, and limitations of, proposed policies; increase trust between the public and the government; and encourage the open public debate foundational to public health.

# **Protecting the Vulnerable**

Inconsistent and uncoordinated support to, and requirements of, medical facilities left our nation's most vulnerable unprotected. In the initial stages of the COVID-19 outbreak,



nursing homes and long-term-care facilities received less national attention than did hospitals.<sup>11</sup> In a Hoover Institution interview with an employee of a Massachusetts nursing home, the interviewee mentioned that the elderly population, care facilities, and its staff should not be an afterthought, and more focus should have been placed upon them, as attention centered on hospitals and workers. In a similar fashion, a clinical professor quoted in a BBC article noted that "nobody was paying attention to what was happening in nursing homes, who were a much higher risk population," as state and national officials were most concerned about hospitals being overwhelmed.<sup>12</sup>

Since the initial outbreak, the medical community has attempted to identify which populations are most vulnerable to COVID-19 infections. The CDC defines these "at-risk populations" as those with a higher likelihood of requiring hospitalization, intensive care, or a ventilator to breathe, and who are at a higher risk of dying. <sup>13</sup> As of August 2020, according to the CDC, older adults and people with underlying medical conditions are the two populations that demonstrate increased risk for severe COVID-19 illness. <sup>14</sup> These vulnerabilities are particularly evident in nursing homes, which have experienced widespread infections and casualties due to the virus.

Other populations are also experiencing higher risk of infection, including ethnic and racial minorities, people experiencing homelessness, incarcerated individuals, people with disabilities, and rural communities. A higher risk of infection has led to a higher number of cases, hospitalizations, and death rates for these groups. The causes are multifold and overlapping, amplifying preexisting socioeconomic and health care inequalities. While this section predominantly focuses on elderly populations, these communities' experiences warrant further attention and greater safeguards in future public health crises.

Nursing home residents represent less than 1 percent of the US population, but have made up over one-quarter of national COVID-19 deaths. 16 As of late August, nursing homes accounted for more than 180,000 confirmed COVID-19 cases and 48,125 total COVID-19 deaths, according to the Centers for Medicare & Medicaid Services (CMS) data sets. Over 115,000 additional suspected COVID-19 cases are excluded from that figure, and nonfederal estimates of COVID-19 deaths stand even higher.<sup>17</sup> The Wall Street Journal and New York Times both attribute more than 65,000 deaths—more than 40 percent of COVID-19 deaths nationwide—to nursing homes. 18 From the earliest stages of the pandemic, it was evident that the elderly were especially vulnerable; age, weaker immune systems, and underlying health complications as risk factors for hospitalization were compounded by confined buildings and flows of workers between rooms and facilities.<sup>19</sup> These trends are just as concerning at the state level. In New Hampshire, for example, deaths in long-term-care facilities are 81 percent of statewide totals.<sup>20</sup> The long-term second-order ramifications of COVID-19 in nursing homes include physical isolation causing physical and cognitive decline for elderly residents, and mental health deterioration of staff and residents.

Some challenges shared by health care facilities across the country, including nursing homes, were the lack of PPE and testing kits, severe personnel shortages, and insufficient funds to continue operations and cover extra costs related to transmission prevention. However, nursing homes also faced unique challenges.

First, compared to hospitals, nursing homes are not equipped with the same level of medical professionals, equipment, and resources, thus making the environment for in-house treatment different from that of hospitals. Nursing homes experienced widespread staff shortages and a lack of infectious-disease expertise when developing their initial COVID-19 response. Nevertheless, a report released by the New York State Department of Health found that pre-COVID-19 nursing home quality ratings did not affect their number of cases. Nursing homes' geography and rate of local community outbreaks proved a larger factor in the spread of COVID-19 than did the preexisting quality of their patient care. Some nursing home advocates have disputed this claim, however, citing the importance of initial staffing numbers and infection-control policies.

Second, due to the structure and nature of some nursing homes, such as room layouts and compliance of residents, it proved difficult for many facilities to properly isolate residents with COVID-19 or to create an isolated section for those with COVID-19.<sup>23</sup> The lack of initial testing materials in nursing homes compounded this problem. Staff members were unable to differentiate the infectious from the noninfectious as they attempted to isolate infected groups to prevent disease spread.

States took a variety of measures to combat COVID-19 in nursing facilities, including forming task forces, disseminating tool kits and guidelines (including on case reporting), approving decontamination systems, and developing testing strategies.<sup>24</sup> Furthermore, local communities were quick to adapt by implementing special hours at stores for the elderly and for volunteer networks delivering groceries and other essential goods directly to the homes of the vulnerable.<sup>25</sup> Some proposed quarantining the elderly as an early strategy. While quarantining elderly patients minimizes their risk of contracting COVID-19, isolation poses its own risks to the elderly and the vulnerable. In addition, the elderly often live in multigenerational households or independently rather than in nursing homes. Consequently, a more comprehensive approach is necessary. In July 2020, the Trump administration announced that, beginning in mid-August, a total of \$5 billion would be distributed to nursing homes through the CARES Act Provider Relief Fund for Nursing Homes to support testing, PPE, isolation facilities, and other COVID-19 expenses.<sup>26</sup> In addition, CMS has announced that nursing home staff in states with high infection rates (5 percent or higher) will be required to take weekly tests once CMS issues a formal rule.<sup>27</sup>

#### **Recommendations**

Improve emergency-response plans and tailor them by facility type and staff Prior to COVID-19, emergency plans focused on natural and technological disaster responses, such



as for flooding or electrical outages. Many states also had plans in place to prevent the spread of the flu, but those plans do not adequately address COVID-19 and other infectious diseases. Emergency plans also should include information on "continuity of operations," in case a facility's leaders become unable to perform their duties. As many facility leadership teams were widely infected, going forward, lower-ranking team members should be educated on protocols and operations at the front end of a crisis. Federal inspections should be improved to ensure that nursing homes have measures in place to prepare for infectious-disease spread and to educate staff if necessary.

Optimize PPE supply in preparation for COVID-19 resurgences and other pandemics Maintaining a stockpile of essential materials, such as masks, hand-hygiene supplies, and hospital gowns will help nursing homes to take quick, preventative action against disease spread, without depending on external suppliers of PPE.<sup>28</sup>

Ensure access to an infection-control expert, including registered nurses, in every nursing home While nursing homes are required to have an infection preventionist (IP) on staff, their role and level of involvement are largely undefined.<sup>29</sup> Oftentimes, directors of nursing or other medical leaders will serve as their nursing home's IP, assuming infection prevention and control (IPC) responsibilities in addition to their full-time position. Many smaller nursing homes have instead hired external consultants for the position. In 2019, the CMS proposed to lessen IP work requirements from it being a "part-time" position to one requiring "sufficient time," which should be opposed going forward. 30 IPs should be required to work part-time, with a specific minimum of hours decided by national diseasecontrol experts. Given the nature of infectious diseases, more flexible options such as remote access should also be considered. Additionally, IPs are required to complete some specialized training in prevention and control, which is often insufficient for the demands of the position. Increased IPC training and certification completion through the Centers for Medicare & Medicaid Services and other state or local programs will help IPs to be better qualified to handle disease outbreaks. While hiring new staff may be financially infeasible for many nursing homes, training existing staff members may be a low-cost alternative. Regardless, nursing homes should prioritize having a well-trained IP on staff, as they will assist in preventing and addressing infectious-disease outbreaks.<sup>31</sup>

# Reform emergency staff protocols and volunteer staffing plans for nursing home staff

During pandemic outbreaks, staff should be interviewed and assessed for a fever or other health problems as often as possible. This prevents staff from bringing disease into the facilities, which was a widespread problem that many nursing homes experienced. Facilities should plan for staff shortages during outbreaks, looking to volunteer organizations and local nursing support. In terms of visitors, family and friends often improve the mental health of residents, especially during times of crisis. However, given the nature of diseases such as COVID-19, maintaining social distancing is essential, even if visitors' tests are negative. Alternatives, such as virtual or phone conversations, have been essential in keeping residents connected with their loved ones.<sup>32</sup>

Reform nursing home staff salary structures Nursing home staff members often are paid roughly minimum wage, and many nursing aides do not receive paid sick leave. Nearly 13 percent of nursing aides live below the poverty line, and almost 36 percent rely on public assistance.<sup>33</sup> Low salaries often require nursing home staff to work a second job, commonly in another high-risk environment, leading to increased spread of infection within elderly communities and externally. Better pay also would allow staff to take necessary precautions during outbreaks, such as not using public transportation. Paid sick leave for nursing home staff could be implemented by allocating emergency government funds (such as California's COVID-19 Supplemental Paid Sick Leave), as this incentivizes nursing home staff to quarantine when necessary, decreasing the rate of infection within the facilities.<sup>34</sup>

**Provide better care and mental health support for nursing home staff** This issue will be discussed in greater detail under "Workforce Resilience."

Improve government communication outreach to nursing homes Many facilities participated in weekly informational phone conversations with departments of public health to keep staff up to date on COVID-19 response recommendations. The conversations allowed staff to ask any questions they had and was an effective communication method.<sup>35</sup> Synthesis of government announcements and pandemic information would help with information reception. Due to the large amount of text and resources released by government entities, some long-term-care advocacy groups such as LeadingAge and the Massachusetts Senior Care Association are helping to simplify information for nursing homes.<sup>36</sup> Government groups and organizations should expand this practice, as it saves time for nursing home staff and highlights the essential practices that nursing homes should follow. In addition, relevant government agencies such as CMS should ensure clear communication to nursing homes of policy updates and changes by standardizing and solidifying communication channels among federal, state, local, and other relevant entities. Such improved outreach and communication would facilitate better coordination and smoother implementation of policies on both ends in the future, with government agencies acting as a partner for nursing homes in the response efforts.

Emphasize local community support and involvement These practices help to supply nursing homes with needed materials, while educating the public on nursing home vulnerabilities and improving the morale of all those involved. Many nursing homes point to the support of local volunteers and donations as lifesaving during the COVID-19 outbreak. Local organizations, fire departments, and individuals have provided PPE, communication methods for residents to speak with their families (iPads, etc.), and donations to assist nursing homes during times of crisis.<sup>37</sup>

At-risk populations, including ethnic and racial minorities, people experiencing homelessness, and rural communities, have experienced higher-than-average COVID-19 infection rates since the start of the outbreak. While these disparities are related to preexisting circumstances such as access to health care, lack of data and research on at-risk



populations, and socioeconomic inequality, these risks can be partially mitigated through several proactive measures. At-risk populations may be assisted by:

- Improving data collection and reporting methods on minority populations and COVID-19 infections;
- Expanding accessibility of testing and health care through increased funding for telehealth services and other outreach programs;
- Financially supporting hospitals and care facilities in low-income communities;
- Setting up testing sites in high-risk communities; and
- Improving language-assistance services for both in-person and online resources alongside broadening outreach to and communication with at-risk communities.<sup>38</sup>

Finally, developing a greater national understanding of existing inequalities and flaws in the US health care system will lead to improved care for at-risk populations. This is only the start to addressing the larger problem of health care inequality, which has increased with the COVID-19 outbreak.

#### North Carolina Sets Up Free Testing Sites in Communities of Color

In North Carolina, the state facilitated "free testing sites in communities of color and [made] sure it [was] free in certain ZIP codes." Latinos make up 43 percent of the lab-confirmed COVID-19 cases in North Carolina despite only representing just 10 percent of the state's population. Within this community, financial strains and fears surrounding immigration status and deportation have been obstacles to health care access.

To tackle these issues, Dr. Viviana Martinez-Bianchi of Duke University, along with Dr. Gabriela Maradiaga Panayotti, founded the Latinx Advocacy Teams and Interdisciplinary Network for COVID-19 (Latin-19), which is a multidisciplinary coalition bridging health care providers, researchers, and community members, in order "to elevate the needs of a people whose access to quality health care has not been equal for years." Dr. Martinez-Bianchi also has participated in the response planning by North Carolina's DHHS for marginalized communities of color. In that work, for the reasons mentioned above, she has "highlighted the need to bring in trusted testing sites to Hispanic communities."

In addition to establishing these testing sites, the state of North Carolina has started publishing some key COVID-related information on its DHHS website in Spanish, which could improve the Hispanic community's access to information.\*

<sup>\*</sup> Anne Blythe, "Embracing Her Latinx Community, Fighting for Equality amid COVID-19," North Carolina Health News, July 29, 2020, https://www.northcarolinahealthnews.org/2020/07/29/embracing-her-latinx-community -fighting-for-equality-amid-covid-19/; Sibani Ram, "Duke Professors Work to Fight COVID-19 in Local Latinx community," [Duke University] *Chronicle*, July 15, 2020, https://www.dukechronicle.com/article/2020/07/duke -university-professors-work-fight-covid-19-latinx-community-durham.

## San Mateo County Designates Three Skilled Nursing Facilities as Centers of Excellence

In late April, San Mateo County Health, Health Plan of San Mateo, and other key local health care partners jointly announced that they will designate three skilled nursing facilities as "Centers of Excellence" as part of their effort to "proactively coordinate care for residents during the novel coronavirus (COVID-19) outbreak." The three facilities were selected based on "their high standards of patient care and expertise with infection control." The three facilities are able to "treat COVID-19 positive patients discharged from local hospitals," as well as "patients from community settings who have COVID-19 and require a higher level of care."\*

Among the three facilities is Pacifica Nursing & Rehab Center, which was reported to have five confirmed cases and one death in late March—but in a month was designated as a Center of Excellence.† Its three-story structure "allowed them to dedicate their entire top floor to treating COVID-19 patients," which is made up of thirty-three private rooms and a separate entrance, lunchroom, and bathroom. Furthermore, Pacifica ensured the mitigation of transmission and protection of staff and patients within the facility by "[splitting] their clinical and housekeeping staff into two groups—those who work on the third floor and everyone else," and making sure that the two groups did not intermingle.‡

Such coordinated approach at the community level may serve as a reference model for other communities across the country.

## Adaptability of the Military

The military was well positioned to surge personnel and supplies to hot spots. Although limited by unknowns, they were able to adapt quickly to serve some of the worst-hit areas. The Department of Defense response by active-duty, Reserve, and National Guard personnel helped prevent the medical systems in hard-hit areas from exceeding capacity and provided support to weary frontline health care providers.<sup>39</sup> The response consisted of three primary components: reinforcing struggling health care personnel, procuring and transporting supplies globally and within the United States, and assisting state governments with a wide range of tasks.

The military successfully surged medical personnel into hard-hit areas early in the outbreak. By the end of April 2020, 61,000 personnel had supported the response, 4,400 of whom



<sup>\*</sup> San Mateo County Health and Health Plan of San Mateo, "San Mateo County Health and the Health Plan of San Mateo Announce Centers of Excellence Program for Skilled Nursing Facilities," news release, April 21, 2020, https://www.smchealth.org/sites/main/files/file-attachments/san\_mateo\_county\_health\_press\_release\_centers\_for\_excellence\_skilled\_nursing\_facilities\_april\_21st\_2020\_1.pdf.

<sup>&</sup>lt;sup>†</sup> Joe Vazquez, "5 Residents At Pacifica Nursing Home Test Positive For COVID-19; 1 Patient Dead," *CBS SF BayArea*, March 31, 2020, https://sanfrancisco.cbslocal.com/2020/03/31/coronavirus-pacifica-nursing-home-5 -residents-positive-1-dead-covid19/.

<sup>&</sup>lt;sup>‡</sup> "Pacifica Nursing Facility Gains 'Center of Excellence' for Handling COVID-19 Patients," *Pacifica Tribune*, August 21, 2020, https://pacificalocalnews.com/pacifica-nursing-facility-gains-center-of-excellence-for-handling-covid-19-patients/.

were doctors, nurses, and other medical personnel.<sup>40</sup> The army and navy were the primary providers of medical personnel, with Urban Augmentation Medical Task Forces (UAMTFs) and Expeditionary Hospitals from the army and USNS *Mercy* and *Comfort* from the navy making up the bulk of these efforts.<sup>41</sup> The air force also contributed personnel, with Air Force Reserve doctors and nurses deploying cross-country.<sup>42</sup> In some cases military personnel were directly integrated into existing hospitals, and in other cases they set up field hospitals in nearby locations, such as the Javits Center, which ultimately treated nearly 1,100 patients.<sup>43</sup> The UAMTFs, which are teams of 85 Army Reserve soldiers composed of doctors, nurses, medics, respiratory specialists, behavioral health specialists, and medical logistics personnel, were deployed with only two weeks' notice.<sup>44</sup> Over a dozen were deployed, each capable of supplying the capacity of a 250-bed hospital. These task forces had never existed previously, yet performed extraordinarily well, which speaks to the agile adaptivity and the pool of courageous and talented personnel the military brought to the fight.

Two issues were identified in deploying military medical personnel to fight COVID-19. First, many personnel in the reserves were already fighting COVID-19 in their civilian professional capacity. Identification of soldiers available for deployment was successful but had to be done by contacting each individual soldier, which was labor and time intensive. Second, USNS Mercy and Comfort and some field hospitals were deployed with the expectation that they would treat non-COVID-19 patients to relieve pressure on the traditional medical system, allowing hospitals to free up space for COVID-19 patients. For several reasons, however, this did not occur as planned and the military was forced to adapt and treat COVID-19-positive patients. Non-COVID-19 hospitalizations dropped significantly as citizens were afraid to enter the medical system unless absolutely necessary. As a result, hospitals were not strained by non-COVID-19 medical patients. This pattern has shown up in past pandemics, such as Ebola in 2014, and is likely to occur in future pandemics. Transferring non-COVID-19 patients from hospitals to ships and field hospitals was a bottleneck, as it required lots of personnel to do properly. Consequently, fewer patients were transferred than initially expected. Furthermore, some of the patients who were believed to be COVID-free turned out to actually be COVID-positive patients whose infection had not been detected or who contracted the disease in hospitals. Therefore, military medical personnel ended up treating COVID-19-positive patients despite the initial plan to focus on non-COVID-19 patients.

The logistic capabilities of the military were critical in collecting supplies from around the globe and distributing them domestically. Indeed, the Department of Defense directly provided 39 million N95 masks, 8,000 ventilators, and 60 decontamination systems. Millions of swabs, hundreds of ventilators, hundreds of personnel, and tons of various cargo have been moved by the air force during the pandemic.<sup>45</sup> These efforts brought vital supplies into the medical system at a time when tests, ventilators, and PPE were in short supply. Repairing medical equipment is another way the logistics systems of the military contributed to the response. The United States Army Medical Materiel Agency (USAMMA)

has three maintenance facilities in the United States, which have been repairing ventilators, oxygen generators, suction apparatus, infusion pumps, and patient monitors.<sup>46</sup> This has facilitated a rapid turnover of damaged equipment and has reduced the strain on frontline medical personnel who would otherwise be working on the aforementioned equipment, and ensures a rapid turnover of damaged equipment. It is cheaper and easier to repair this type of equipment than to build more, so this effort cuts cost and time. At the same time, the DoD's logistics expertise made the department the right choice to lead the whole of government approach to acquiring new material as well. The under secretary of defense for acquisition and sustainment, Ellen Lord, established the COVID-19 Joint Acquisition Task Force (JATF). Crucially, this team serves as the single entry point for industry to the DoD acquisition enterprise for federal government requests for assistance. On July 10, the JATF opened a Commercial Solutions Opening (CSO) to solicit concepts from industry in support of domestic industrial capacity for the JATF and HHS COVID-19 response priorities. The CSO was administered by AFWERX, the Air Force agile contracting entity, which has honed its expertise in rapid acquisition through its ownership of the Air Force's Small Business Innovation Research program. Without help from military logistics, equipment and PPE shortages in March and April would have been even more severe.

An issue with logistics is that the logistic capabilities of the military are only useful if they know where to deliver supplies. The early outbreak was mainly in large cities, making visibility a nonissue. However, if future outbreaks occur outside of major cities, supplies may not be distributed efficiently. Lack of federal and state visibility into medical-sector needs threatens to undermine the effectiveness of future military responses.

Other notable state-level efforts include the response of the National Guard, which has been the workforce of choice for states seeking to fill personnel gaps in the crisis, as they were prepared to respond to emergencies. However, the Guard have been used in widely varying ways across states, and no best practices have emerged as yet. There also seems to be little to no coordination between states about developing these best practices. The National Guard has been used to create medical-care sites,<sup>47</sup> staff testing sites,<sup>48</sup> process unemployment claims,<sup>49</sup> engage in contact tracing,<sup>50</sup> transport PPE,<sup>51</sup> and run elections,<sup>52</sup> among other tasks. Some of these tasks could likely be performed by other agencies, which would free up the Guard to handle tasks in which they have a greater comparative advantage. There also has been tension between states and the federal government over funding, with responsibility shifting back and forth over the course of the pandemic. This has led to political conflict between states and the federal government at a time when close cooperation is necessary.<sup>53</sup> Sorting out funding responsibility would be a helpful step in planning for future pandemics.

#### **Recommendations**

Recognize the capabilities that the military possesses The military response to COVID-19 has been a resounding success even while other aspects of the US COVID-19 response have encountered difficulties. Without the personnel and logistics the military provided,



the medical systems in hard-hit areas would have experienced even more severe strain on personnel and critical medical supplies. In a future pandemic, policy makers should recognize the deep pool of talent and capabilities within the military and incorporate them into response plans.

Develop mechanisms to check availability of medical personnel in the reserves Since many reserve medical personnel already were engaged in the fight against COVID-19 as civilians and it would have been disruptive to pull them out of that fight and deploy them elsewhere, mobilization was complicated. Creating a registry of medical personnel, their civilian medical occupations, and their availability in terms of how quickly they are able to deploy would speed mobilization efforts in a future pandemic. Personnel should be organized by city, state, and military unit to facilitate visibility into their availability by geography. The registry data should be housed at the brigade or command level and should be centralized so that it is readily shareable beyond medical commands and updated regularly as agreed upon by the leadership of the various reserve forces.

Plan to treat infectious patients Military hospital ships and field hospitals should plan to treat or at least be agnostic in treating patients afflicted with the disease in circulation, rather than focusing on treating noninfected patients. Initial plans to treat primarily non-COVID-19 patients were complicated by lack of demand and bottlenecks and had to be adapted early on. As these patterns have shown up in other pandemics, personnel should be deployed with the expectation that they will treat infectious patients from the outset.

Institutionalize and sustain funding for medical task forces The Urban Augmentation Medical Task Forces performed superbly and are a model that should be retained in military plans for a future pandemic. Other federal entities such as HHS's National Disaster Medical System and the US Public Health Service Commissioned Corps rapidly deployed medical teams to augment health care systems as well. The ability to rapidly reinforce faltering medical systems is a capability with great potential and one that also could be applied to other types of mass-casualty events.

Ensure visibility into the medical system Knowing where and when personnel and supplies are needed is a necessary precondition for an effective response, and this knowledge is not guaranteed in a future pandemic. The lack of a centralized health care system in the United States makes visibility a challenge that must be overcome with effective data sharing and collaboration between different levels and entities in government. States have different systems that should engage in data sharing to allow the Federal Emergency Management Agency (FEMA) and the military to identify areas of the highest need. For example, HHS's National Health System Preparedness Program relies on information sharing as the foundation for its cooperative agreement programs with state and local jurisdictions and private sector partners. Information sharing on the number of active COVID cases, staffing levels, and remaining intensive care unit (ICU) capacity per hospital would allow the

military to best understand which facilities are most in need of additional personnel, and respond accordingly.

Develop best practices and tasks for deployment of the National Guard in pandemics — The wide variety of tasks that states have assigned National Guard forces to complete has made it difficult to develop lessons to apply to a future pandemic. The organization and skills that the National Guard brings are better suited to sets of tasks such as constructing medical care facilities and transporting PPE, and have less of a comparative advantage in other tasks such as processing unemployment claims. An effort should be made to determine which tasks fall into which category and communicate that across state lines so the Guard can be used as effectively as possible in a future pandemic. This also would enable the National Guard to train and prepare more effectively for future pandemics. Clarification of mission also would clear up funding responsibilities between the national and state governments.

## Regulation and Mobilization

Misunderstandings across multiple levels of government about regulatory standards hindered the rapid mobilization of critical medical supplies and tests. Failure to adapt regulations to real-time needs slowed the response. The initial mobilization of critical medical supplies was hindered by information asymmetry toward regulatory standards for PPE, particularly at the state and private-hospital levels. As new manufacturers of PPE entered the market with newly minted Food and Drug Administration (FDA) registration numbers, procurement teams unfamiliar with FDA, CE, or National Institute for Occupational Safety and Health (NIOSH) certifications struggled to react quickly to the demand for PPE. Accordingly, in such a dynamic market, prices continued to surge while inexperienced professionals drafted into acquisition efforts struggled to differentiate among which certifications were valid, accepted by the FDA, or falsified. These difficulties were further exacerbated by continual updates to FDA policies regarding acceptable masks, with new manufacturers being added to and dropped from approved import lists daily on its website; such information was not always readily consulted by state and private procurement teams.

Moreover, as different countries and manufacturers label similar products differently and use different materials in production, understanding regulatory compliance of foreign-manufactured PPE often proved difficult. This inexperience of acquisition teams and unfamiliarity with appropriate regulations were evidenced in conversations with procurement teams from a major state governor's office, which repeatedly asked if masks were OSHA certified, though such a certification does not exist for masks. State-level difficulties resulted from leaders' decisions to deploy preexisting deliberate action-planning strategies instead of the crisis action response from the federal government. While states were delayed by bulky procurement forms, federal agencies quickly adapted to changing



requisites for PPE import. However, limited transparency regarding evolving federal regulations hindered a wider adoption of the crisis action response. Coordinating efforts led by the national government's COVID-19 response team, however, were able to get a concrete understanding of the necessary regulatory standards for mask acquisition and transport. Such initiatives have helped to lessen the initial supply chain crisis, yet continued attention to COVID-19 hot spots and private care facilities remains a critical policy initiative.

Throughout the pandemic, many civilian medical workers have been willing to care for COVID-19 patients, but have not been effectively mobilized. It is clear that the United States' primary issue is not a lack of adequate personnel to respond to the crisis, but rather great difficulty in mobilizing appropriate staff for locations in need. For example, in states such as New York, where the mayor of New York City Bill de Blasio called for 45,000 additional medical personnel in April and May,<sup>54</sup> 90,000 retired and active health care workers volunteered to serve in New York.55 The bureaucratic process's pace impeded swift and appropriate mobilization, as did the confusing nature of the application process. An updated, streamlined processing response is greatly needed across the country. Nongovernmental organizations such as the United States Civilian Corps (USCC) played a crucial role in mobilizing, and assisting in the vetting process of, in-demand medical professionals. The USCC successfully mobilized five thousand surge personnel in New York and New Jersey.<sup>56</sup> Medical facilities also have a role to play in making use of these resources; they need to systematize and solidify plans for integrating surge resources that do not come from staffing agencies, so that they have the processes in place to make use of outside resources in times of need.

Legislation to ease the mobilization of civilian personnel across state lines is less accommodating. Because medical occupational licensing happens at a state level, it can be difficult to confirm the necessary license in a state that is not the practitioner's home state. In 2018, Washington State adopted the Uniform Emergency Volunteer Health Practitioners Act (UEVHPA), which allows volunteer physicians and health practitioners to practice without the delay of obtaining a Washington license, as long as their home-state license is current and in good standing. In response to the COVID-19 pandemic, Washington activated the UEVHPA to ease the mobilization of needed personnel across state lines. <sup>57</sup> Eighteen states as well as the District of Columbia have enacted UEVHPA legislation. <sup>58</sup> Where the legislation has not been adopted, volunteers can be asked to pay hefty licensing fees and undergo delays before being able to practice in a state with immediate needs. It is crucial that this type of legislation be expanded to all states for preparedness in the event medical personnel need to be mobilized across state lines.

Furthermore, to allow more health care workers into the national workforce, numerous medical schools have expedited the graduation and licensing of medical students. Additional nurses, doctors, and specialists joined response teams in hospitals. These efforts generally allowed qualified-but-not-yet-licensed health care professionals to join the

workforce faster. Initiatives to integrate retired or inactive medical professionals into the COVID-19 medical-response workforce were also eased by waivers from thirty-nine states to expedite renewal of licensing for these professionals.<sup>59</sup> As of May 2020, additional efforts included measures to waive the two-year foreign residence requirement for foreign medical graduates in exchange for full-time work under H-1B visa classification for no less than three years in a shortage area.<sup>60</sup> This effort complemented the Conrad 30 waiver program, introduced in 1994, which allows J-1 foreign medical graduates to waive their foreigner residence requirement by working as medical providers in rural or urban areas of the United States facing shortages in physicians.<sup>61</sup>

New and existing legislation supported civilian personnel mobilization, such as initiatives to expedite the renewal of credentials for out-of-practice professionals and to protect medical professionals from the potential liability that results from practicing in a variety of evolving environments with a new virus. Moreover, legislation such as the 2020 CARES Act, among other older regulatory and legislative acts, allowed for liability protection of medical and nonmedical professionals and volunteers in the response to COVID-19. Many states implemented greater protection for those fighting the virus. This provided greater flexibility to treat an unknown virus, while additionally protecting frontline workers.

#### **Recommendations**

**Update bureaucratic processes for vetting civilian surge resources at the state, city, and hospital level** Updated infrastructure to support volunteer applications and processing would ease mobilization efforts. This may be through collaboration with an organization such as the USCC, or through the development and expansion of dedicated processing bodies such as HHS's Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP). The creation of national standards and recommendations for states to follow when credentialing medical volunteers and professionals and mobilizing them across state lines would facilitate greater civilian personnel mobilization in a future public health crisis.

## Enact emergency authorization for medical licensing to become valid across state

**lines** Legislation such as the UEVHPA, which allows out-of-state medical professionals with an active license from their home state to be mobilized across state lines to practice immediately upon arrival, should be expanded. This will be a crucial step in preparing the medical field to have adequate access to health care providers in the event of another pandemic at this scale. In the event of hot spots developing in different parts of the country, the ability to quickly mobilize necessary personnel across state lines would be crucial.

Invest in long-term, greater interprofessional education to better prepare the medical workforce for a large-scale public health crisis such as a pandemic Interprofessional education (IPE) or education opportunities that allow students from two or more professions



to learn together, and from each other, in order to build skills allowing for higher-quality health care and more effective collaboration, is crucial preparation for medical students and public-policy students who may face large-scale public health crises. The University of Washington Health Sciences Interprofessional Education Initiative is an example of interprofessional education for health care students. Composed of the six health sciences schools at the university—dentistry, medicine, nursing, pharmacy, public health, and social work—this initiative supports cross-disciplinary education to support students as they enter the field of health care.<sup>62</sup> The University of Michigan also offers IPE in its medical school with courses including Team-Based Clinical Decision Making and Interprofessional Clinical Experience (ICE).<sup>63</sup> Additionally, the University of Texas at Austin's Center for Health Interprofessional Practice and Education has compiled resources of interprofessional education opportunities that focus on the response to COVID-19 in the health care field.<sup>64</sup> Greater opportunities for health care students and public-policy students to become more knowledgeable and flexible across disciplines will allow for a more resilient, more adaptive health care workforce in the event of future public health crises.

Establish a nationwide reserve program for medical professionals While many governmental and independent institutions exist at home and abroad, a national program for former medical professionals would be extraordinarily helpful to identify and mobilize surge resources. HHS's ESAR-VHP proved insufficient. In partnership with the American Hospital Association and the American Medical Association, and in coordination with state licensing boards, an independent third party should create a "fast track relicensing" process for former professionals in critical specialties who are willing to deploy in times of crisis. This could include periodic training and a limited-use license with interstate reciprocity.

## **Competition Hindered Coordination**

Care facilities, government organizations, and the private sector actively bid against each other for critical medical supplies and personnel. Robust and resilient supply chains are an essential element in a successful fight against COVID-19. This pandemic has laid bare a number of key structural weaknesses in critical US supply chains, particularly those for personal protective equipment (PPE). Many of these issues existed well before COVID-19, but their far-reaching and dangerous consequences have only recently come to light. Months into the pandemic, PPE shortages continue to present major challenges for health care providers and other frontline workers across the country. PPE acquisition teams had limited coordination beyond the federal level, and as they entered foreign markets to compensate for limited initial American manufacturing capacity, private health systems and state governments actively competing for the same limited resources abroad inadvertently drove up prices for critical medical supplies. This deadweight loss of resources for PPE and ventilators initially proved challenging to hospital systems overwhelmed by the pandemic. Recent efforts from HHS and the federal government to create regional dashboards have helped to remediate this problem, yet some regions of the country still have critical demand for PPE.

As care facilities, government, and private actors competed to get access to PPE factories and stockpiles, once the equipment was obtained it was often delayed by weeks due to a bottleneck in foreign customs and air freight. Reduced demand for air travel severely impacted airlines and air freight carriers, which were forced to limit flights capable of transporting PPE. Information asymmetry between these actors prevented the initial creation among at least the federal acquisition teams of a central dashboard to prioritize international and domestic PPE shipments as well as negotiate available space on flights and transoceanic shipping routes. In order to ship commercially out of China, bottlenecks at customs required American buyers to often use local private handlers to expedite the process of getting packages on planes, disadvantaging underresourced procurement teams' efforts to acquire materials: one private health care facility had to wait three weeks for critical materials to leave Beijing's airport. While the federal government developed a private dashboard for their equipment, for nongovernmental and many other actors, chartered planes and ships have emerged as the only viable method to move large amounts of cargo, which has caused exorbitant shipping costs: one major private aviation company shared that it is at least holiday rates all the time now. Furthermore, the sheer volume of PPE imported into the United States limits potential avenues for freight shipping. For example, nitrile gloves cannot be shipped by air freight cost-effectively due to weight restrictions; accordingly, gloves from Southeast Asia have to be shipped for nearly two weeks by boat to reach the United States.

Domestic PPE manufacturers and distributors were similarly confronted with limiting factors in raw materials such as plastics and rubber. These materials are largely manufactured in China, and manufacturers encountered significant difficulties in finding cargo space for bulk raw materials. Challenges in exporting raw materials were worsened by severe limitations on the amount of the raw materials allowed to leave the country by the Chinese government, which worked to protect domestic PPE manufacturers and retain its own stockpile. The material-science industry in China is also capable of producing these materials at a significantly lower cost than American competitors because of the low cost of labor; labor cost inhibits the United States from possessing a similar infrastructural capacity to produce these materials at the same scale as the Chinese.

As COVID-19 patients overwhelmed emergency rooms and long-term-care facilities across the country, credentialed and licensed medical professionals were at a premium. Medical facilities grappled with the lack of appropriately trained medical personnel in many parts of the country, and staffing agencies stepped in to help fill the void. Many hospitals had preexisting relationships with staffing agencies, which were used to operating with days or weeks of advance notice. As a result of the COVID-19 pandemic, these timelines shortened; hospitals needed people much quicker to meet demands of patient surges and sick staff. Since COVID-19 cases often arrived in clusters, specific geographies were particularly taxed, putting medical facilities in competition with one another for scarce resources. This led staffing agencies to raise rates for scarce talent; in New Jersey, during the pandemic a



Certified Nursing Assistant (CNA) could cost a facility \$100–\$115 per hour. Although just \$60 went to the provider, this still represented a dramatic increase over the typical \$25 hourly rate. Agencies have claimed that these higher compensation rates are crucial to recruiting adequate personnel. In some instances, facilities would bid against one another for the right to get the next available CNA, registered nurse, or whatever qualification was needed. Unfortunately, the uncertainty around transmission of the virus and safety protocols (e.g., availability of PPE, risk of exposure), among other changes in circumstances, often led workers to opt out of employment.

Facilities with the resources to offer hazard pay were better able to mobilize surge personnel, but even they faced hurdles. For example, in some parts of the country, staffing agencies approached employed medical providers and repeatedly offered them higher pay to work at another facility. <sup>66</sup> At the same time, lockdowns forced hospitals and health care facilities providing services deemed nonessential to furlough many nurses and medical staff, who had difficulty finding new positions. In this sense, even with an increase in unemployed medical professionals, it was difficult for some health care providers to locate hospitals and health care facilities in need of extra staff, just as it was difficult for care facilities to hire additional staff to cope with the COVID-19 crisis.

#### Recommendations

## Stockpile critical medications and personal protective equipment at the hospital

**level** Instituting new hospital-level stockpiles would improve domestic readiness for future crises or a worsening of the pandemic. Central to these new stockpiles would be operationalizing crisis responses, contrary to the present deliberate action responses that hinder timely reactions to national crises. Looking at the success of hurricane equipment positioning, the government should similarly target hospital locations where there would be the most critical need for equipment.<sup>67</sup> Moreover, the federal government should designate medical centers in critical areas as stockpiles for vital reserves of storing raw materials to manufacture PPE such that the raw-material supply chain (largely from East Asia) does not hinder domestic PPE manufacturing.

Bypass competition for personnel through on-call response teams The state of Maryland bridged the gap from immediate need to a sustainable staffing solution by implementing "strike teams" composed of medical personnel including "National Guard personnel, representatives of local and state health departments, EMS and clinicians from local hospitals." The National Disaster Medical System, under HHS's assistant secretary for preparedness and response (ASPR), provided three federal disaster medical assistance teams (DMATs) composed of physicians, paramedics, and safety officers. These teams are deployed to facilities as needed. Once a request is sent to the state emergency operations center by a local health officer and local emergency manager, a strike team is deployed if all three parties deem it necessary. Originally the prime focus of these teams was nursing homes and group-living facilities where COVID-19 presented, but the scope of support has since

widened to other facilities including assisted-living facilities and group homes for children. Once deployed, these strike teams evaluate the situation on-site to determine what supplies or equipment may be needed. They are also capable of collecting and sending specimens for COVID-19 testing, as well as carrying out on-site medical triage to stabilize residents of these facilities. The United States Army Reserve has a similar structure in the form of Urban Augmentation Medical Task Forces (UAMTFs) that also mobilize quickly and effectively across the country for hospitals in need. These types of quick-response task forces should be adopted at the state and county levels across the country in order to provide greater support for hospitals and health care organizations that find themselves strained under a growing caseload.

Relocate furloughed personnel to hospitals and medical organizations in need As of April 2020, approximately 1.4 million health care workers had been laid off. Relocating furloughed personnel to areas hit hardest and fatigued by the virus would allow for valuable skills to be best utilized in whatever part of the country is in need.<sup>69</sup> For instance, thirty-four nurses in Colorado employed at a hospital that was not, at that point in time, strained by a high percentage of COVID-19 cases flew to New Jersey to support hospitals struck badly by high numbers of patients with the virus.<sup>70</sup> A national scheme allowing for furloughed or underutilized health care workers to be relocated to facilities in need would ease competition for personnel that is hindering coordination.

## **Contact Tracing in American Society**

All 50 states had instituted some system for contact tracing as of the writing of this report. States followed one of three general models:

- In-house: State/local officials leading, hiring, or recruiting volunteers as needed.
- Contracting: State contracts with a company or organization.
- Partnering: State leads efforts but relies on partners for training/staffing.<sup>71</sup>

Contact tracing in the United States faces three main issues of scale. First is that of the size and growth of the caseload in the early days of the pandemic. Contact tracing in the United States has not been able to match the scale of the outbreak because of two interrelated reasons: too many cases and too few resources. The sheer volume of cases has overwhelmed the capacity of the public health system to engage in contact tracing. As of August 31, the United States had witnessed 289,865 cases in the previous seven days. That exceeds the total caseload for most European countries since the pandemic began and is dozens of times higher than the maximum rate of weekly infections those countries saw in March and April of 2020. Countries that have been held up as the gold standard for contact tracing, such as South Korea, Liceland, and New Zealand, have a total combined caseload of less than one day (during June, July, and August of 2020) of new infections in the United States. A contact



Table 1. Contact tracing methodology by state

Staffing/personnel	State		
Hiring of outside contact tracers	AK, AR, CT, DC, DE, FL, GA, IL, IN, KY, LA, ME, MA, MI, MN, NV, NJ, NM, NC, ND, OH, OK, OR, PA, SC		
Government employees	AK, AZ, AR, CA, CO, CT, FL, HI, ID, IL, IA, KS, KY, ME, MD, MI, MS, MO, MT, NE, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD		
Recruitment of volunteers	AL, CA, CT, MA, MN, MO, MT, NV, NC, OH, PA		
Engagement with students	AZ, CO, FL, GA, HI, IN, KS, MD, MA, MN, MO, MT, NJ, ND, OH, RI		
National Guard assistance	AK, AZ, DE, IA, MT, NH, NV, OK, RI, SD, WA, WV		
COVID-19 Response Corps	CO, IL, NJ, PA		
Funding Type			
CARES Act funds	AL, AK, AZ, AR, CA, FL, ID, KY, MN, MO, MT, NV, NH, SC, WI		
Other federal funds	AL, AK, CO, IL, ME, MO, NY, OH, OR, PA, VA, WY		
State funding	AZ, AR, CA, CO, DC, DE, HI, IL, IN, KY, LA, MA, MI, MN, NH, NJ, NM, NC, OR, PA, TN, TX, UT, WY		
Funding through donation	CA, NY		
Private funding	CA, NJ		
Technology and Process			
Automated technology	AK, AZ, MI, NM		
Statewide platforms	AK, CA, CO, CT, DE, GA, IL, IN, KY, MD, MA, MO, NV, NH, NJ, NM, NY, NC, OH, OR, RI, SC, TN, TX, UT, VT, VA, WA, WV, WI		
Social media	AK		
Smartphone apps	AL, HI, NV, NY, ND, OK, OR, RI, SC, SD, UT, VA, WY		
SARA Alert System	tem AZ, AR, ID, ME, PA, VT, VA		

Note: At least forty-four states use manual phone calls first in the contact tracing process; ten states also use text or email, and a small number of states also include in-person visits, online surveys, and traditional mail.

**Source:** "State Approaches to Contact Tracing during the COVID-19 Pandemic," National Academy for State Health Policy, August 31, 2020, https://www.nashp.org/state-approaches-to-contact-tracing-covid-19/.

tracing program has never successfully operated at the scale of new infections currently happening in the United States. Even countries that suffered a major outbreak and then brought it under control are witnessing their contact tracing systems falter in the face of a second wave.<sup>77</sup> Scaling up public health interventions is one of the most difficult challenges governments have to overcome, and simply applying best practices from South Korea or New Zealand that have been linearly scaled up is unlikely to achieve the desired results.

The second issue of scale is a lack of personnel and funding. Only 40,000–50,000 out of the 100,000–270,000 contact tracers required have been hired and trained.<sup>78</sup> Efforts

to scale up contact tracing nationwide have been unsuccessful thus far despite the CDC sending about \$11 billion in relief funds to states to expand contact tracing. A survey of state health departments by National Public Radio (NPR) in June revealed that there were 37,000 contact tracers in place nationwide, with an additional 31,000 in reserve when needed. The workforce—a mix of government employees, volunteers, and contract workers hired by outside companies or nonprofit organizations—still falls short of the 100,000 that the CDC has recommended, and far from George Washington University's contact tracing workforce estimator of 271,246 required contact tracers.<sup>79</sup> A follow-up survey by NPR one month later in July revealed that the workforce has only barely grown to 41,122 workers, although the actual number is likely somewhat higher.<sup>80</sup> This inability to scale stems from two main issues: reliance on volunteers and heterogeneous sources of funding. The federal platforms for tracking and vetting medical volunteers to respond to this crisis, including ESAR-VHP and Medical Reserve Corps, have largely been underutilized and ineffective. Few states have maintained active directories through this method, and many states do not even have an information-sharing capacity such as a website to allow volunteers to sign up for vetting and mobilization. Overall, this has not been a consistent or successful means by which personnel have been mobilized in response to COVID-19. Many states initially relied on volunteers for contact tracing labor, but this did not yield adequate numbers of trained, reliable contact tracers. Without monetary incentives, recruitment was incredibly difficult in many cases. Training also contributed to delays in mobilizing adequate numbers of contact tracers. Early efforts focused on recruiting volunteers, but the time commitment, training requirements, and perceived danger of contact tracing (if done in person) led to states missing their targets for contact tracers by wide margins. Funding for building contact tracing teams came from a wide variety of sources and in varying amounts. Funding for these efforts has come from the CDC, state-level health agencies, county-level health agencies, and even private donors. In the absence of a strategy to coordinate this funding, building nationwide contact tracing infrastructure will be very difficult.

The final issue concerns testing delays and asymptomatic spread of the virus. Protracted delays in testing results have hampered contact tracing efforts, as speed in both is critical to lowering the rate of infection. When testing plus contact tracing takes more than three days total, the R value of COVID-19 will not fall below 1.81 When widespread testing was made available in the United States, an unfortunate externality was that testing turnaround time lengthened, reducing the effectiveness of contact tracing. Georgetown's COVID-Local Guide recommends that contact tracers reach 75 percent of each positive patient's close contacts within a day of testing.82 Contact tracers across the country struggle to meet the recommendation: Miami-Dade's county health department was reaching an average of only 18 percent of positive cases in July; contact tracers in DC reached 60 percent in their first tries; in Louisiana, contact tracers had only a 48 percent response rate in early June.83 The high rate of around 40 percent of asymptomatic cases also makes contact tracing less efficient.



With the delay between onset of symptoms and testing, between testing and receiving a positive result, and between receiving a positive result and tracing all contacts, it becomes significantly more difficult to rely on the individual's recollection for contacts' details, since the critical contacts from the infectious period would have been from nearly two weeks earlier. Contact tracing would work ideally if contacts can be traced before the end of the case's infectious period.<sup>84</sup>

Beyond issues of scale, contact tracing also faces a number of cultural incompatibilities in American society. Many Americans see contact tracing as a violation of their civil rights and are unwilling to share information with contact tracers. The *New York Times* revealed that the city's Test and Trace Corps has interviewed 64 percent of the nearly 20,000 positive cases in June and July, but only 35 percent in June and 42 percent in July have shared information about their close contacts. There has been difficulty not only in reaching all potentially exposed contacts, but also in engaging these contacts to cooperate. While in Miami contact tracers had poor outreach of only 18 percent of the infected in the last two weeks of July, 25 percent of the contacts refused to pick up the phone in Maryland. In Houston, New Jersey, and Southern California, half of the contacts who picked up the phone refused to cooperate. Alternatively, in Philadelphia, half of the patients claimed that they had no contacts. Even after contact tracers advise close contacts of a confirmed exposure to self-quarantine, many refuse to follow such guidelines, rendering the contact tracing effort futile. In Seattle, 80 percent of contacts asked to self-quarantine did not do so. Percent of contacts asked to self-quarantine did not do so.

The majority of states conduct initial contact tracing outreach via manual calls, followed by emails and text messages for those who fail to answer the phone. Due to suspicion over picking up telephone calls from unknown numbers out of spam and fraud concerns, contacts choose not to answer the phone from contact tracers. While the tracers need to first ascertain the identity of the contacts before sharing more private information, direct, personal questions up front (such as asking for the contact's address) can exacerbate the sense of suspicion and decrease the likelihood of cooperation.

Contact tracing apps face a number of challenges and are unlikely to be as successful as initially desired. The major challenges in obtaining an effective contact tracing app are to overcome data privacy concerns, achieve widespread adoption of an app, and engineer an app's data inputs to supplement Bluetooth and improve accuracy. Americans are overwhelmingly wary of data privacy. According to Pew Research polls, 60 percent of Americans think location tracking through cell phones will not make a difference in limiting the spread of COVID-19. In addition, a 2019 survey found a large majority of Americans believed the potential risks of data collection by companies and the federal government outweighed the potential benefits. The majority of concerns stem from the average citizen's lack of knowledge about data, its collection, and its uses. Individuals, especially minority populations who face discrimination, will remain skeptical unless the

government delineates which data would be collected, how data would be used, how long it would be kept, and with whom it would be shared.

Contact tracing apps relying on Bluetooth technology also face several technological challenges. While Bluetooth allows rapid tracking of possible contacts, the technology cannot differentiate between a one-foot distance between two people and a ten-foot distance. Its inability to calculate distances between individuals within Bluetooth range leads to a higher probability of reporting contacts that should not be of concern. For example, a phone may connect via Bluetooth to a grocery shopper one aisle over from where another shopper is standing. If one of them tests positive, it will notify the other app user even when direct contact was unlikely to have occurred. In another situation, signal strength may be disrupted by walls, pants pockets, or other factors. Given these issues, one must take into account the resulting false positives and false negatives. A solution to this problem is to combine Bluetooth technology with geolocation data collection in any contact tracing app or use triangulation in the app to pinpoint location.

In conclusion, contact tracing apps cannot be relied on as the sole guarantor of ending an epidemic. Their use is not worthless, as they can quickly notify users of potential contact with COVID-19-positive individuals. However, they must serve only as a supplementary tool to standard contact tracing.

#### **Recommendations**

Decentralize contact tracing Engaging businesses and schools is necessary to scale up contact tracing sufficiently to match hundreds of thousands of new cases per week. Instead of states or counties hiring tracers, another model would be recommending that businesses and schools operate their own contact tracing effort where it is necessary to increase confidence in opening or to protect against large-scale transmission in work environments that require employees to be in close proximity to one another (e.g., meat-packing plants). These teams could consist of as few as one person depending on the size of the institution and would be in charge of tracing contacts within the institution. The businesses and schools would be responsible for training the contact tracers according to local or state guidelines. Businesses would record which employees had overlapping shifts, and schools would monitor students and faculty who took classes together. If an employee, student, or faculty member tested positive, contact tracers would inform other employees, students, and faculty members whom the sick individual had interacted with and recommend that they quarantine themselves for two weeks. This model has several advantages over current practices:

Scalability. Recommending decentralized contact tracing in appropriate scenarios
allows the government to distribute responsibility for tracing to a wider group of
stakeholders, and allows institutions to adapt their contact tracing methods to the



environment they operate in for the specific purposes they identify. As long as the benefits institutions gain outweigh the costs they incur by hiring contact tracers, they will have a positive incentive to participate. Several companies and schools have already created these teams without government intervention, such as Harvard, Ohio State, General Motors, and Tesla. Partnerships between public health agencies and institutions allows the agencies to disseminate best practices and expand the number of contact tracers while allowing businesses and schools to reopen while keeping their employees safe. Over half of US companies are already planning to enact contact tracing plans; partnering with them to do so will improve the final result.

- Speed and adaptability. Engaging businesses and schools in contact tracing will allow faster tracing of contacts, which will slow the rate of infection. Identifying potential contacts and getting in touch with them can take a substantial amount of time, as tracers have to work out the patterns of life of each sick individual and then reach out to those they were in contact with. This is especially difficult if the initial patient is suffering from symptoms and cannot talk at length with contact tracers. Decentralizing tracing allows each business or school to design a system best suited to their environment. The system a school needs is not the same as the system a restaurant needs and is not the same as the system an office environment needs. Instead of having contact tracers with no knowledge of the environment try to figure it out, a more decentralized model allows institutions to have data on hand about likely contacts and act immediately on that information.
- Trust. Decentralizing contact tracing to the businesses and schools that citizens work in or attend makes it more likely that sick individuals will divulge information about their contacts, especially if they know that information will not leave their institution. As discussed above, distrust of the government has hamstrung contact tracing efforts in the United States. Americans trust their employers and schools substantially more than they trust the government, and this is a valuable resource that is not being utilized in the current centralized model.

However, this decentralized approach will encounter some difficulties and incur some trade-offs:

• Costs. Many smaller businesses and schools will struggle to pay for the costs to run contact tracing programs, especially given the economic downturn. This may lead to some institutions not actually implementing contact tracing, doing a poor job of implementing contact tracing by cutting corners, or not opening because of the cost. A grant program through the federal government, states, or counties could alleviate this burden, but would be expensive.

- Coverage. This model would optimally provide coverage for all employed Americans (158 million) and all students (77 million), for a total of around 235 million people. 97 However, this does not include about 100 million Americans who are too young to be in school, are unemployed, or are retired. Different methods of contact tracing will be needed to cover them. Advertising for contact tracing apps or local efforts at COVID-testing sites' waiting lines would efficiently produce higher participation and coverage. 98
- Blind spots. By limiting the responsibilities of in-house contact tracers to employees and students, a few areas are missed. Businesses would not be responsible for reporting exposure to customers (although they could if they wanted to by coordinating with local health departments). Other problems not covered are exposure in public areas (parks, hiking trails, etc.) and on public transportation. Tracking down family members or friends who may have been exposed is also not included in this model, although that is probably best handled by sick individuals anyway. Overall, this proposed system does not cover every possible interaction between individuals but provides a potential method to rapidly scale up contact tracing in a resource- and compliance-constrained environment.

When the use of contact tracing is appropriate, contact tracers must be paid and not volunteers Tracers also need to be able to work in the languages that minority communities in the region do. Enough resources need to be put in to support anyone expected to self-quarantine with regard to food, necessities, and insurance, in order to gain trust from the contacts through support instead of through surveillance.<sup>99</sup>

Quick testing turnaround is necessary for contact tracing to be effective Speed of contact tracing is more consequential than tracing coverage in containing outward transmissions, and rapid testing turnaround is necessary to achieve that speed. If testing takes more than three days, no contact tracing strategy will be able to bring the  $R_{CTS}$  (the reproduction number for the contact tracing strategy) below  $1.^{100}$  If testing takes more than one day, then the tracing delay must be less than one additional day, or tracing coverage has to be more than 80 percent to keep  $R_{CTS}$  below 1. If there is a trade-off between testing and tracing delays, minimizing testing delays is more important than minimizing tracing delays because the longer infected individuals are not aware of their health status, the further the infection may spread. A tracing strategy with minimized tracing delays, such as through an app-based technology, is significantly more effective than conventional contact tracing with long delays, even with a coverage rate as low as only 20 percent. Rapidity of testing should be optimized to reduce delay, and mobile-app technology can serve to reduce tracing delays and improve tracing coverage.

States should send text messages or emails to possible contacts prior to calling This ensures that the contacts know to expect a phone call and would be more likely to answer.



The preliminary emails and texts can either indicate a forthcoming phone call interview or send out an electronic contact tracing survey for the contacts to complete. Should the contacts not complete said survey by a deadline designated by the public health agency, contact tracers can then reach out via manual phone calls. The CDC has recommended that all contacts be interviewed within 24 hours, and optimally be interviewed as soon as possible, so the emails and texts should emphasize the time-sensitive nature of the communication. Furthermore, contact tracers should try to call three times before marking a contact as unreachable, as the repetitive outreach would alleviate suspicion over it being one-off spam. Communications should emphasize that sharing information will save lives and facilitate the fight against the virus, in the hope of persuading contacts to speak immediately and honestly with tracers.

Governments at all levels should be wary of reliance on contact tracing Given the immense difficulties in rapidly building up contact tracing teams, governments should be wary about relying on contact tracing to combat epidemics when caseloads grow to the hundreds of thousands. Contact tracing is a proven method for containing outbreaks at an early stage and helping keep them under control once the rate of growth has slowed. However, if caseloads overwhelm the public health system, it will be difficult to scale contact tracing to the appropriate level, especially if there are issues with testing or compliance. Contact tracing should remain a tool to bring outbreaks under control, but it cannot be the only tool in the toolbox. If the decentralized model we propose or another model turns out to be scalable and effective, this recommendation should be revisited. However, the current model of contact tracing is not capable of suppressing major outbreaks in the United States.

#### **Workforce Resilience**

The stresses of responding to the COVID-19 pandemic have taken a great toll on the American medical workforce.<sup>101</sup> A study carried out by Feedtrail and HOLLIBLU on the effect of COVID-19 on nurses in April 2020 found that 74 percent of respondents were experiencing high levels of stress and anxiety at the time of response, with 67 percent responding that they were planning to leave either their place of work or the industry as a whole.<sup>102</sup> A follow-up survey in May 2020 found that 61 percent of responding nurses still hoped to leave the industry due to their experiences responding to the pandemic, while 46 percent were likely to leave their current position or specialty and 50 percent of respondents reported experiencing high levels of emotional stress and anxiety.<sup>103</sup> Furthermore, a Physicians Foundation Survey conducted in August 2020 found that 58 percent of physicians currently suffer from feelings of burnout, while only 40 percent of physicians shared those feelings in 2018.<sup>104</sup> The experience of being a medical worker on the front lines of the COVID-19 response has resulted in what is known as critical incident stress. Critical incident stress is felt by workers responding to emergency events and disasters as a result of the things they have experienced such as witnessing death or serious injuries, which in many cases strains their ability to function as usual. Critical incident stress usually

lasts between two days and a month but can develop into post-traumatic stress disorder (PTSD), which lasts longer than four weeks after the incident.<sup>105</sup>

Medical professionals have been through a prolonged exposure to critical incident stress throughout the pandemic, and the stresses of operating in this field have evolved throughout the crisis. Issues with lack of proper protective equipment for medical workers have been a source of stress throughout the pandemic, but were more intense in the beginning weeks and months. <sup>106</sup> Stress was further compounded as health care workers witnessed the deaths of their fellow clinicians, both from COVID-19 and suicide as a result of the intense pressure of serving during the pandemic. Unlike other professions operating in areas and incidents of crisis, such as firefighters and the military, health care professionals were faced with leaving their families in order to protect them, and living isolated without the support system they previously relied on and without a constant support system that can be derived from living with colleagues in the same position. Moreover, medical professionals generally do not have adequate psychological first aid and critical incident stress training to respond to crises such as the COVID-19 pandemic. It is crucial that this training be implemented on a broad scale across the medical field in order to best cope with the next crisis.

As of the writing of this report, the Occupational Safety and Health Administration (OSHA), an agency of the United States Department of Labor, has no standards that "apply to the hazards associated with critical incident stress." The agency recommends sharing information detailing the characteristics of critical incident stress, its signs and symptoms, and how to manage it. This information includes a recommendation for Critical Incident Stress Debriefings (CISDs) as an early-intervention process. 107 FEMA recommends that these meetings be held within seventy-two hours of the critical incident. While CISDs can serve as a tool in the context of critical incident stress management, they would be insufficient to address critical incident stress for frontline medical workers who are serving around the clock during a pandemic. Instead, critical incident stress management training programs that utilize pre-incident training, psycho-education, peer support, and crisis management briefings would be hugely beneficial to the medical community. Existing, exemplary training and support programs are detailed in Table 2.

Countries such as the United Kingdom have implemented critical incident stress management services in the National Health Service to provide medical staff on a broad scale with support following traumatic or critical events. Due to the nature of US health care, it is difficult to implement this type of service on a wide scale; however, a training program through state health departments may be more effective and easier to implement in the lives of American health care workers.

While the long-term effects of the stress of the COVID-19 pandemic on medical professionals are unknown, it is vital to learn from similar crises such as the Ebola epidemic.



Table 2. Existing critical incident stress support and training programs

Program	Organization	Type of program	Features
Nebraska Critical Incident Stress Management Program	Nebraska Department of Health and Human Services	State program— broad focus	Designed to give volunteer peer training to provide crisis support for law-enforcement officers, firefighters, and emergency health care professionals.
			Source: "Critical Incident Stress Management," Nebraska Department of Health and Human Services, http://dhhs.ne.gov/Pages /EHS-Critical-Incident-Stress -Management.aspx.
Certificate in Critical Incident Stress Management (CCISM)	University of Maryland, Baltimore County	Private university— occupation focus	Designed for the public health workforce to cope with the stress of their jobs.
			<b>Source:</b> "CCISM - Certification in Critical Incident Stress Management," UMBC Emergency Health Services, https://ccism-cert.org.
National Interagency Wildland Fire and Aviation Critical Incident Stress Management Program	US Department of the Interior	Federal program— occupation focus	Includes components that can be used before, during, and after a crisis, for example, Pre- Incident Education (PIE), which provides for resiliency, planning and preparedness, acute crisis management, and postincident follow-up.
			Source: "Critical Incident Stress Management," National Interagency Wildland Fire and Aviation Critical Incident Stress Management Program, https:// gacc.nifc.gov/cism.
Critical Incident Stress Management (CISM) and Peer Support Program	Federal Law Enforcement Training Centers (FLETC), Department of Homeland Security	Federal program— occupation focus	Offers four programs:
			Source: "Critical Incident Stress Management (CISM) & Peer Support Program," Resources, Federal Law Enforcement Training Centers, https://www .fletc.gov/critical-incident-stress -management-cism-peer-support -program.

**Table 2** (continued)

American Red Cross Psychological First Aid Program	American Red Cross	Nonprofit	Course aims for individuals to support themselves and others through basic principles of providing psychological first aid, "including how to recognize and manage stress [and] how to lend support to family members, friends and coworkers during and following the COVID-19 outbreak."
			Source: "Psychological First Aid: Supporting Yourself and Others During COVID-19," American Red Cross Training Services, https:// www.redcross.org/take-a-class /classes/psychological-first -aid%3A-supporting-yourself -and-others-during-covid-19 /a6R3o0000014ZIg.html.
Public Health Preparedness – Building Workforce Resilience through the Practice of Psychological First Aid – A Course for Supervisors and Leaders	National Association of County and City Health Officials	Professional organization	Designed for those in a health or emergency-management role who face responding to a disaster or crisis within their organization.  Source: "Building Workforce Resilience through the Practice of Psychological First Aid — A Course for Supervisors and Leaders," Courses, National Association of County & City Health Officials, https://www.pathlms.com/naccho/courses/4592.

Organizations charged with the response, such as the United States Agency for International Development (USAID), have seen a significant effect on the mental health of their workforce due to the stress developed from handling crises such as those in public health. In a 2015 report, it is detailed that the private sector and nongovernmental-organization partners were the organizations that had developed better support mechanisms for their workforces than USAID.<sup>109</sup> In this sense, it will be crucial to partner with private-sector partners to develop greater support mechanisms for the frontline medical workforce in the United States.

Furthermore, the American public as a whole is seeing a rise in indicators of anxiety and depressive disorders. In the first half of 2019, according to the National Center for Health Statistics (NCHS), 8.2 percent of Americans surveyed suffered from symptoms of anxiety disorder, 6.6 percent suffered from symptoms of depression, and 11 percent reported suffering from symptoms of anxiety and/or depressive disorders. In July 2020, the proportion of Americans suffering from symptoms of anxiety or depressive disorders rose



to approximately 40 percent.<sup>111</sup> In this sense, it is imperative that mental health support measures are amplified to help the US population through this crisis.

#### **Recommendations**

Train health care providers in all roles to prepare them for a potential crisis such as a pandemic Due to the fact that such a wide range of health practitioners have been involved in the treatment of the virus, it is important that these professionals at every level be given the preparation they need to better cope with the stress of a similar crisis. Furthermore, in the midst and aftermath of a crisis, it is important that greater mental health support be put into place for those in the medical field. This may include more frequent mental health screenings and greater access to mental health professionals. If mental health screenings are put in place, it is crucial that they do not affect the licenses of health practitioners, so as to allow them to be as honest as possible, resulting in better support. It is crucial that the measures put in place be permanent and long lasting, as the effects of critical incident stress are long lasting and could develop even weeks after the incident has occurred.

Leverage public-private partnerships to develop training and support models For example, the University of North Carolina in collaboration with Google has created an application that is designed to give mental health support to frontline medical workers. Entitled Heroes Health Initiative, "the app offers mental health self-assessments each week, creating a summary report of symptoms and analysis. It also offers links to immediate help and free and low-cost mental health resources." In crises where health care providers are mobilized across county or state lines, mobile, technology-supported resources can target support to providers and supplement in-house medical-facility resources.

Sustain support for nonprofit organizations who are serving American frontline workers An example of such an organization is Energize Colorado, a nonprofit "dedicated to helping Coloradans recover and rise" from the pandemic. One of their schemes, Energize Colorado Therapy Connection, has mobilized volunteer mental health professionals to offer free or low-cost therapy to anyone in need, with a response time to applicants of two to three business days. This program is similar to that of the Therapy Aid Coalition, a volunteer-run organization that offers free or low-fee therapy for essential workers.

**Expand mobilization of in-house medical facility resources** Examples of in-house medical facility resources include social workers, psychologists, and chaplains who can conduct mental health webinars on handling stress and burnout, be available for on-site screening and counseling, and help refer to more resources if needed. This type of in-house support must be expanded to offer sufficient support for the stress caused by a pandemic. For instance, the army has combat stress control teams that are often embedded in units stationed in conflict zones to provide on-site support for troops who might be experiencing operational stress. Treating critical incident stress quickly is crucial in long-term stress

reduction and prevents the development of more serious stress disorders or responses. An initial in-house touch point for resources will ensure workers get the support they need.

## PART 2: OVERCOMING BARRIERS TO INNOVATION

In the beginning stages of the pandemic, the US government needed to mobilize all available resources to join the battle against COVID-19. When the demand for public health care surged, it was critical to draw on additional resources and capacity from the national-security innovation base, "the American network of knowledge, capabilities, and people—including academia, National Laboratories, and the private sector—that turns ideas into innovations, transforms discoveries into successful commercial products and companies, and protects and enhances the American way of life."<sup>113</sup> In April, President Trump called for the "greatest mobilization of our society since World War II, deploying every scientific, governmental, medical, and military resource to defeat the virus."<sup>114</sup>

Private-sector engagement has taken shape in government funding, public institution—private company partnership, shift in production output, and direct donations from companies. The majority of people had high expectations for private companies to adapt to the crisis and address new challenges for their customers. Based on the high level of trust between individuals and their employers, not only did the private sector have more direct influence on people's experience in the pandemic, there was twice as much trust in a combined government—private sector effort as in a government-alone response (45 percent versus 20 percent).<sup>115</sup>

# **Increasing Private Sector Integration**

Private sector engagement in the response to COVID-19 took shape in two prominent ways: public-private partnerships to combat the virus and the private sector's innovation to survive during the pandemic. Public-private partnerships during COVID-19 saw robust private sector participation in the realm of medical countermeasures. In particular, BARDA (the Biomedical Advanced Research and Development Authority) is a component within HHS that provides funding and technical support to industry partners to develop medical countermeasures that rapidly and effectively detect, prevent, and treat the medical consequences arising during public health medical emergencies. BARDA places a special emphasis on innovation and, during the COVID-19 pandemic response, has coordinated efforts through its Market Research Portal and Tech-Watch Program to bring together industry and government stakeholders to discuss innovative products and solutions that can serve as critical components of the federal response to the pandemic. As of September 1, BARDA had established 97 public-private partnerships and had provided funding and technical assistance to accelerate the research of seven vaccines, nine therapeutics, and 32 diagnostic tests for COVID-19 with 15 being granted EUA by the FDA. Those 15 developers have shipped over 45.2 million diagnostic test kits. 116 BARDA also uses a streamlined contracting mechanism under the EZ-BAA that allows BARDA to provide funding to



innovators to accelerate the early stage development of promising technologies addressing the nation's biggest health care challenges.<sup>118</sup>

Outside of BARDA, the FDA began working directly with federal health partners, academia, and industry to advance medical countermeasures against COVID-19 through a new program called the Coronavirus Treatment Acceleration Program (CTAP) to move new treatments to patients as soon as possible, while at the same time finding out whether they are helpful or harmful. By the end of July 2020, over 570 drug-development programs were in planning stages, over 270 trials were reviewed by the FDA, and two COVID-19 treatments were authorized for emergency use. <sup>119</sup> Furthermore, most notably, Operation Warp Speed was launched in May as a partnership among the federal government (HHS–Department of Defense joint project), the scientific community, and the private sector to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021. Congress has directed almost \$10 billion to this effort through supplemental funding, including the CARES Act. <sup>120</sup>

In addition, to combat the spread of COVID, the private sector's innovation was mobilized to help support the livelihood of their workers and local communities despite the pandemic. Large companies such as Ford, Twitter, GM, and outdoor retailer Recreational Equipment, Inc. (REI) in Seattle have made long-range plans for remote work, expecting employees to continue working remotely throughout the year. Meanwhile, these companies have taken the opportunity to reimagine the work space. Amazon has even added offices in six cities to house thousands of workers due to a surge in its business.<sup>121</sup> These companies have adopted an agile mind-set, shifting their perspectives to find new opportunities with the same expertise. Most commonly, private companies have repurposed their resources and knowledge in innovative ways to either help combat COVID-19 or seek to maintain their business. For instance, companies in the alcohol industry, including Pernod Ricard and Anheuser-Busch, have shifted to producing hand sanitizers; diaper manufacturers and apparel brands such as Under Armour have shifted to producing masks; and Amazon, Tesla, Blue Origin, and SpaceX have repurposed their rocket enterprises into 3D printing of face shields for essential health care workers.<sup>122</sup> Large companies have been pivoting their production for commercial-driven or PR reasons, but struggling small businesses have been forced to adapt. Seventy-nine percent of US small businesses say COVID has caused them to incorporate a change to meet their customers' needs. 123 Seven percent have pivoted to offer new goods and services to help fight the virus.<sup>124</sup> Additionally, some investment firms prioritized putting capital into companies that could help mitigate the pandemic or assist with rebuilding more robust response systems. <sup>125</sup> Popular themes of innovative business during COVID-19 include community care, mental health, food security, helping vulnerable groups, exercise, cooking, and serving essential workers.

Local governments have also partnered with businesses to protect local communities. The National League of Cities' COVID-19 Local Response Tracker sponsored by Bloomberg

Philanthropies, the most complete collection of municipal responses to COVID-19, has indicated that out of the 2,796 policies tracked up to August 31 that affected over 97 million people across 522 cities in the United States, there were 218 policies that emphasized public-private partnerships. <sup>126</sup> Key policy areas with private sector contributions include preventing COVID transmissions and flattening the curve, helping local populations with basic securities during the pandemic, and preparing businesses and schools for reopening in the future.

Private communication technologies pose significant legal challenges, as current US privacy laws have ambiguity on the role of private firms in data sharing. The United States' primary health-privacy law, the Health Insurance Portability and Accountability Act (HIPAA), includes language allowing federal officials to waive privacy rules in case of a public health crisis, and officials have already exercised those provisions to allow for greater sharing of patient medical records for public health purposes. The Office for Civil Rights (OCR) at the Department of Health and Human Services has announced that it is using its enforcement discretion and will not impose penalties for using HIPAA-noncompliant private communications technologies to provide telehealth services during this public health emergency.<sup>127</sup> Nonetheless, the 1996 law was passed when health data was primarily in the hands of hospitals, physician offices, and insurance companies—before Apple, Facebook, Amazon, and Google became major possessors of personal information. Legitimate concerns around the ethics, potential loss of privacy, and long-term impact on civil liberties resulting from the use of individual mobile data to monitor COVID-19 must be addressed. 128 A key concern is that the pandemic is used to create and legitimize surveillance tools used by government and technology companies that are likely to persist beyond the emergency. Such tools and enhanced access to data may be used for purposes such as law enforcement by the government or hypertargeting by the private sector.

## **Recommendations**

Use technology through private firms' participation to make data sharing more efficient as the public system of data collection, representation, and sharing is technologically obsolete The US health care industry is structured on the historically necessary model of in-person interactions between patients and their clinicians. Governments and public authorities frequently lack a digital mind-set in processing complex health information. Publicly available data is not detailed enough or updated frequently enough due to its manual input in the US hospital-data system. The private sector can contribute to digitization of data collection and automation of data representation through dashboards, smartphone applications, or maps. These technologies include artificial intelligence, big data, smart-city infrastructure, and geographic information system (GIS) technologies.

Leverage the private sector's flexibility and agility to work across sectors and regions An effective response requires multidisciplinary expertise (e.g., mixing location and health data



with specialized modeling) and establishment of necessary interdisciplinary collaborations. The private sector can easily collaborate with academia and the public sector to collect expertise from public health science communities beyond the government. It can also establish platforms for data sharing across a variety of jurisdictions, such as between subnational jurisdictions of different countries. Furthermore, the private sector can contribute its existing business network to facilitating connections, such as through the venture capital network of relationships. <sup>129</sup> Each of these capabilities may be put to use to generate a plan to more quickly characterize the next virus than we did with COVID-19 in order to better inform policy decisions early on.

# **Regulation and Testing**

Regulations and policies struggled to meet demand for the variety of testing options. FDA Emergency Use Authorization (EUA) regulations delayed the use of other, potentially faster and easier tests developed by the private sector. Though scientists at commercial labs, major hospitals, and universities began developing their own coronavirus tests, these were undeployed until March due to the FDA's slow and stringent EUA approval process. The stringent criteria discouraged some labs with novel tests from seeking FDA approval, and potentially disincentivized others from developing their own tests. Hence, though the United States has among the most-skilled scientists, bureaucratic regulations meant that it lagged behind other countries in testing for the virus. The FDA was concerned that false test results from poor-quality tests would exacerbate the public health crisis. It struggled to achieve a balance between rapidity and reliability of tests.

This issue was addressed starting February 29, 2020, when the FDA loosened regulations. It allowed high-complexity labs<sup>132</sup> to develop and begin using for clinical testing their own validated coronavirus tests "before the FDA has completed review of their [EUA] requests."133 The policy of retroactive FDA approval for qualified labs allowed the FDA to expedite testing availability without lowering its standards for issuing EUAs. Starting March 12, the FDA issued EUAs to a series of diagnostics companies, such as LabCorp and Quest Diagnostics.<sup>134</sup> And on March 16, the FDA updated its policy to allow state public labs to authorize tests at other labs without the need for additional FDA approval, passing regulatory authority for COVID-19 diagnostic testing to states. 135 Furthermore, the FDA's February 29 policy was expanded to allow commercial manufacturers to distribute their validated tests prior to FDA official review, under certain conditions.<sup>136</sup> Over time, the US innovation base of commercial labs and academic institutions produced easier and faster tests. These include Yale's "game-changer" saliva test, SalivaDirect, which received FDA EUA on August 15.137 No longer was the United States dependent on a single test—the CDC 2019-nCoV Real-Time RT-PCR—or on the few labs able to run that test. Nonetheless, the delay in mobilizing the private sector had exacerbated the challenge of containment. By February 27, evidence of community spread was already detected in California (see Seattle Flu Study Anecdote).

#### **Anecdote: The Seattle Flu Study**

The Seattle Flu Study illustrates missed opportunities to leverage the private sector's testing capacity due to rigid regulations.\* The Seattle Flu Study found an innovative local solution to the United States' testing problem—repurposing their extant flu-study nasal swab samples to quickly identify infection spread in the community. The study, directed by Dr. Helen Chu, was collecting hundreds of nasal swabs every week from residents experiencing flu symptoms, in order to study the spread of respiratory viral illnesses in the community. Hence, when the coronavirus pandemic struck, they already had an infrastructure in place to rapidly test thousands of precollected samples and identify virus spread in the Puget Sound region.

However, several regulations hindered this repurposing: Chu's lab was a research, not a clinical, lab; it had created its own coronavirus test that was not yet FDA approved; and it did not have the explicit permission of the flu-study subjects to repurpose their samples for coronavirus testing. Hence, the researchers could not report their coronavirus test results to anyone outside their research team. Discussions with state, CDC, and FDA officials for a solution were futile. A CDC official, Gayle Langley, wrote in a February 16 email, "If you want to use your test as a screening tool, you would have to check with F.D.A." However, the FDA could not approve their coronavirus test because their lab was not certified as a clinical lab under Centers for Medicare & Medicaid Services regulations—a process that could take weeks.†

By February 25, the frustrated research team had decided to proceed with testing their samples using their unapproved coronavirus test. On February 27, they detected their first positive COVID-19 case—a local teenager with no recent travel history. The finding suggested that community spread was already occurring on American soil, undetected. (As the virus's transmission into the United States coincided with the annual influenza season, syndromic surveillance systems tracking respiratory illness in outpatient settings and emergency departments did not detect "unusual trends during the early part of the acceleration period.")‡

Though technically prohibited from doing so, the research team decided to report to the local health authority, which confirmed the test result the next morning. The teenager was located and stopped right before he entered his school building. However, in discussions with CDC and FDA representatives about the incident, the Seattle Flu Study was told to stop testing for COVID-19. The next day, officials partially relented, allowing them to test and report cases, but only in future samples. They had to use a new consent form explicitly mentioning that the coronavirus test results may be shared with local health officials. They could not test their thousands of previously collected samples. However, on March 2, the Seattle Flu Study's Institutional Review Board (IRB) "determined that it would be unethical for the researchers not to test and report the results in a public health emergency." The study researchers found and reported many more cases, until they were stopped again on March 9 by state officials who noted that they had to complete their certification as a clinical lab to proceed with clinical testing.§ This backand-forth illustrates how bureaucratic red tape hampered innovative approaches to testing during the public health emergency. It also reveals difficult trade-offs between privacy and security during rises.



<sup>\* &</sup>quot;Welcome to the Seattle Flu Study," Seattle Flu Study, https://seattleflu.org/scan.

<sup>†</sup> Sheri Fink and Mike Baker, "'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response," *New York Times*, March 10, 2020, https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html.; https://www.propublica.org/article/cdc-coronavirus-covid-19-test.

<sup>‡ &</sup>quot;Public Health Response to the Initiation and Spread of Pandemic COVID-19 in the United States, February 24–April 21, 2020," Morbidity and Mortality Weekly Report, CDC, https://www.cdc.gov/mmwr/volumes/69/wr/mm6918e2.htm.

<sup>§</sup> Fink and Baker, "'It's Just Everywhere Already."

While regulatory barriers to new testing had been lowered, many academic, commercial, and state labs still lacked the operational capacity to handle a large volume of tests. They were unprepared to handle surging demand for testing, particularly following announcements of expanded testing criteria, and soon had a backlog of patient swabs. Meanwhile, supply shortages in testing components (e.g., swabs, virus control samples, reagents, RT-PCR instruments) meant that other labs could not fulfill their theoretical operational capacity. 139

#### **Recommendations**

Public-private partnerships need to create an approach that does not force customers to choose between privacy and safety It is important to ensure data minimization, time sensitivity, and anonymization, and in particular that current technologies and data will not be repurposed in the future for commercial advantage. There needs to be more effort spent on building trust and ensuring transparency in private-sector engagement than on the actual solution. In the United States, since there will be no government-mandated technology (e.g., a mandatory contact tracing application), it is important to provide guidance through private companies' products. In addition, educational programs on civil liberties for the public and on privacy laws for technology companies can address concerns around private-sector engagement in the response to COVID.

Scientific research exemption must be made more broadly available to private-sector organizations under established legal boundaries DPAs should confirm that data-protection laws provide that scientific research is exempted from some of the data-protection law requirements (refer to Article 89 of the General Data Protection Regulation). Private companies would be better equipped to decide between adhering to privacy laws and public interest under complete legislation. In addition, data-protection laws require that data be accurate, relevant, and adequate to the stated purpose for which it was collected. Therefore, a voluntary basis for data provision can result in inaccurate and biased results due to the insufficient amount of data collected. The government may consider taking a stronger stance to ensure that some data is shared with public entities when necessary. 141

The federal government must provide purchase guarantees for private, domestic manufacturers of PPE While private firms had the incentive and capability to pivot production to PPE or ramp up production in existing manufacturing facilities, the key challenge to scaling up PPE production was the fear of having no buyer. Indeed, companies would be far more willing to surge and sustain production capacity over the long term if the federal government were to provide guaranteed contracts to purchase PPE for government stockpiles. Sustained production capacity during noncrisis times will ultimately be key to being able to successfully ramp up production during the next pandemic. While the will to do so might be strong in the immediate term, as COVID fades into the background in the

coming years, legislative action from Congress will likely be needed to legally mandate HHS to purchase a minimum amount of PPE each year.

Establish routine management of private-sector engagement in the public health sector through building long-term partnerships These must include mixed, diverse expertise for immediate and rapid action. These "standing" mixed teams can include collaboration among infectious-disease modelers, epidemiologists, and researchers of mobile network—operator laboratories, in addition to the support from public health authorities. They would work with up-to-date technology and predefined legal prescriptions and protocols on data access, possession, and utilization. During regular time, these standing organizations would not require significant funding to maintain. For instance, the C19 Coalition estimates that \$1 million would be able to support its network for more than 10 years. 142

# **Leveraging Testing Niches**

The United States must develop a testing strategy for this and future pandemics. A strategic testing response will shift at different stages of a pandemic. Comprehensive testing of travelers early in a global pandemic helps guard against travel-related importations of a disease. However, especially as community spread occurs, it is essential to quickly identify the infection spread and severity, and the groups most susceptible. For COVID-19, an expanding testing tool kit is at policy makers' disposal. Each type of test has a specific use and niche that could fit into a larger testing strategy. This section describes the uses and limitations of three prevalent COVID-19 tests: RT-PCR, antigen tests, and antibody tests.

Real-time reverse transcription polymerase chain reaction (RT-PCR) testing is the primary method for diagnosing an individual with an active SARS-CoV-2 infection. The RT-PCR test specifically detects viral genetic material from a collected sample (nasopharyngeal, nasal, oral, or other sample type) and then amplifies the DNA exponentially through the PCR amplification process until a cycle threshold (Ct) is achieved for a positive diagnosis.<sup>143</sup> These highly sensitive and specific tests produce results in a few hours but require highly trained personnel to operate the complex laboratory equipment for testing. While RT-PCR results provide the most accurate results, they do not differentiate between RNA from infectious virus particles and RNA from remnant inactive genetic material, and therefore cannot provide information on infectiousness. Additionally, if the Ct for the RT-PCR is set too high to increase test sensitivity, the likelihood of producing false positives also increases. False positives can also result from cross contamination due to poor testing quality. RT-PCR testing capacity was hampered at the start of the US epidemic due to an internal CDC preference for an in-house diagnostic test to be distributed to the public health labs around the country instead of implementing a commercially available foreign diagnostic test at both public and private labs to quickly increase testing rollout and capacity.<sup>144</sup> Further delays occurred due to contamination issues with the CDC test kit, while FDA regulations and lengthy review processes added to the loss of precious time to find and



isolate early cases of infections, allowing the virus to spread throughout communities across the country. The CDC did not tap commercial manufacturers to help develop and distribute the RT-PCR test kit early enough, and they did not initially engage commercial laboratories that would be doing the bulk of the diagnostic testing, rather than the public health laboratories. It is clear that high demand for testing without enough testing infrastructure and test kits can cause backlogs that delay test results and data sharing.

Similar to RT-PCR, rapid antigen tests can identify active SARS-CoV-2 infections by detecting specific proteins of the virus as it is replicating. 145 Antigen tests have the advantage of being performed at a point-of-care setting, such as a doctor's office, with results provided in under 30 minutes, and thus do not require expensive equipment beyond a reader for some tests or trained professionals to conduct the tests. Additionally, they are cheaper to produce, can be made in large quantities, and do not require a cold chain for distribution. However, they are less sensitive than PCR tests, despite manufacturers' claims, and are therefore more likely to produce a false result. April antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest, rather than in general screening that includes asymptomatic cases. Rapid antigen tests are a type of lateral-flow assay that, due to the lack of signal amplification, is less sensitive than RT-PCR tests. The lower sensitivity has resulted in highly varying concordances (0-94%) to RT-PCR in a number of recent published studies. Since antigen tests may miss true positives, it has been suggested by CDC and others that an RT-PCR test should be used as a confirmatory test on antigen-negative samples if the patient is symptomatic or has been exposed. New World Health Organization (WHO) guidelines for the use of antigen tests indicate that only rapid antigen tests with demonstrated test performance of greater than or equal to 80 percent sensitivity and greater than or equal to 97 percent specificity compared to a reference RT-PCR assay should be used in various scenarios, including when there is limited RT-PCR testing or the turnaround times are unhelpful for clinical utility. 147 It is key that recipients of antigen tests must understand that a negative result is only presumptive and may require a confirmatory RT-PCR test.

Antibody tests, also known as serology tests because they use a blood sample for testing, measure the presence of SARS-CoV-2-specific antibodies to determine whether an individual has had an infection in the past. Antibodies are a sign of an immune response to an infection. Antibody tests come in a variety of testing formats from laboratory based to point-of-care rapid tests and their testing performance, especially their sensitivity, varies widely. It is crucial to note that *the presence of antibodies does not equate to protective immunity*. Multiple scientific articles suggest that SARS-CoV-2 antibody levels decline over time, implying that COVID-19 immunity is not long lasting, though the research on this very important topic is ongoing in order to learn whether other components of the immune system contribute to any form of protection from infection.<sup>148</sup> Instead of using antibody tests to determine individual immunity, representative cross-sectional serosurveys

Table 3. Testing type niches

Test type	Attributes	Limitations		
RT-PCR	Detects active SARS-CoV-2 infection High sensitivity High throughput testing	Slow result turnaround <i>if</i> demand > lab testing capacity Expensive and labor intensive		
CRISPR	Detects active SARS-CoV-2 infection Point-of-care results Inexpensive	Technology still in development Requires equipment and some level of skill to perform Not widely available yet		
Antigen	Detects active SARS-CoV-2 infection Point-of-care testing Inexpensive	Low sensitivity Requires high viral load for detection Requires a confirmatory test		
Antibody	Detects previous SARS-CoV-2 infection High-throughput laboratory testing Point-of-care testing Essential to determining infection fatality rate	Performance of a single test likely to provide false positive results to individuals Low sensitivity if tested within 0–2 weeks after symptom onset (false negative)		

should be conducted repeatedly to map the change in disease prevalence over time. These serosurveys also provide important information on key demographics (age, race, etc.) of who is most likely to be infected and where, indicators that would help target specific groups and communities to prevent further transmission. Additionally, such efforts would help the scientific community identify the virus's infection fatality rate and help policy makers determine both the seriousness of the danger and the distribution of resources across the nation according to disease prevalence. Accuracy around the serosurveys is of major concern, though, given the performance of current tests granted Emergency Use Authorization by the FDA. Furthermore, sensitivity is extremely low for nearly all tests if patients are tested within the first seven days of symptom onset when antibodies have not developed yet. It is advised that samples be taken at least three weeks after symptom onset. Even so, a test with low sensitivity (below 95 percent) will produce many false positives that will result in an elevated disease prevalence unless a second confirmatory test is used in a serial testing format. Antibody tests, when used in the right setting, can provide key insights into the epidemic that no other type of test can provide.

As long as PCR testing personnel and resources are limited and data lags are still an issue, there will be a trade-off. Increasing reliance on antigen tests compared to PCR tests will provide quicker data collection, reduce lags, and allow a greater proportion of the population to be tested, but carries the risk of a higher number of false negatives and false positives due to antigen tests' low sensitivity. On the other end, sidelining antigen tests in favor of PCR tests lowers the risk of false negatives but increases false positives because of PCR's higher sensitivity. Under excess demand, PCR tests succumb to lab analysis backlogs, data delays, and limited testing supply.



In any public health emergency, point-of-care testing is a necessity to provide timely results and to meet demand. Current technologies cannot provide highly specific and rapid point-of-care results, but future innovative efforts could focus on achieving this objective. Two possible avenues in improving pandemic diagnostic response reside in mass spectrometry and more-sensitive antigen tests.<sup>149</sup>

#### **Recommendations**

Utilize pool testing early on in the public health emergency Limited testing supplies, supply chain bottlenecks, and lofty expenses are all realistic concerns in epidemics and pandemics alike. Labs may adopt pooled testing in order to increase testing capacity. Pooled testing is when more than one sample is combined into a "pool" and tested in one RT-PCR test. If the pool result is negative, then each sample tested in the pool is assumed to be negative. If the pool result is positive, then it is necessary to deconstruct the pool and test each sample individually to determine which sample(s) is positive. Pooling allows increased testing efficiency by using fewer testing supplies, but the trade-off is a slight decrease in testing sensitivity. The efficiency that is gained with pooling can be obtained only if the positivity rate in a region is relatively low, preferably under 10 percent. Early in disease outbreaks, pooling is recommended because the positivity rate is still relatively low and there is a higher probability of supply shortages to meet demand as supply chains become functional.

**Employ an antigen-first, RT-PCR-second testing algorithm** For this strategy to work, the antigen test must have a high sensitivity, closer to that of the PCR test. The inexpensive, point-of-care antigen test allows rapid testing of a large number of individuals. Those with a positive result should self-quarantine and cooperate with contact tracers. Individuals with a negative antigen test result should follow up with a highly sensitive RT-PCR test for confirmation of the negative result.

Conduct a two-round serial antibody-testing algorithm in communities to help determine the infection fatality rate (IFR) and allocate resources A serosurvey would allow medical and public health officials to understand the spread of the virus in a population by identifying both symptomatic and asymptomatic individuals at a given point in time. It must be noted that timing of the antibody sample matters and is a limitation of this type of testing. If the antibody test is conducted too soon after exposure, it will not detect a significant level of antibodies. If the test is conducted too late postexposure, antibodies may have declined below detection levels. Although some of the antibody tests available now have sensitivities and specificities greater than 90 percent, when applied to large testing populations where the prevalence is suspected to be low, the antibody test will identify more false positives than true positives. Given our knowledge from other diseases, such as HIV, it is recommended that two or more tests be used in a serial-testing algorithm to determine the presence of antibodies in a sample. This increases the overall positive predictive value and

provides a much more accurate picture of COVID-19 prevalence. Such tests do not have to be performed on the whole population. They may be randomized at first, then later expanded according to clinical needs.

# **Therapeutics and Vaccines**

SARS-CoV-2 will likely not be eradicated because of its airborne transmission, its ability to mutate, and uncertainty over permanent immunity. Realistically, societies may expect mitigation of the virus through a combination of vaccinations, societal immunity, and therapeutics. A vaccine alone cannot serve as a silver bullet, but there is a potential for drugs to reduce disease severity, decrease fatality, inhibit secondary infections, and ameliorate symptoms.<sup>152</sup>

Therapeutics in the COVID-19 pandemic and future pandemics may attempt to intervene directly in the virus life cycle and should also focus on preventing secondary infections. As the scientific community learns more about the virus's behavior and transmission, more medications targeting different stages of the replication cycle are being developed, which will make the virus more manageable.

Instead of dedicating efforts solely to developing new medications that will eliminate the SARS-CoV-2 virus, it may be advantageous to consider currently available medicines used in previous coronavirus outbreaks as potential treatments.

Early in the COVID-19 pandemic, researchers tested orphan drug compounds, primarily antivirals, and tested them for efficacy on SARS-CoV-2.<sup>153</sup> This research led to the development of experimental drugs that, although their immediate effectiveness is impossible to determine, signal to society that therapeutics will be developed over time and used as tools in the fight against the novel coronavirus.

Therapeutics alone, while saving lives, will not drastically reduce the number of COVID-19 cases unless there is a drug that may be taken as a prophylactic. Herd immunity is often achieved through a combination of vaccines and natural immunity. Advocating solely for natural immunity in a virus to which immunity is likely temporary may harm the vulnerable because passing the threshold would require a vast majority of the population to become infected within a short time period. Relying solely on vaccination for immunity is ineffective because it uses one or a few epitopes to trigger the immune response, while natural immunity leads to many different viral epitopes. In an analogy, a vaccine is like blocking the virus with a single key (monoclonal) whereas natural immunity blocks the virus with many keys (polyclonal). Natural and vaccine immunity in tandem can be a successful initial viral control.



#### **Recommendations**

**Examine past scientific literature and focus on existing therapeutics before designing new therapeutics** Instead of beginning from a blank slate, one should examine the literature from past epidemics of similar diseases. In the case of SARS-CoV-2, it would be beneficial to initially identify successful drugs from the SARS-CoV-1 epidemic and try to recycle those drugs if they are effective. Then, the focus may shift to designing new therapeutics.

**Recognize and publicize the potential benefits of therapeutics to return to "new" normalcy** Existing and new drugs that disrupt different stages of the viral life cycle or inhibit secondary infections are all tools that could reduce a disease's mortality rate. If symptoms are abated or the infectious period is reduced, there could be shortened self-quarantine times and quicker recovery. One might assume that if there are sufficient measures to support recovery, fears of the consequences of catching the virus would be reduced. This knowledge may be especially useful once safe and effective vaccines are developed and distributed to stabilize the spread of a novel virus.

Engage in community outreach for vaccine uptake Community leaders must begin outreach before the vaccine is distributed. It is critical that the public recognize a shared community responsibility to be vaccinated. The government must also provide correct and comprehensive information to the public related to any possible vaccination, including the vaccination's effectiveness and the possibilities and probabilities of serious side effects. Clear communication and proactive encouragement rather than shaming is the optimal method of increasing vaccine uptake.

Continue research partnership with the private sector to pursue and distribute a safe and effective vaccine The United States is a global leader in vaccine research and advancing safe, promising clinical trials, as evidenced by Operation Warp Speed. However, a vaccine will only be as effective as our ability to distribute it effectively. Operation Warp Speed, BARDA, and similar public-private partnerships should continue.

Apply lessons from early PPE supply chain challenges to vaccine production and distribution. Vaccine distribution is likely to be confronted by similar challenges to early PPE distribution as actors and states from different regions compete for a finite supply. The federal government should continue to prepare for supply chain bottlenecks of the various components of the drug and housing that might threaten the potential for immediate distribution of the vaccine agent. For example, estimates predict a bottleneck in pharmaceutical-grade glass that will trigger hoarding of initial vaccine supplies potentially ready for American citizens. Vaccine distribution efforts will also be impacted by the number of doses required for immunization; the need for multiple injections would place a multiplier effect on the supply chain, particularly for understockpiled materials like pharmaceutical-grade glass. There is precedent for emergency-use authorization for

distribution of medical supplies in the distribution of antibodies for anthrax after 9/11, but the COVID-19 vaccine distribution would be on a larger scale and would need to overcome significant logistical challenges.

# **Incentivizing PPE Production**

There are insufficient economic incentives for US companies to produce critical medical supplies domestically. Additionally, there are insufficient incentives for companies poised to innovate new solutions, especially given how they might be profiting from the current just-in-time nature of the supply chain that takes advantage of efficiencies gained from low inventories, supplier concentration, and economies of scale. The primacy of single-use disposable masks in American markets allows for manufacturers to profit without investing in more-expensive raw materials to produce multiuse masks. Physicians treating COVID-19 patients at varying times during the pandemic were forced to reuse masks intended for single use or that were exposed to COVID-19-positive patients.<sup>157</sup> Further investment in the manufacturing capacity of more-expensive N95, N99, or N100 medical masks would benefit American physicians and citizens. As the personnel and machines that make materials for such masks are costly and would require at least minimum-wage compensation, these masks are not profitable to make in times of limited demand. The low margins for production extend to generic drugs and other medical material, which poses a health risk to the nation when global supply chains cannot procure sufficient equipment to address the pandemic. While the private sector might have the incentives to engage in such production during a crisis, to reduce the initial response time during the next pandemic the government must step in as a guaranteed buyer.

Without a sufficient domestic manufacturing capacity, countries like the United States become beholden to the so-called "mask diplomacy" of other countries, such as China, in order to procure enough PPE to meet demand. Geopolitical interests and tensions give rise to the risk of adversarial states having dangerous leverage over the United States. In addition to manufacturing capacity, the supply chains for the raw materials necessary for PPE production must be closely examined, as a similar risk exists. While manufacturing capacity can be increased if demand spikes, the process of increasing such capacity is complicated and takes far too long to be able to meet immediate need, which leads to insufficient supplies and ultimately more deaths.

## **Recommendations**



ultimately giving HHS a healthy medical-industrial base akin to the Department of Defense, which also has a network of labs across the globe to deal with emerging diseases, among other issues of force protection. Under such a system the HHS would have the required ability to manage a US-based manufacturing base that can surge in response to future crises, including pandemics or natural disasters such as wildfires.

Engaging the international community is essential in negotiating economic incentives for PPE production Cooperative manufacturing and distribution networks with American allies would increase production of PPE and address national security concerns associated with mask diplomacy. Government-to-government contact would benefit the United States by targeting production in nations with greater manufacturing capacity where PPE materials are produced and would ease the flow of PPE across borders. Determining the degree to which the United States should rely on allies for raw material and equipment production would require dialogue between government leaders. For example, leaders may express different levels of comfort with sourcing masks from Honduras or Mexico rather than from China, or they may prefer that they all be American made. Furthermore, having an adequate supply of PPE could enable the United States to lead a future global response to the next pandemic.

## CONCLUSION

This study is meant as a starting point for those who are developing policies and practical solutions that improve our ability to respond to a biomedical emergency or crisis. It will have achieved its purpose if organizations across the public and private sectors use this study to ensure a higher degree of preparedness. The issues included in the study, as well as those beyond the scope of this report (e.g., implications of the pandemic response for the continuation of chronic care and mental health of the population) warrant further investigation. However, this report has captured a number of preliminary lessons to facilitate the mobilization of the biomedical response to an emergency. The application of these lessons must rise above the partisan vitriol and focus on areas of agreement to produce targeted and effective policies that will save as many lives as possible, and that will inspire unity, cooperation, and collaboration from the state house to the White House, from the local promenade to the National Mall, and from the family room to the classroom.

The resources on which this study is based can be accessed at the Hoover Institution Library & Archives. For more information, please call (650) 723-3563.

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## **ABOUT US CIVILIAN CORPS**

Founded in 2018, the US Civilian Corps (USCC) is a 501(c)(3) nonprofit whose mission is to strengthen America's resilience by creating pathways to public service. The USCC vision is for a country where every American is able to serve, strengthening our nation's social fabric and galvanizing the free will of the American people to counter authoritarian forces around the world. The organization initially focused on part-time, remote, volunteer service to the nation's national security enterprise, harnessing the perspectives of Americans around the world to inform policy makers.

In response to the COVID-19 pandemic, USCC partnered with executive search firm Odgers Berndtson to form a coalition of business leaders, public health officials, academics, and military leaders to mobilize human resources for state and local governments and health facilities. USCC's first product, a trusted human-capital ServicePlace, connects available health care professionals to health facilities needing additional personnel.

USCC soon began to share lessons learned from engagements with government leaders and health care professionals. Thanks to the vision of LTG (Ret.) H. R. McMaster, USCC has partnered with Stanford University's Hoover Institution to capture and contextualize those lessons in this report. It is a testament to the courage, sacrifice, and insights of so many patriots. Through the report and their trusted human-capital ServicePlace, USCC's aspiration is to make our nation better prepared and more resilient in the face of future health crises.

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# **Synopsis**

The medical response to COVID-19 was hampered in speed and effectiveness by obstacles to effective coordination across federal agencies, between local, state, and federal governments, and among public and private-sector organizations. Drawing on interviews with practitioners and opensource research, this report describes those obstacles and recommends policies and actions to help overcome them and improve our nation's response to this pandemic as well as future biomedical crises.

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