A Compendium of the Findings of the Obama PCAST Ad Hoc Subgroup on Pandemic Preparedness and Response

December 23, 2020

Introduction

A subset of the former members of President Obama’s Council of Advisors on Science and Technology (here OPCAST)—ten individuals who played particularly important roles in producing the six OPCAST reports between 2009 and 2016 that dealt with issues related to pandemic preparedness and response¹—came together starting in March of this year to consider how insights from those studies might be combined with more recent research and current observations to develop suggestions about how the U.S. response to the COVID-19 pandemic could be improved.

The Subgroup has produced six reports, addressing

- the national strategic pandemic-response stockpile (May 20)
- the role of contact tracing (June 18)
- the role of public health data in controlling the spread of COVID-19 (July 28)
- testing for the pathogen (August 18)
- recommendations for the coming COVID-19 commission (September 21)
- needs for improved epidemiological modeling (September 28)

Each report was distributed, upon completion, to selected members of the Trump COVID-19 team and the Biden campaign staff, selected governors and members of Congress, selected public health experts outside government, and the media. The reports have also been posted on the OPCAST team’s website, http://opcast.org, together with a few opinion pieces based on them.

In the current volume, we have assembled all six reports in full, preceded by a set of brief summaries. Four of the reports are followed by short updates taking account of developments since the reports first came out.

The members of the team are: Christine Cassel, University of California, San Francisco; Christopher Chyba, Princeton University; Susan L. Graham, University of California, Berkeley; John P. Holdren, Harvard University (OPCAST Co-Chair, COVID-19 Team Convener); Eric S. Lander, Broad Institute of MIT and Harvard (OPCAST Co-Chair); Richard Levin, Yale University; Ed Penhoet, University of California, Berkeley; William Press, University of Texas, Austin (OPCAST Vice Chair); Maxine Savitz, National Academy of Engineering (OPCAST Vice Chair); and Harold Varmus, Weill Cornell Medicine (OPCAST Co-Chair).

The members have participated on their own time and as individuals, not as representatives of their institutions. The joint effort has had no sponsors and no budget.

¹ Those reports—which dealt with the H1N1 epidemic (August 2009), the vaccine-production enterprise (August 2010), Health Information Technology (December 2010), Drug Discovery, Development, and Evaluation (February 2012), Systems Engineering for Healthcare (May 2014), and Meeting Biological Threats (November 2016)—are all available at https://obamawhitehouse.archives.gov/administration/eop/ostp/pcast/docsreports,
The Subgroup has tried to avoid duplication of the work of the COVID-19 committee chaired by Harvey Fineberg at the National Academies of Science, Engineering, and Medicine, with which it has stayed in contact, and it has not addressed issues related to the development, testing, and distribution of vaccines or the development and testing of therapies.

We have been very much aware, in developing the recommendations in our reports, that the United States exhibits immense diversity in the characteristics germane to pandemic preparedness and response. Our recommendations, which are aimed largely at decision-makers at the national level, will be therefore be most effective if local conditions and behaviors are accounted for, whenever appropriate, in their implementation.

We thank the many experts who generously shared their ideas with us over the course of this work, but we hasten to say that the responsibility for the results is entirely our own. We also thank the many recipients who have responded and, in particular, a number of members of Congress and their staffs who followed up with questions and ideas about legislation.

There is much more to be done before this country and world will be able to say that the COVID-19 pandemic has been mastered. We hope our work has made at least a small contribution toward that outcome.

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Summary of the Report on the National Pandemic-Response Stockpile

Eight months since declaring the COVID-19 a national emergency, the federal government has still not resolved the problems of availability and distribution of sufficient Personal Protective Equipment (PPE) and other medical equipment and devices. Now the number of new cases is surging, the flu season is approaching, and colder weather is forcing people indoors, resulting in greater demands on hospitals and healthcare organizations. The availability of adequate PPE and medical supplies is once again an urgent matter.

The CARES Act provided $16 billion to the Strategic National Stockpile (SNS) for critical supplies. As of July 31, 2020 (the last date for which we have information), the Department of Health and Human Services (HHS) reported it had obligated $8.4 billion of the $10.7 billion it had planned to use for SNS.

The May 20 report on the SNS by the OPCAST pandemic team provides information regarding the background, rationale, funding, and organization of the SNS. In 2013, the SNS was reauthorized until the end of FY2018. On October 1, 2018 the full responsibility for the SNS was transferred from the Centers for Disease Control and Prevention (CDC) to the HHS Assistant Secretary for Preparedness and Response (ASPR). On April 2, 2020 the longstanding mission of SNS was changed from providing adequate supplies to state, local, tribal and territorial responders during a health emergency to supplementing state and local PPE and medical supply needs.

In the absence of a national SNS plan, the work of federal and state governments and the private sector to secure supplies is fragmented, leading to increases in prices as multiple sources bid against one another for the same products. Implementation of the Defense Production Act (DPA) appears to have been sporadic and relatively narrow, with some misuse of funds. In addition to the issue of the adequacy of the supply of PPE, there is concern about the quality, particularly of masks.

The CARES Act gave the Food and Drug Administration (FDA) the authority to monitor the supply of PPE and medical devices. The FDA and the National Institutes of Standards and Technology (NIST) need to work together with standard-setting groups to develop and promulgate standards for N95 respirators and other PPE. For the federal government to assume its appropriate role in protecting the American public, it is also necessary that the federal government, states, public health groups, and health systems know where supplies are and how they can be allocated to those in greatest need.

The recommendations made in our May report are even more relevant and urgent now. Additional concerns are described in our November update to that report, including leadership and management, the use of the DPA, the role of the FDA, and the coordinated use of existing PPE and medical supplies and devices. Our two most important recommendations follow.

Recommendation 1. The White House should appoint a COVID-19 stockpile and supply chain coordinator, whose office would coordinate with the relevant agencies the development of a national plan including the logistics of manufacturing and distributing PPE, medical equipment, therapeutics, vaccines, and test kits both for the national stockpile and for the states. (November update)
Recommendation 2. In the next stimulus or supplemental appropriation legislation, Congress should appropriate $30 billion for federal and state stockpile replenishment and preparedness. (May 20 report)

Please see the report and the update for additional recommendations.

**Summary of the Report on Contact Tracing**

SARS-CoV-2, the coronavirus that causes COVID-19, is primarily transmitted directly from one infected human being to another when viral particles from the infected person enter the body, most commonly through the respiratory tract. The only definitive way to know whether people are infected by SARS-CoV-2 is to test them for the presence of viral RNA, normally done using sensitive polymerase chain reaction (PCR) molecular tests.

Transmission can occur before an infected person exhibits symptoms; some infected people remain asymptomatic but are contagious, nonetheless. Although further transmission can be prevented by isolating people as soon as they are exposed to an infected person—and can be reduced by keeping people apart (social distancing) and by blocking some viral particles through the use of face masks—in practice, close contact with infected people and attendant transmission will still occur for a variety of reasons.

Once an infected person is identified, using contact tracing to identify the other people to whom the newly identified infected person might have transmitted the virus can reduce the spread of the virus. Additionally, by identifying the person from whom the virus was transmitted and sequencing the viral genomes of both parties to the transmission, much can be learned about the evolution of the virus.

Contacts must be identified and tested or quarantined quickly, to reduce the spread of the virus. Infected and possibly infected people then must be given advice and assistance, medical and often financial. Identifying contacts can be done by a combination of expert human interviews and digital tools. Human contact-tracing has a history of success, but it is labor intensive and subject to delays and lack of subject cooperation. Digital contact tracing can identify contacts unknown to the infected person quickly and notify those contacts immediately of possible exposure, but it is an emerging technology with incomplete infrastructure and uncertain user acceptance. Both forms of contact tracing can raise privacy concerns.

Digital contact tracing has been used successfully in other countries and in some U.S. states. As of mid-November, fifteen states and the District of Columbia have rolled out public health apps using digital technology based on the Google-Apple Exposure Notification framework. As states roll out their apps, there needs to be more consistent, positive, and persuasive messaging.

The topics summarized above are discussed in detail in our contact-tracing report of June 18. An update to the report summarizes some successful deployments of testing and contact tracing since then, the slow but promising rollout of digital contact determination, and some means to increase the numbers of trained human contact tracers.
It is not too late to strengthen the Nation’s attack on the COVID-19 pandemic and its preparedness for future pandemics. Better testing, contact tracing, and methods for controlling the spread of this and other infectious diseases are essential. To that end, the report and the update make the following recommendations.

Recommendation 1. Establish a unit with responsibility for testing and contact tracing at the Department of Health and Human Services (HHS). The unit would serve as a clearing house for the development of digital contact-tracing tools, determine the amount of funding needed to carry out combined human/digital contact tracing and immediate testing of people exposed to the virus, and analyze and document experiences and best practices in testing, contact tracing, and quarantining that have been used by Federal, state and local entities to reduce COVID-19 transmission.

Recommendation 2. Provide adequate Federal funding for contact tracing and diagnostic tests, in some combination of already authorized funds and additional appropriations. The April 2020 Paycheck Protection Program and Health Care Enhancement Act provided $11 billion directed to states and localities for testing and contact tracing. The May 2020 House HEROES Act contains $75 billion in its COVID-19 National Testing and Contact Tracing Initiative ($60 billion for testing and $15 billion for contact tracing), but the Senate did not act on that proposed legislation.

Recommendation 3. Provide both short-term and long-term funding for multi-agency research to advance the use of science and technology to control and reduce the spread of infectious disease. Topics might include efficient screening mechanisms in public places for pre-symptomatic people, more effective and efficient diagnostic and serological tests, more effective methods for human and digital contact tracing, human factors that govern the success or failure of methods to control and reduce disease spread, security and privacy considerations and their interplay with policy directives in times of emergency, and scientific understanding of the nature of coronaviruses and the mechanisms by which they spread.

Recommendation 4 (from the Update). Institute digital contact tracing in all major Federal government facilities, including military bases, agency buildings and campuses, the White House and executive office buildings, and judicial facilities. Digital contact tracing should be integrated with diagnostic testing and human contact-tracing programs in every facility, and with state and international programs where they exist.

Summary of the Report on Public Health Data for Pandemic Response

The response to the COVID-19 pandemic has exposed weaknesses in the US public health system and inadequacies in the nation’s ability to anticipate, prepare for, and respond to serious infectious epidemics. The experience of 2020 shows the need to strengthen the infrastructure for collection, analysis, and sharing of data to enable an effective public health response to any threat.

U.S. health data come from state and regional data bases, some of which are reported to and synthesized by the Centers for Disease Control and Prevention (CDC). The federal system creates challenges for optimal data collection, but modern digital data technology exists that could largely overcome those problems. The primary barriers to achieving dynamically reported shared data are:
(1) barriers to the access to clinical data; (2) lack of stable, consistent governance shared by CDC and states; and (3) chronic underfunding of public health entities at every level.

The 2009 HITECH Act charged the National Coordinator for Health Information Technology with creating a national data infrastructure that “improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks”. The major focus of the Office of the National Coordinator (ONC) to date, however, has been to implement electronic health-record (EHR) systems for hospitals and clinical settings by linking payment incentives to adoption and “meaningful use” in patient care.

Too little attention has been paid to data sharing that would allow the efficient use of the same data for public health purposes such as syndromic surveillance and early identification of illness clusters. The information-blocking practices of EHR vendors led to a provision in the 21st Century Cures Act requiring open data access. This laudable legislation was focused on the important goal of giving patients access to their own complete health records, but it is also important to make the same data available for authorized public health purposes.

States and local public health entities have various data-reporting requirements, and they share data with CDC, which has its own surveys and data centers. While recognizing the significance of the states’ constitutional responsibility for public health, we think COVID-19 has demonstrated the need for a more substantial federal capability to coordinate and share data and analytics for timely national policy efforts. There have been several constructive attempts at collaborative governance models linking CDC and states in data gathering, reporting, and response, but these efforts have not proven adequate to the challenge of the current pandemic and have not been sustained. A stable, high-functioning, governance model, coupled with a state-of-the-art, platform-architecture design and adequate incentives for data sharing and the development of apps, is necessary for the success of a national public health infrastructure.

CDC and state/local public health entities have been hampered for decades by underfunding. Clinical services (funded by the Centers for Medicare and Medicaid Services) and biomedical research (largely funded by the National Institutes of Health) have too long dominated the federal health funding agenda. COVID-19 has exposed the consequences of this unevenness in the national biomedicine and public health system. Short-term funding to create strategic data capabilities and to link state and federal data systems is urgently needed. Equally important is longer-term investment in modernizing the data-science capabilities of public health operations at every level. Investments for both time scales should be foremost in recovery/stimulus legislation before the Congress this year but also must be part of the national health agenda for the future.

Modern data science, were it put to use, could both serve public health needs and make the U.S. healthcare delivery system more patient-centered and more efficient. Our July 28 report makes a number of actionable recommendations to these ends. The three most important are:

**Recommendation 1.** Accelerate implementation of Interoperability requirements for EHRs to allow data sharing with public health authorities, which could be done easily through ONC regulatory changes initiated in the 21st Century Cures Act.
**Recommendation 2.** Initiate and support effective shared governance between states and the CDC. The COVID-19 experience is a burning example that ought to motivate the key players to get this done.

**Recommendation 3.** Use some of the COVID-19 recovery funding to build up the digital expertise and infrastructure at CDC and at the state level. There is already $500 million in the CARES Act that could be used for this purpose.

**Summary of the Report on Testing**

Tests for active infection by SARS-CoV-2—to diagnose disease patients with symptoms or to identify asymptomatic people who are infected—are critical elements in efforts to monitor and control the Covid-19 pandemic. But the launch of such tests in this country was slow; they have not been used in optimal numbers, especially for identifying contagious asymptomatic people; and a well-funded national plan for testing and contact tracing has not been designed or executed.

To persist and spread, any virus must be transmitted from infected to uninfected people. Since that occurs almost exclusively in the case of SARS-CoV-2 through personal interactions, any outbreak could in theory be ended by completely separating everyone from everyone else for two weeks, the duration of most infections. This socially unacceptable solution can be effectively replaced by a more realistic strategy that depends on reliable tests to identify individuals who are infected and that keeps them quarantined when they are infectious.

Sensitive methods for detection of chemical components of virus particles (viral RNA or proteins) enable such an approach, and many tests for SARS-CoV-2—nearly all for detection of viral RNA with a polymerase chain reaction (PCR)-based method—have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA). Such tests have been fundamental to ascertaining a diagnosis of COVID-19 in symptomatic individuals, but they have not been optimally used to survey asymptomatic people to identify and isolate those who are contagious. Much of that deficiency can be attributed to a lack of personnel, funds, testing facilities, and public compliance—the result of poor federal leadership and governance, mismanagement of data, confused communication about testing, and inadequate budgets for tests and contact tracing.

To address the persistent inadequacies of testing in the US during the pandemic, our report recommends the following four actions by the federal government.

**Recommendation 1.** Enact legislation that would provide the funds included in the House-passed version of the HEROES bill ($60 billion for testing and $15 billion for contact tracing).

**Recommendation 2.** Establish a registry maintained by the Centers for Disease Control and Prevention (CDC) to communicate the rationales for and results of testing.

**Recommendation 3.** Conduct a Congressional review of the responsibilities, including testing-related actions, assigned to major federal agencies during public health emergencies.

**Recommendation 4.** Develop, in those agencies, public health tools (e.g., research platforms, point-of-care devices, improved informatics infrastructure) to strengthen national preparedness for future epidemics.
Summary of the Report for the Coming COVID-19 Commission

The U.S. mortality rate from the COVID-19 pandemic is one of the highest in the world. A non-partisan COVID-19 Commission is needed to examine why and how this disaster happened, and to recommend steps to ensure the United States acts more effectively in future pandemics. Here we offer recommendations for the topics the Commission should address.

The COVID-19 Commission will repeatedly encounter the undervaluing and underfunding, in the United States, of public health capabilities and practices. A prominent manifestation of this shortfall has been the chronic underfunding of the Centers for Disease Control and Prevention (CDC), as well as underfunding of state and city public health agencies. The Commission should address how to place public health agencies on a more appropriate and stable footing. Management of public health data should be a particular focus of the Commission’s attention.

In considering the causes of the current pandemic, the Commission will need to improve understanding of the origin of the novel coronavirus and its presumed entry into human populations from animal hosts. It will be important to know more about the roles played by other countries and international organizations at the early stages of the COVID-19 pandemic.

The Commission must evaluate the adequacy of pandemic planning in the United States prior to the COVID-19 outbreak. The failure to have adequate supplies in both the Strategic National Stockpile (SNS) and state stockpiles should be understood, with lessons drawn for future readiness.

The Commission will also need to evaluate the ways in which various components of the nation’s medical infrastructure—public health agencies, hospitals, public and private research institutions, and regulatory bodies—responded to the emergency once the virus began to spread in the United States. This focus will need to include the development, provision, and use of tests that detect SARS-CoV-2, including the failures of the CDC to facilitate testing early in the pandemic and to guide the use of available tests later in the pandemic. The Commission should also examine the nation’s capacity to provide the funds and trained personnel to perform sufficient contact tracing. Finally, the Commission should examine efforts to speed the development, testing, and production of a vaccine, with lessons drawn for both future outbreaks as well as vaccine production under non-crisis conditions.

The role and effects of the U.S. and state governments, news programs and websites, and social media in spreading information, misinformation, and conspiracy theories should be examined and illuminated. The Commission should produce a classified annex on the role of any foreign nations’ misinformation campaigns targeted at government leaders, news programs, or the public.

An especially high burden of disease has been recorded among certain demographic groups. The Commission should probe the reasons for these disparities and consider how to minimize them in the future.

New infectious agents with pandemic potential are certain to emerge into the human population in the coming decades. The COVID-19 Commission must help the nation do much better next time, and all the times after.
Summary of the Report on Epidemiological Modeling

Epidemiological modeling in the first months of the COVID-19 pandemic did not leave the public with a favorable impression. Some models predicted a near-future peak followed by a permanent decline, while others predicted a series of cycles continuing for years. Predictions of cases and deaths varied widely. The strengths and weaknesses of different models—and their dependence on input data—were poorly communicated. Consequently, it was not well understood that as an observational field of science allowing few, if any, controlled experiments, epidemiology must rely on mathematical models to assimilate, combine, and interpret necessarily circumstantial data.

Today’s epidemiological models span a range of complexity and employ a variety of algorithmic and statistical techniques. The most advanced require the use of supercomputers. All are improved by more and better data. A diversity of approaches is beneficial when there are institutional mechanisms for evaluating models, developing those that show the most promise, and transitioning them to readiness for operational use in a pandemic. Unfortunately, in the United States, these institutional mechanisms have been weak-to-nonexistent.

There is little coordination among the alphabet soup of agencies that provide partial resources for epidemiological modeling, and the trend has been towards decreasing support. The National Institutes of Health (NIH) was at one time a leader, but a combination of budget cuts and retiring staff have hollowed out its program. The National Science Foundation’s (NSF) program is of high quality, but not specifically directed towards human disease. Responding to COVID-19, the Centers for Disease Control and Prevention (CDC) has begun to curate and distribute the consensus predictions of models from multiple academic groups, a commendable but ad hoc effort; but CDC has not responded to the needs of the academic community, nor those of the private sector, for access to better and more timely data.

In short, epidemiological modeling is an important but under-supported field of science that lacks a clear home among the federal science-funding agencies. Additional basic research and translational work in the field are needed between pandemics, and greater operational capabilities are needed during epidemics. A close analogy is the federally supported “value chain” that leads from basic atmospheric research (led by NSF) to timely available weather predictions provided by the National Oceanic and Atmospheric Administration (NOAA). The economic value of an analogous value chain for epidemiological modeling and prediction would be large—over time in the trillions of dollars. The overriding need is a clear assignment of responsibility to appropriate federal agencies, along with appropriate budgets for those responsibilities.

Recommendation 1. Designate NSF as the lead research agency in epidemiological modeling. NSF has superior outreach into fields necessary for the success of this interdisciplinary field and operates supercomputer centers. Partnering by NSF with both NIH and the Department of Energy (DOE), two agencies with experience in operationalizing translational research is also necessary. NIH engagement can tether modeling to the biological realities of particular human diseases. DOE is a leader in the use of large-scale modeling in support of its missions and can mobilize the resources of its National Laboratories.
**Recommendation 2.** Designate the CDC as the lead *mission* agency, with primary responsibility for operationalizing research results, the analog of NOAA’s National Weather Service. Only CDC has the ability to gather data from state and local public health agencies and to distribute back to them actionable recommendations.

Additional recommendations are detailed in our September 28 report: consensus-building technical workshops under the auspices of the National Academies; university-based national research centers; the creation within CDC of a new Office of Epidemic Forecasting and Analytics; and a new subprogram in epidemiology within DOE’s existing Advanced Scientific Computing Research (ASCR) supercomputing program.
**Recommendations for the National Strategic Pandemic-Response Stockpile**

By an Ad Hoc Pandemic-Response Subgroup of Former Members of President Obama’s Council of Advisors on Science and Technology

May 20, 2020

**Background and Rationale**

In 2002, the federal government established the Strategic National Stockpile (SNS), a pharmaceutical and vaccine stockpile, jointly managed by the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS), to provide for public health emergencies. The SNS extended earlier stockpile programs for use in case of chemical, biological, radiological or nuclear attack.¹ In 2006, Congress funded the addition of protective equipment to the stockpile, adding 52 million surgical masks and 104 million N95 respirator masks.² That legislation assigned to the HHS Assistant Secretary for Preparedness and Response (ASPR), responsibility for coordination of the stockpile for the Secretary of HHS. During the spring 2009 H1N1 pandemic, much of the mask stockpile was depleted.³

In March 2013, Congress enacted the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013.⁴ Section 403 of the Act

“Reauthorizes the Strategic National Stockpile for FY2014-FY2018. Requires the Secretary of HHS to: (1) submit to the appropriate congressional committees, to the extent that the disclosure of such information does not compromise national security, the annual review of the contents of the Stockpile; and (2) review and revise the contents of the Stockpile to ensure that the potential depletion of countermeasures currently in the Stockpile is identified and appropriately addressed, including through necessary replenishment.”

On October 1, 2018, the full responsibility for the SNS was transferred from CDC to ASPR.⁵ The stockpile was not replenished, however. In March 2020, the Secretary of HHS reported that the stockpile held 30 million surgical masks and 12 million N95 masks.⁶

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⁴ Pub.L. 113–5, H.R. 307
During the period from 2006 until now, many studies have projected the needs, in the event of a pandemic, for surgical and high-intensity respirator masks, other personal protective equipment (PPE), durable equipment such as ventilators, and supplies used for testing, together with estimated quantities that should be stockpiled to help satisfy that need. In 2016, the National Academies of Science, Engineering, and Medicine (NASEM) held a workshop to study the SNS program and recommend improvements.

The result of the failure to act on the recommendations of these studies and to appropriate and carry out the funding and actions authorized in Public Law 113-5 (as well as the failure to renew the authorization beyond 2018) has been that the United States was unprepared for the supply needs of the Spring 2020 COVID-19 pandemic. The extraordinary shortage of supplies in Spring 2020 has been well-documented in the press and has been exacerbated by supply-chain changes such as just-in-time manufacturing and globalization, and by the lack of a coordinated Federal/State plan to deploy existing supplies rapidly to locations of greatest need. There has been a persistent shortage of ventilators, testing kits, masks and other PPE, mitigated only in part by funding appropriations in late March and in April.

The fault is not with the Federal Government alone. According to Greg Burel, Director of SNS from March 2007 to December 2019, SNS planning assumed that state stockpiles would also be in place, as they were in the past. For the most part, however, those stockpiles were not replenished and maintained after the 2008 financial crisis.

Sections 3101, 3102, and 3103 of Title III of the recently enacted Coronavirus Aid, Relief, and Economic Security (CARES) Act are relevant to the stockpile recommendations. Sec. 3101 provides funding ($1.5 million) to NASEM for a consensus study of America’s stockpile supply chain security. Sec. 3102 adds items to the SNS to be used for a bioterrorist attack or other public health emergency. Sec. 3103 concerns use of respiratory protective devices. Congress has appropriated $27 billion to the Public Health and Social Services Emergency Fund to remain available until September 30, 2024 to cover the items in the above sections. Of the $27 billion, not more than $16 billion is available for the SNS for critical medical supplies, PPE, and life-saving medicine; $3.5 billion is for the HHS Biomedical Advanced Research and Development Authority (BARDA). Funds, amount not specified, from the $27 billion may be used to develop

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8 Studies have also analyzed the needs for pharmaceuticals and vaccines, which are not summarized here.


and demonstrate innovations and enhancements to manufacturing platforms to support the SNS.\textsuperscript{12}

It is possible that the 2020 phase of the COVID-19 epidemic will decrease during the late spring, but it also may well be that there is a resurgence in the fall. Preparation for such a resurgence needs to be initiated now. It needs to be at a national level, in close collaboration and coordination with state and local officials. Even after this current phase tails off (if in fact it does so), focus on curtailing the disease needs to be maintained as the country pursues its financial recovery. Indeed, the second requires the first.

It is imperative that the SNS be rebuilt by September 1, 2020, and that state and local stockpiles be ramped up as well. As U.S. supply chains for relevant tests, masks, PPE, etc. increase, and begin to provide quantities needed, continued domestic manufacturing should be encouraged for stockpile replenishment. It will likely be necessary to continue to invoke the Defense Production Act.\textsuperscript{13} The acquisitions need not be limited to U.S. suppliers.

The SNS and other stockpiles are intended to serve not only pandemic response but the response to other emergencies as well. The hurricane and wildfire seasons are approaching. In addition to funding the stockpile, it may be necessary to replenish the FEMA $50 billion Emergency Fund. We have not explored that issue.

Even if the stockpile had been maintained at levels projected to be needed, the COVID-19 experience illustrates that the demands of a particular public health emergency (or the occurrence of multiple overlapping emergencies) may exhaust the stockpile before the needs have been satisfied. For robust preparedness, stockpile planning must incorporate “on the fly” provision of additional supplies.

Public and private groups in the United States, in concert with the international community, are devising a variety of creative solutions to the COVID-19 supply shortage. Among them are fast manufacturing techniques for ventilators and other equipment\textsuperscript{14}, reuse of supplies such as masks that are normally used once and discarded\textsuperscript{15}, rapid conversion of public and private spaces to emergency care facilities\textsuperscript{16}, methods for rapid test development, deployment, and analysis, etc. In addition,

\textsuperscript{12} On May 14, as this memorandum was being completed, the White House issued a fact sheet announcing and describing the Trump Administration’s “plan to restructure the Strategic National Stockpile” to “address the challenges and stockpile deficiencies uncovered during the initial coronavirus response.” White House Fact Sheet, May 14, 2020, https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-ensuring-strong-national-stockpile-industrial-base-needed-meet-challenge/

\textsuperscript{13} The Defense Production Act of 1950 was enacted in response to the Korean War. It has been reauthorized over 50 times and remains in force. It has been invoked multiple times to help with emergencies such as war, hurricanes, and terrorism prevention.


\textsuperscript{15} Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), April 17, 2020. https://www.sages.org/n-95-re-use-instructions/

some industries are re-purposing their manufacturing capabilities to make needed supplies. The successful innovations and manufacturing capabilities should be embedded in the stockpile mission – repositories should be supplemented by just-in-time augmentation and replenishment plans.

Recommendations

Until April 2, 2020, the ASPR described the mission of SNS as follows:

“Strategic National Stockpile is the nation’s largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that the right medicines and supplies get to those who need them most during an emergency. Organized for scalable response to a variety of public health threats, the repository contains enough supplies to respond to multiple large-scale emergencies simultaneously.”

We believe that version of the mission statement is the appropriate one. We offer the following recommendations to facilitate its being carried out.

Recommendation 1. To quick-start the building of the stockpile and, at the same time, launch a high-level process to structure it for the longer term:

a. In the next stimulus or supplemental appropriation legislation, Congress should appropriate $30 billion for COVID-19 stockpile replenishment and preparedness. At a minimum, these funds will provide for a major initial boost in the following critical supplies: testing kits, including reagents and swabs; surgical and N95 masks; personal protective equipment for health workers, service personnel, and the population at large; ventilators and other assistive breathing devices; and hospital beds.

b. Within 30 days of enactment, HHS (drawing on ASPR, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration), in consultation with DHS (utilizing FEMA), the Department of Defense, the Veterans Administration, governors, and mayors, and with the assistance of an independent and scientifically and technically knowledgeable, bipartisan advisory group, should submit a detailed plan to Congress as to what tests and equipment and quantities are to be stockpiled, a schedule for acquisition, criteria for allocation and distribution of items, and an allocation of the appropriated funds between the Federal stockpile sites and the state stockpiles.

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17 The administration changed the wording of the ASPR’s description of the SNS on this date. The current wording may be found at https://www.phe.gov/about/sns/Pages/default.aspx

18 This back-of-the-envelope number derives from assuming 10% of 300 million people in the population affected, at $1000 per person. The CARES appropriation of $16 billion for SNS would cover funding only for the replenishment of the stockpile for the current phase of COVID-19. The $30 billion would provide funds for critical supplies for the Federal government and states for the next waves of COVID-19 and future health emergencies.
c. In that same period, Commerce and DOD shall submit a plan to Congress identifying sources of repurposed rapid manufacturing to supply the necessary acquisitions.

d. Every month after the 30-day plan is submitted, the Secretary of HHS and the Secretary of DHS should provide to Congress, Agencies within the Administration, Governors, Mayors, County executives, the advisory board and the public, the status of the national emergency stockpile readiness. Those reports should continue until the annual reporting of Recommendation 3 has begun.

Recommendation 2. In order to strengthen the supply chain as the stockpile is being depleted, Congress should appropriate, in the next stimulus or supplemental appropriation legislation, $100 million dollars to HHS to fund CDC and FEMA to memorialize and evaluate the supply chain innovations and enhancements used in the COVID-19 pandemic; to update regulations and introduce approvals to facilitate their use; and to inform Congress and the public of changes that have been made.

Recommendation 3. In the next 6 months, as part of a National Strategy for Preparedness, Congress should authorize the replenishment and maintenance of the SNS for a period of 5 years. Congress should appropriate an additional $12.5 billion, to remain available until September 30, 2025, directing some of that funding for replenishment and maintenance of state stockpiles. In addition to funding for equipment and supplies, that legislation should include funding for
a. Stockpile maintenance to replace expired supplies and equipment (as in the 2013 Authorization)
b. Annual reporting (including a publicly releasable version) to the President, Congress, Governors, Mayors, and County executives on:
   i. the state of the stockpile (including quantities of key components, the distribution of expiration dates for those components, and numerical targets for each component and anticipated timescales to reach those targets);
   ii. the sustainable use of equipment and supplies, e.g. reuse of PPE such as masks; and
   iii. the capability to ramp up the supply chain quickly when needed.
c. An in-depth study by NASEM every 3 years to assess changes in the needs addressed by the stockpile and the means to address them, taking into account particularly advances in biomedicine, technology, and supply chain management.

Recommendation 4. Congress should direct the Federal Trade Commission (FTC) to provide special scrutiny for transactions that affect the provision of health and emergency care, including changes to healthcare providers, equipment providers, pharmaceuticals, and first responders.19

19 For example, the Newport Medical Instruments/Covidien merger inhibited the availability of portable ventilators.  
Conclusion

The Strategic National Stockpile has been a key component of U. S. preparedness since 2002. In recent years the Nation has let down its guard. It is imperative that the SNS, and in particular, the U.S. pandemic preparedness stockpile be rebuilt by September 2020, and then sustained into the future.

Note: On May 25 edits were made to the wording of Footnote 18 and Recommendations 1.a and 2 in the interest of clarity.
Update to the Stockpile Report (12-15-20)

Introduction

In May 2020, this group issued a report expressing concern about the inadequacies of the Strategic National Stockpile (SNS) and making recommendations to strengthen the SNS in both the short and longer terms. That report recommended that both federal and state stockpiles be replenished by September 1, 2020, in anticipation of a possible fall surge in cases. Nine months since declaring the COVID-19 a national emergency, the federal government still has not resolved the problems of availability and distribution of sufficient Personal Protective Equipment (PPE) and other medical equipment and devices.

The General Accounting Office (GAO) documented this state of affairs as of mid-September, 2020, in its CARES-Act-mandated report.¹ States and other non-federal entities reported having trouble tracking supply requests made to the federal government and, thus, difficulty planning for future needs. The most recent CARES-Act-mandated report was issued on November 30.² That report asserts that although shortages of swabs and transport media for testing and some PPE largely had been alleviated, shortages of other testing supplies and PPE remain. The Department of Health and Human Services (HHS) has not implemented GAO’s September recommendations. The number of new cases continues to increase rapidly, the flu season is upon us, and colder weather has driven people indoors, resulting in still greater demands on hospitals and healthcare organizations. Although progress has been made, the inadequate availability of some PPE and medical supplies is urgently in need of solution.

The CARES Act provided $16 billion to the SNS for critical supplies. As of October 31, 2020 (the last date for which we have information), HHS reported it had obligated $8.7 billion of the $10.7 billion it had planned to use for SNS and had expended $4.1B.³ We have been unable to determine how long the remaining funds will last.

The September GAO report summarizes the quantities of equipment and PPE that have been provided by Federal agencies as of September 1, 2020, but not the quantities that are needed. Eight unidentified states were sampled by the GAO. Four reported that they had at least a 30-day supply of most PPE; one reported that it was still short of several items of PPE; and the other three reported that they were still in the planning stages.⁴ N95 respirators and nitrile gloves are in particularly short supply.

³ Ibid., pg. 77
Subsequently the office of the HHS Assistant Secretary for Preparedness and Response (ASPR) established 90-day supply inventory targets for 3 categories of critical supplies – PPE, pharmaceuticals, and testing supplies. ASPR officials report that they expect contracts awarded by ASPR and DOD as of October 2020 to meet the 90-day targets for listed PPE other than gloves, but gloves remain problematic. Although current requests for swabs and transport media were being met as of October 2020, there were shortages of pipette tips. The SNS has been unable to accumulate inventories of these materials because of current demand for them.

The situation for nursing homes is considerably more fraught. The U.S. Public Interest Research Group (PIRG) reported that “The problem of PPE shortages spanned the entire three-month period we analyzed. Amazingly, 20 percent of nursing homes reported they were completely out of one or more types of PPE at some point from late May through late August. In addition, 46 percent of all nursing homes nationwide reported they didn’t have a one-week supply of at least one type of PPE at some point from May through August. A one-week supply is considered the minimum acceptable.”

The PIRG analysis predated the surge in cases commencing in October 2020. The September and November GAO reports include some self-reported nursing home data that suggest that although some shortages have been alleviated, shortages of PPE remain a problem, particularly in light of PPE used for increased testing requirements for nursing homes.

The recommendations made in the May 20 OPCASt report are even more relevant and urgent now. Since that report appeared, other concerns have come to light, including leadership and management, the use of the Defense Production Act (DPA), the role of Food and Drug Administration (FDA), and the coordinated use of existing PPE and medical supplies and devices. These topics are covered in this update.

**Leadership and Management**

Although the federal government has taken some steps to improve availability of PPE and medical supplies, there are still supply-chain inefficiencies and shortages of materials, and many healthcare providers continue to be without federal assistance. Even as supply constraints continue, no plan has been developed by HHS and FEMA outlining specific actions the federal government will take, including the use of DPA authorities, to mitigate gaps in the medical supplies needed to respond to the pandemic. A fragmented approach by federal and state governments and the private sector to securing supplies persists, leading to increases in prices as multiple sources compete for the same products and bid against one another. Federal reimbursement rates are uncertain.

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4 September GAO report, pg. 139
6 November GAO report, pg. 72
7 PIRG report, pg. 15
The White House Coronavirus Task Force led by the Vice-President has failed to address these issues. With respect to fragmentation, responsibility for the SNS was transferred to ASPR, and the September GAO report states that plans are underway to consolidate medical supply management within HHS, largely within ASPR.\(^9\) ASPR does not have the necessary authorities it needs for this purpose, however, as its main function is coordination of health preparedness and response across government. Subsequent to publication of our May report, it was revealed that Senior Advisor to the President Jared Kushner had created, in March, a “shadow volunteer task force” comprised of a dozen individuals, all in their twenties and from the finance sector, with no expertise in government procurement or medical equipment.\(^10\) They were reportedly tasked to procure supplies from Trump allies, not from the most experienced and cost-effective vendors. The task force failed to procure sufficient equipment, forcing medical workers to improvise.

The problems arising from the lack of a national plan to mitigate medical-supply gaps in a timely way and to replenish the stockpiles are even more severe now. In the absence of a national plan, some states have attempted to fill the void. For example, Governor Cuomo of New York announced on May 3 the formation of a consortium of seven northeast states to create a regional PPE supply chain.\(^11\) This effort seems to have progressed only slowly, however.\(^12\) At the end of September 2020, Governor Newsom of California signed two stockpile-related bills, one requiring that acute-care hospitals must maintain a 90-day supply of PPE beginning April 1, 2021\(^13\); and the other requiring that, by January 1, 2023, all hospitals, skilled nursing facilities, dialysis clinics, and medical practices that are part of an integrated health system must maintain a 45-day stockpile of PPE and provide an inventory of their holdings to the California Division of Occupational Safety and Health.\(^14\)

While state and regional efforts are an understandable effort to mitigate the lack of federal action, they run the risk of (1) further limiting the national availability of PPE and supplies for immediate use, because some of those supplies are stockpiled; (2) increasing costs to individual care facilities; and (3) putting states and regions in competition with one another for these PPE and other supplies. Far better would be to have a well-stocked, physically distributed national stockpile and a robust supply chain that could quickly satisfy regional surges in demand.

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\(^9\) September Gao report, pg. 19  
\(^13\) CA AB 2537, [https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB2537](https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB2537)  
\(^14\) CA SB 275, [https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB275](https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB275)
Defense Production Act (DPA) and supply chain

Our May report stated that invoking the DPA would be needed to rebuild the stockpile and supply chains. A July 2020 report from the Congressional Research Service analyzes the use of the DPA for Covid-19 purposes.¹⁵ The report notes that of the $1 billion allocated under the CARES Act for DPA purchases of medical equipment and PPE, $688 million was spent by DOD on semiconductors, shipbuilding, space surveillance, engine parts, and other such uses. The report concludes that “The Administration’s DPA implementation pattern appears sporadic and relatively narrow. Although the volume of DPA actions has increased, no new DPA Title I prioritization orders for health articles have been observed since April 14. Most direct Title III funding has been awarded to the defense industrial base.” It goes on to say “In a media interview, White House trade advisor Peter Navarro reiterat ed past assertions that the Administration wielded DPA authorities to compel voluntary action without the need to actually implement them.”

Even when awards have been made, concerns have been raised about implementation. In April, Mr. Navarro negotiated with the medical device maker Royal Phillips a $647 million contract to make thousands of ventilators under an accelerated schedule. Navarro agreed to pay Philips five times as much per ventilator as the Obama administration had paid.¹⁷ In September, the company announced that the remainder of the contract had been cancelled and Philips would deliver only 12,300 of the 43,000 machines that had been ordered. In September, DOD awarded more than $1 billion in federal contracts to companies for disposable gowns. The majority of the awards went to inexperienced companies, even though many credible, experienced companies submitted bids.¹⁸ For example, a $323 million contract went to JLKaya, whose only prior federal contracting work was a $7,296 project to make gauze. The November GAO report says “ASPR officials told us that a contract awarded by DOD for nitrile gloves was not fulfilled because the subcontractor sold them to another entity, but that DOD was continuing to work with the contractor to fill the order.”¹⁹

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¹⁶ Peter Navarro, the White House Trade advisor, with no experience in government contracts or DPA, was appointed the policy coordinator for the DPA in March 2020.
¹⁹ November GAO report, pg. 78
FDA Quality Control of PPE

Section 3121 of the CARES Act requires manufacturers of certain devices to notify the FDA of a permanent discontinuance in the manufacture of the device or interruption in the manufacture of the device that may lead to a disruption in supply of that device during a declared public health emergency. The FDA is required to provide a publicly available current list of devices that are in shortage or unavailable. A list of 20 items, including surgical gowns, masks, respirators, and testing equipment, was published August 14, 2020; a cardiac monitor was added Sept. 24, 2020. For most of the items the estimated shortage time is the duration of COVID-19 pandemic. The list has no quantitative information and no indication of what efforts are being made to remedy the shortages.

The FDA has issued Emergency Use Authorizations (EUAs) to certain manufacturers for some PPE products, including face shields, surgical masks, and respiratory protective devices such as N95 masks and other respirators. The FDA has authorized use of some respirators not certified by the CDC’s National Institute for Occupational Safety and Health (NIOSH) but certified by the originating country. Starting in October 2020, however, no new respirator models originating in China are being added to the list, because of quality concerns. The Federal Emergency Management Agency (FEMA) began supplying PPE to some nursing care facilities in June, but quality concerns have arisen with those supplies as well.

PPE, particularly masks, are being worn by millions of Americans and will be essential to safe social and commercial interactions for many more months. There are currently no uniform standards or labels to enable consumers and healthcare workers to determine how well the product will protect them and the people with whom they come in contact. A recent CDC article suggests that healthcare workers should use surgical masks or N95 respirators, not cloth masks, but that cloth masks are acceptable for the public. There have been many disagreements as to how much protection can and should be promised. ASTM International, which develops standards on a wide range of products ranging from amusement rides to drones, is working with a group of scientists, industrial hygienists, government officials, and manufacturers, to develop a voluntary standard that manufacturers can adopt and advertise on their products. In addition, the International Safety

24 Effectiveness of Cloth Masks for Protection Against Severe Acute Respiratory Syndrome Coronavirus 2, Abrar A. Chughtai, Holly Seale, and C. Raina Macintyre, EID Journal 26, 10, October 2020, https://wwwnc.cdc.gov/eid/article/26/10/20-0948_article
Equipment Association (ISEA), which makes standards for protective equipment such as hard hats for construction, is attempting to develop its own standard. Multiple standards would be confusing to manufacturers and consumers. Standards for a mask for the general public are in a gray area.

The National Institute for Occupational Safety and Health (NIOSH) certifies respirators used in occupational settings, while the FDA regulates masks intended for medical purposes. The National Institute of Standards and Technology (NIST) is usually the lead government agency for developing test procedures and working with standard-setting groups.

**Sharing the existing supply of PPE**

Ideally, in a time of national emergency, the SNS, state public stockpiles, and privately held supplies would be pooled and provided to the institutions having the greatest need. Some city hospitals did this with ventilators in the early days of the pandemic. Even with the best of intentions, however, such voluntary pooling is difficult. Institutions are reluctant to give up their own supplies when there is no assurance that the government has strengthened the supply chain enough to ensure that supplies will be available when they need them. Conversely, knowing that orders would be fulfilled in a timely fashion might both reduce hoarding and encourage sharing.

Perhaps more importantly, there is no inventory of supplies that are held outside of the stockpile, and there are challenges to creating such inventories. There is no standardized nomenclature for describing most PPE items. For example, the same surgical gown can have over 130 unique descriptions and item numbers. The infrastructure that would make reporting practical does not exist. It would be worthwhile for a non-government group such as the National Academies of Science, Engineering, and Medicine (NASEM) to study the feasibility, from both technology and policy perspectives, of putting such a system in place.

The nation is facing a surge of more than 200,000 new COVID-19 cases per day, and, once again, shortages are being reported episodically by different communities and facilities. If the federal government is to assume its appropriate role in assuring supplies to those in greatest need, it is imperative that the federal government, states, public health groups, and health systems know where supplies are and how they can best be allocated to areas of greatest need. A universal UPC bar code identifies everything from groceries to household goods to sporting equipment, but no such systematic data identification is in place for PPE or essential devices, and no robust method to determine availability exists.

**Recommendations**

The earlier stockpile recommendations of this OPCODE subgroup are still relevant and should be implemented. The following are additional recommendations to ensure that the stockpile and supply chain will function during the current pandemic, future pandemics, and natural disasters such as hurricanes and wild fires.

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25 Conversation with staff members of Premier, Inc. October 8, 2020
Recommendation 1. The White House should appoint a senior COVID-19 stockpile and supply-chain coordinator, whose office would coordinate with the relevant agencies the logistics of manufacturing and distributing PPE, medical equipment, therapeutics, vaccines, and test kits, both for the national stockpile and for the states. Under delegation of authority from the President, the coordinator’s responsibilities would include overseeing aggressive and appropriate use of the Defense Production Act for as long as the pandemic emergency exists. The Coordinator should also work with the Secretary of HHS on SNS planning, as described in Recommendation 1b of our earlier report. Until the coordination office is up and running, no further changes to agency organizational responsibilities for supply acquisition, distribution, and stockpiling should be made.

Recommendation 2. The White House stockpile and supply-chain coordinator, in consultation with the Secretary of HHS and the heads of other agencies responsible for supplying PPE and medical supplies and devices, should report at least quarterly to Congress, state governors, and the public the status of the activities being undertaken with regard to stockpiles and supply chains. Reports should include accomplishments, expenditures, and planning.

Recommendation 3. All proposals to divert funds allocated for SNS and state stockpiles and COVID-related supplies, whether with regard to the Defense Production Act or other appropriations, should be submitted to the White House stockpile and supply-chain coordinator and require his or her approval.

Recommendation 4. FDA and NIST should work quickly with standard-setting groups including ASTM International and ISEA to develop and promulgate standards and labels for N95 respirators, surgical masks, and other protective equipment such as face shields, gowns and gloves. The government should encourage these two named groups to work together for a consistent standard. FDA and NIST should determine which additional medical devices and supplies should have labels and standards and provide funds to develop those standard labels.

Recommendation 5. The Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats of NASEM should conduct a rapid-response study on the requirements and feasibility of creating and maintaining a continuously-updated national inventory of PPE and medical supplies for treating COVID-19, be they in the SNS and state stockpiles, in stockpiles held by healthcare providers, or available for purchase from vendors. To the extent possible, the inventory database should also estimate demand, delays, and other inhibitors to satisfying need.
The Role of Contact Tracing in the Control of Microbial Epidemics, Including COVID-19

By an Ad Hoc Pandemic-Response Subgroup of Former Members of President Obama’s Council of Advisors on Science and Technology

June 18, 2020

Rationale

The United States has fared relatively poorly during the current COVID-19 pandemic, in part because, unlike some others, this country failed to institute rapid and far-reaching methods to identify infected persons and their contacts and then quarantine them in early stages of the pandemic. In this report, we describe ways in which testing, contact-tracing, and isolation methods might be improved to reduce morbidity and mortality rates in later phases of the COVID-19 pandemic and in future epidemics.

Background

SARS-CoV-2 is a novel coronavirus that causes coronavirus disease 2019 (COVID-19). Like other coronaviruses, SARS-CoV-2 is primarily transmitted directly from one infected human being to another, when viral particles from the infected person enter the body of the other person, most commonly through the respiratory tract.

The only definitive way to know whether people are infected by SARS-CoV-2 is to test them for the presence of virus particles, most commonly done using sensitive molecular tests for viral RNA. Once an infected person is identified, it is important to determine the source of that infection and to identify the other people to whom the source and the newly identified infected person might have transmitted the virus (i.e., their contacts). By sequencing the viral genomes of the source and the infected person, much can be learned about the rate of virus evolution by following sequential changes (usually nucleotide substitutions) in the genome in relation to established contacts; and by identifying the contacts of an infected person, the spread of the virus can be reduced.

To identify people who have been exposed to an infected person, it is necessary to construct the set of individuals with whom any infected person has recently interacted, a process called contact-tracing. When any person on the list of contacts is found to test positive for viral RNA, that person’s contacts should be identified and tested in turn. Contact tracing has a proven track record in enabling government health officials to contain and shut down the spread of infectious disease. For example, it played a key role in containing the 2003 SARS-CoV-1 coronavirus outbreak. 

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1 A commonly used virology diagnostic test is RT-PCR (reverse transcription-polymerase chain reaction). This topic is elaborated in our forthcoming report on testing and immune response.

What makes the use of diagnostic testing and contact tracing difficult?

There are many challenges, both scientific and logistic, in using contact-tracing to combat COVID-19 and other infectious diseases. In a fast-moving epidemic, an important purpose of identifying newly infected individuals quickly is to keep them from infecting other people. Other purposes are to monitor the individual and to treat symptoms such as respiratory distress, which may be life-threatening; to reduce the severity of that person’s infection, if methods exist to do that; and to develop an understanding of the collective (population-level) properties of the virus. The newly infected individuals are identified by testing for the presence of the causative agent – in this instance, SARS-CoV-2. Isolating (and, if needed, treating) a person who tests positive is then appropriate.

It is desirable to identify and test contacts immediately, before second-order exposures occur. The task is complicated, however, because:

- **It is difficult to identify the set of possibly infected contacts quickly.** As discussed subsequently, contact tracing can be done either by human interviewers, by use of digital tools such as smartphones, or by some combination of the two. A person who is interviewed may either deliberately or inadvertently fail to disclose some contacts. Some people may refuse to be interviewed. In addition, interviews take time and human labor, which will slow the process. A smartphone (a proxy for a person) can detect proximate smartphones, but not proximate people who are not carrying phones.

- **Some personal interactions are more likely than others to transmit virus.** In general, many viral particles are required to initiate an infection. The number of particles transmitted from an infected person to a contact is affected by how long the people are in contact, how close they are to one another, and how forceful is the emission of particles from the infected person. If low-duration, large-distance contacts can be identified, they can be given lower priority for testing, freeing up resources.

- **It is difficult to use diagnostic tests to identify quickly the subset of contacts who are infected.** Even if a sample for testing is moved quickly to a test site or if the test is performed where the sample is taken, the testing process inherently takes time. More time will be lost if there are delays in transporting a sample to a laboratory or in reporting the results. If the person is tested too soon after exposure to an infected person, moreover, the test may be negative because the virus has not yet completed enough rounds of replication to produce amounts of virus detectable in the tested sample. In other words, detection of the agent in a newly infected person will be influenced by virus latency (the time required for a virus to enter a cell and produce progeny particles), by the number of rounds of virus replication (in which viruses from initially infected cells infect other cells and increase virus titers exponentially) to produce enough virus particles for a positive test, and by the sensitivity of the test (which is measured by the number of virus particles required to produce a positive result). Test sensitivity may be affected by the number of rounds of virus replication – viruses from the first infected cell then infecting other cells and increasing virus titers.

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exponentially – required to produce enough virus particles to produce a positive test. Inadequate numbers of particles in the upper respiratory tract to allow detection or inadequate swabbing of the mucosa are the likely explanations for the relatively high false negative results (up to 30%) and for the recommendation that at least two tests are needed to make a negative test reasonably reliable. (False positive test results are rare and generally attributed to lab contamination or faulty procedures of other kinds.)
• The appearance of symptoms is not an adequate substitute for a test that unambiguously identifies a person who can transmit the infectious agent. There is generally a 2- to 6- day period between exposure to SARS-CoV-2 and the appearance of symptoms. During that time, a pre-symptomatic person may be shedding virus and infecting others. Diagnostic tests for virus are generally positive during that time and will identify an infected contact much sooner than the appearance of symptoms. In addition, some symptoms that suggest COVID-19 instead may be caused by other diseases.

What if there isn’t enough diagnostic testing and contact tracing?

Diagnostic tests are important not only for use in contact tracing, but also for protecting vulnerable populations – people in high-contact living or working environments such as health facilities, manufacturing facilities, dormitories, prisons, densely-populated cities, and so forth; and people whose age or health condition heighten the risk that infection would be severe and life-threatening. Yet SARS-CoV-2 tests have been a seriously limited resource in the U.S. (and in some other countries), because of the failure to develop new tests or to provide reliable test kits for existing tests based on RT-PCR at the onset of the SARS-CoV-2 pandemic and to ramp up production and distribution of testing capabilities rapidly.

In practice, even when tests are widely available, priorities must be set for testing. In the current pandemic, in which tests have been in short supply or inadequately distributed or inadequately funded, priority has been given to individuals who have symptoms characteristic of COVID-19 that may require hospitalization or to people who are known to have had extensive exposure through home or work to a person known to be infected with SARS-CoV-2. When tests are unavailable, contact tracing is based on the presence of symptoms as a proxy for a positive result of a test for the virus. Contacts can be quarantined and watched, but inhibiting their exposure to others may come too late.

3 Symptoms may appear later in some infected individuals, or not at all in asymptomatic infected people. For that reason, possibly infected people are usually quarantined for 14 days.
Knowledge of the actual or likely exposure to the virus is retrospective; it is only after an individual tests positive or has symptoms that the contacts are known to have been exposed. By then they may already be infected. If testing and contact tracing have not been done effectively at the start of an outbreak, when the number of cases is very small, the number of people who have been in contact with infected individuals becomes very large, and contagion cannot be controlled. That large collective risk is often addressed by quarantining all contacts, whether or not they have tested positive or exhibited symptoms. In the extreme, that leads to the recent lockdown policies, in which everyone is, in effect, quarantined and businesses are closed. If tests are available, widespread testing of asymptomatic socially active people can reduce the burden on contact tracing. Social distancing and the wearing of protective masks are seen by some as a less onerous compensation than quarantine for a lack of testing and contact tracing. By reducing contact proximity and particle transmission, the likelihood of contagion is reduced.

Lockdown and social distancing have negative as well as positive consequences. Those protective policies to fight COVID-19 have led to economic downturn, job loss, educational disruption, social isolation, food insecurity, and societal discontent. Once transmission rates have decreased sufficiently, rapid testing and contact tracing become important tools to relax lockdowns in favor of selective isolation and quarantine.

**How is contact tracing done?**

Contact tracing to control virus contagion has a long history. It is normally carried out by interviewing individuals. That strategy has helped in managing other viral epidemics such as HIV/AIDS, H1N1-influenza, and Ebola. The strategies need to be adapted to the characteristics of the relevant viruses, however, especially to the modes of transmission. Among the advantages of human contact tracing are the ability to reach disadvantaged people and the benefit that social interaction has in helping them deal with the threat or actuality of disease. Among the disadvantages are flawed human memory for identifying the contacts, unwillingness to reveal some contacts, or unwillingness to be interviewed, and the labor-intensive nature of human tracing, which leads to delay. If the virus can spread rapidly, or if contact tracing starts late, the availability of enough human interviewers is a barrier. There is also a potential loss of privacy, since contacts are identified and the information is centrally stored.

During the COVID-19 pandemic, many groups have proposed to use digital information to approximate or supplement human contact-tracing. Digital data that indicate where an individual was at a given time include GPS data from mobile phones, credit card usage, public cameras, and public-transit records. A pool of possible contacts can be determined by identifying people who were in the same place at the same time. This approximation is imprecise – in general, the data might not record the distance between interacting individuals or the duration of the interaction. Consequently, care must be taken in how the data are used.

Another way to obtain contact data is to use BLE (Bluetooth Low Energy) to allow a smart device to record other smart devices (call them “smartphones” for convenience) that are close to it at a particular time. As with the use of GPS, it is phones that are being tracked, not people. Although in the developed world each phone is normally carried by a unique individual, phones are often shared in the developing world, complicating interpretation of the data. Unlike GPS
data, which are obtained from cell towers, BLE contact data are stored on each phone, typically in encrypted form, and shared more widely only if they are uploaded to some central service. The data can include the duration of the contact. The uploaded data might, but need not, contain the location of each contact. By its nature, the interaction recorded by the smartphones implies propinquity of the two individuals, but the opportunity for transmission of viruses may have been modulated by virus barriers such as face masks.

Digitally enabled contact tracing together with extensive testing appears to have been used successfully early on to contain COVID-19 in South Korea and, until recently, in Singapore. It is reported that South Korea used low-privacy contact tracing with GPS, security-camera footage, and credit card records. Their Corona app notifies individuals if they come within 100m of an infected person.6 Singapore deployed an opt-in BLE app (TraceTogether) to track proximity7. Users are notified immediately or retrospectively if they were near an infected person. The Israeli Health Ministry has used the HaMagen opt-in app to track proximity, using GPS data maintained by the government security agency8.

Many additional apps are being developed9. Most of them are intended for peer-to-peer notification of possible exposure, and most of them are opt-in. Depending on the app, users can report either COVID-19-like symptoms or the presence of infection determined by a diagnostic test and can upload their proximity data to a shared repository or database (whether or not they have symptoms). The users are identified by unique IDs (sometimes called pseudonyms) – users need not reveal their identities. To protect privacy, the IDs are changed frequently – over time a given user will have multiple IDs, making it difficult to track the user. Users of the app can be notified immediately if they have been exposed to the virus with high likelihood (because of a contact individual who is symptomatic or infected but asymptomatic) and should self-quarantine or take other measures. That notification can direct the person to testing, to a human interviewer, or to some other resource.

There is strong evidence that, from a technical perspective, high-quality apps can be built. The apps need to have two parts. First, there must be a system-level capability to discover and record the phone-to-phone proximity information – a process that depends on how BLE peer-to-peer communication works on a particular phone with a particular operating system. Then there must be user-level capabilities that access those data and use them to notify users about relevant contacts, when they occurred, and for how long. On April 10, 2020 Apple and Google announced a collaborative effort to create needed the system-level capability for each of their

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6 Canada Covid-19 Response: Deep-dive on testing and tracking, Boston Consulting Group, March 30-2020
7 An opt-in app is one in which the user must take an action to activate the app.
9 The github summary document Unified research on privacy-preserving contact tracing and exposure notification for COVID-19, which is updated regularly, listed 64 projects in early April. On June 9, 81 app. developer projects are listed.
operating systems and to provide a common API (application program interface) that user-level apps can use to access the contact data\(^\text{10}\).

**Why digitally enabled tracing is needed**

A research team from the University of Oxford recently developed a model of infectiousness and transmission using existing data from China and Singapore on SARS-CoV-2 and its spread\(^\text{11}\). The authors determined that between a third and half of all transmissions come from infected people in a pre-symptomatic phase, before symptoms of COVID-19 appear, probably because the individuals remain active and are unaware of their infection\(^\text{12}\). To control further spread of the disease, time is of the essence. The longer an infected person is in contact with others, the more people that person can infect.

The model presented in the paper uses two key parameters – the proportion of cases (symptomatic people) who are isolated or otherwise prevented from infecting others and the proportion of contacts that are identified and quarantined – and considers the elapsed time between case identification and contact determination\(^\text{13}\). The authors show that even if all cases are isolated and all contacts are found and quarantined, whether symptomatic or not, human contact tracing alone is not fast enough to control the spread of SARS-CoV-2\(^\text{14}\) (although it was for some other pandemics in which pre-symptomatic people did not shed virus particles). With a smartphone app, however, contact identification and notification is almost instantaneous. In that case, if enough symptomatic individuals are identified and isolated and enough of their contacts are quarantined quickly, the epidemic could be controlled. The authors observe that their model does not incorporate indirect tracing (tracing the contacts of all exposed contacts even before it was known whether they were infected), which might make the technique even more effective, since contacts of contacts would be expected to quarantine even before they were symptomatic or had been tested.

The extent of isolation and quarantine needed to control an infectious disease depends, in part, on the efficiency of transmission of the virus – how many individuals, on average, one infected person infects if nobody has immunity. As part of a long discussion of testing and contact tracing that builds on the work of the Oxford team\(^\text{15}\), Tomas Pueyo argues that in order to use testing and

\(^{10}\) A high-level infographic is at \url{https://blog.google/documents/57/Overview_of_COVID-19_Contact_Tracing_Using_BLE.pdf}. Preliminary technical specifications have also been posted \url{https://www.apple.com/covid19/contacttracing/}.

\(^{11}\) L. Ferretti et al., *Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing*, *Science* 10.1126/science.abb6936 (2020). \url{https://science.sciencemag.org/content/368/6491/eabb6936}

\(^{12}\) That result is confirmed by another recent study: M. M. Arons, K. M. Hatfield, et. al, *Presymptomatic SARS-CoV-2 Infections and Transmission in a Skilled Nursing Facility*, New England Journal of Medicine, April 24, 2020, \url{https://doi.org/10.1056/NEJMoa2008457};

\(^{13}\) The model uses the appearance of symptoms rather than the result of a diagnostic test.

\(^{14}\) Finding and quarantining the contacts is assumed to take 3 days on average. Even if it takes 2 days, the success rates for identifying and isolating cases, and for identifying and quarantining their contacts would each have to be well above 80%.

\(^{15}\) Tomas Pueyo, *Coronavirus: How to Do Testing and Contact Tracing Part 3 of Coronavirus: Learning How to Dance*, medium.com, April 28, 2020, \url{https://medium.com/@tomaspueyo/coronavirus-how-to-do-testing-and-
tracing, together with isolation and quarantine, in place of lockdowns, 70-90% of a symptomatic individual’s contacts must be traced (depending on the degree of contagion) and then tested or quarantined. His analysis shows that for COVID-19, that level of tracing cannot be achieved without digital contact tracing. Moreover, for digital contact tracing to achieve those percentages:

- the system-level, proximity-gathering app must be installed and enabled on virtually all smartphones – which can be done via the operating system;
- the app that accesses and can upload those data must be installed and enabled on the phone by default. Studies show that if the user must opt-out, i.e. the app is active unless the user disables it, the app almost always remains enabled, whereas if the user must opt-in, inertia will lower use of an app substantially; and
- if the user is infected, the contact data are uploaded to human investigators.

**Will a digital-tracing implementation provide enough tracing?**

Will there be sufficient adoption of digital contact-tracing apps to stem transmission in the absence of lockdowns? The evidence thus far is inconclusive. According to the Pew Research Center, as of February 2019, 96% of Americans owned a cellphone, and 86% owned smartphones, so cellphone availability is not a barrier to adoption. It is widely asserted, however, that digital contact tracing will carry risks to privacy. But that need not be the case.

The threat to privacy comes not from the pseudonymic contact data stored on one’s own phone, but from what happens to the data after the contacts are uploaded to a shared database. To mitigate the privacy threat, user-level apps need to be developed that have the following properties:

- Contact data that are uploaded and stored contain neither location data nor non-pseudonymic identifying information.
- Contact data are used only for the intended purpose – namely, to notify users about contact with a symptomatic or infected person, and to tell them what to do about it.
- Uploaded contact data are deleted when contact risk has subsided – after 30 days at most.
- Uploaded contact data are held by a trusted source – a public-health organization rather than a commercial entity.
- Contact-tracing software installed on a phone is automatically removed when the need for it has passed.

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18 *Big Data and Privacy: A Technological Perspective*, Report to the President, President’s Council of Advisors on Science and Technology, May 2014, [https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf](https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf)

19 Location information is available from GPS records, but might not be easily linked to contacts. Some people regard tracking where they have been as a breach of personal privacy.
Apart from de-identified data, those same properties (encryption, restricted use, data deletion, and trusted database ownership and access) are all necessary for privacy protection in human contact tracing.

On April 23, Apple/Google renamed the service they plan to provide from “contact-tracing” to “exposure notification”, signaling that they did not intend to provide the user-level apps. The companies posted a Frequently Asked Questions (FAQ) explanation of the technology they will provide. According to the document, their system will have the following properties:

- The system uses unique IDs; they are changed every 10-20 minutes.
- The system does not collect location data and does not share identities with other users, Apple, or Google
- “Access to the technology is granted only to public-health authorities. Their apps must meet specific criteria around privacy, security, and data control.”
- “Google and Apple will disable the exposure notification system on a regional basis when it is no longer needed.”

The way notification will work is that the user can choose to report a positive diagnosis of COVID-19 to their public-health app, in effect, uploading “their most recent” pseudonyms to the positive diagnosis database maintained by the public-health authority. Those pseudonyms will be downloaded to all phones running the public-health app and compared with the contact IDs stored on the phone. If there’s a match, “the system will share the day the contact occurred, how long it lasted, and the Bluetooth signal strength of that contact.” The signal strength is a measure of distance.

Unfortunately, the Exposure Notification addendum to the Apple Developer Program License Agreement greatly weakens the usefulness of the system-level app. Section 3.4 states “You agree that neither You nor your Contact Tracing App will derive, collect, use, or store any Rolling Proximity Identifiers.” In other words, the user-level app cannot upload contact pseudonyms to a public-health authority; it can only send messages to the contacts themselves. The policy satisfies the five privacy requirements given above not by requiring protection of uploaded data, but by prohibiting the collection of data altogether. Public-health authorities must rely on contacts to reach out to the authorities, rather than the authorities being able to reach out to contacts, as they do in human contact tracing.

Furthermore, the Apple/Google rules do not satisfy the criteria for contact tracing described by Tomas Pueyo. Apple/Google rules require that the user opt-in to the system-level contact collection running on their phone. We see no reason why that enhances privacy. Also the user must explicitly download the public health app. If no data can be uploaded to public health authorities without user consent at the time of upload, we see no reason why the phone cannot be

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“ready to go” by having the app already installed. We have not been able to determine whether the Apple/Google public-health app can send messages to contacts (for example, reminding them to call, inviting them to be tested, or asking them to self-quarantine). If enough contacts would identify themselves to public-health officials in response to requests from the infected individuals, then the fact that the app does not identify contacts would not inhibit effective contact tracing.

**Will contact tracing reach enough contacts?**

Pueyo’s analysis and recent reports from Johns Hopkins University and Harvard’s Safra Center make clear that public-health authorities need to combine digital contact tracing with human contact tracing, to provide a more robust way to identify, test, and/or quarantine individuals likely already to be infected or become so. Individuals identified digitally should have the same opportunities for testing, guidance, and treatment as those identified by human tracing.

Human contact tracing and digital contact tracing have complementary strengths and weaknesses. Both methods provide incomplete contact information: human interviewees may have faulty recollection of their contacts and may deliberately hide information they regard as confidential; digital methods depend on users carrying mobile phones equipped with proximity tracing and apps. Human interviews necessarily reveal identity; digital tools may conceal it. Both methods carry privacy risks, with or without privacy-protecting policies. Human methods are labor-intensive and may not scale to large numbers of new cases per day. Digital methods can identify contacts who are strangers, such as proximate protesters in the demonstrations following the death of George Floyd. But digital methods will not reach individuals who do not use smartphones.

Several states and large cities have initiated contact-tracing programs, largely to relax lockdown rules. In early April 2020 the state of Massachusetts launched the Massachusetts COVID-19 Community Tracing Collaborative (CTC), a collaboration between three state groups and Partners in Health, a nonprofit health organization with a strong track-record in human contact tracing. They will hire nearly 1000 contact tracers, drawing from a pool made possible by the large biomedical workforce in Massachusetts and the availability of people sidelined by social distancing requirements.

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22 Apple installs many apps on your phone automatically as opt-out, even some regarded as intrusive by many users. Siri is an example.


24 Roadmap to Pandemic Resilience: Massive Scale Testing, Tracing, and Supported Isolation (TTSI) as the Path to Pandemic Resilience for a Free Society, Edmond J. Safra Center for Ethics, Harvard University, April 20, 2020, [https://ethics.harvard.edu/files/center-for-ethics/files/roadmaptopandemicresilience_updated_4.20.20_1.pdf](https://ethics.harvard.edu/files/center-for-ethics/files/roadmaptopandemicresilience_updated_4.20.20_1.pdf)


On May 7, 2020 National Public Radio summarized many of the other programs under way. More programs continue to be added. Estimates of the number of human contact tracers are based on percentage of population, but it is the number per new active cases that is the more salient measure. So far, these programs have not incorporated digital tracing, some because the appropriate apps and infrastructure are not yet available, and some because it is an unfamiliar change to previous practice.

Human contact tracers have also expressed concern that for privacy reasons the digital methods do not include location data. Location data are useful for identifying hotspots (sites at which considerable transmission occurs) and for understanding the nature of disease transmission. Another way to identify hotspots is to post smartphone-like devices in densely occupied places. Those devices, which need to support only proximity-gathering, not telephony, would record all contacts. If one or more of the contacts are determined to be infected, and there were many other simultaneous contacts, the location is a hotspot. Of course, to use such devices, public-health apps would need to be able to check whether the pseudonyms of an infected person are place-based contacts, to determine the number of proximate contacts at that location, and to notify the proximate contacts that they had been in a location with infected people.

Contact-tracing policies must also distinguish between data about infected individuals and data about contacts who do not become infected (as determined by negative tests or the passage of time). Data about infected persons must be privacy-protected as long as they are retained; data about individuals not infected by a particular contact should be discarded.

Contact tracing shows great promise for reducing the need for lockdowns and for enabling the economy to restart. The widespread availability of tests to detect the pathogenic agent, in this case SARS-CoV-2 is an important factor in the effectiveness of contact-tracing. Testing is important not only to confirm that a user with COVID-19-like symptoms has the virus, but also to identify pre-symptomatic carriers in light of their proximity to COVID-19 victims. Had a test been available and administered when an early unexplained death occurred in California on February 2, 2020, or shortly thereafter, many fewer people might have been infected and fewer would have died.

Effectiveness also depends on sufficient identification and access to contacts. Social distancing and the wearing of face masks can reduce the number of contacts of an infected person. But it is known that some people are unable to distance themselves because of home or work situations,
and some are unwilling to distance themselves or to wear masks. In light of the current distrust of telephone solicitations from strangers and the lack of trust in public institutions, it is not known whether enough contacts will cooperate with public-health workers and whether enough digitally identified contacts will reach out to public health workers. An effective public-communications strategy in partnership and dialogue with local and professional communities will be necessary to achieve sufficient participation. The experience from the Massachusetts CTC project suggests that providing resources to those who are infected or need to quarantine is essential as well.\textsuperscript{31}

**Recommendations:**

**Recommendation 1.** Establish a unit for testing and contact tracing at the Department of Health and Human Services (HHS).

Testing, contact tracing, and the use of technology are essential in slowing the spread of SARS-CoV-2 and reducing the need for lockdowns. The United States has been unprepared to use these tools to their full effect in the present pandemic. In its next relief legislation, Congress should establish and fund a permanent organization, managed and overseen by HHS, to develop and maintain these aspects of pandemic preparedness\textsuperscript{32}. Among the organization’s responsibilities would be

a. through CDC, to coordinate and serve as a clearing house for the development of digital contact tracing tools by state and regional public health organizations, and to facilitate public-private partnerships aimed at ensuring that the tools best meet the needs of public health. The first generation of these tools should be in use in some states and cities by September 1, 2020.

b. in collaboration with the Office of Management and Budget (OMB) to determine the amount of funding needed to carry out combined human/digital contact tracing and immediate testing of people exposed to the virus at the levels recommended by the National Security Council (NSC)\textsuperscript{33}.

c. in collaboration with the National Institute of Standards and Technology (NIST), the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), the Biomedical Advanced Research and Development Authority (BARDA), and the relevant professional societies, to analyze and document experiences and best practices in testing, contact tracing, and quarantining that have been used by Federal, state and local entities to reduce COVID-19 transmission. These studies would inform plans and practices for the COVID-19 pandemic and for future pandemics.


\textsuperscript{32} The organization could be part of a broader Federal Office of Pandemic Preparedness if such an office is established.

\textsuperscript{33} In 2016 the NSC issued the Playbook for Early Response to High Consequence Emerging Infectious Disease Threats and Biological Incidents, https://assets.documentcloud.org/documents/6819703/WH-Pandemic-Playbook.pdf, a guide to decision making.
Recommendation 2. Funding for contact tracing and diagnostic tests.

Congress should continue to increase the funding for widespread COVID-19 testing and contact tracing. The relief package, Paycheck Protection Program and Health Care Enhancement Act (COVID 3.5) signed into law April 24 provides $25 billion in total, but only $11 billion for states and localities for testing and tracing, together with $1 billion for Centers for Disease Control(CDC) surveillance measures and $1 billion for BARDA; and a mandate that the Trump administration establish a national strategy to help states and localities, which are required to outline their own plans for testing. That is only a first step. The Health and Economic Recovery Omnibus Emergency Solution (HEROES) Act passed by the House on May 15, 2020 proposes $75 billion in its COVID-19 National Testing and Contact Tracing Initiative, but that bill has not passed the Senate. Congress should appropriate funding at the level specified by the HEROES Act in the next few months. If the analysis resulting from Recommendation 1(b), determines that more funding is needed, the additional funding should be appropriated as well.

Recommendation 3. Funding for research related to contact tracing.

Congress should fund the government research enterprise – including the National Science Foundation (NSF), NIH, BARDA, and the Defense Advanced Research Projects Agency(DARPA) – on an ongoing basis to advance the use of science and technology to control and reduce the spread of infectious disease. As examples, in the near term, that research should develop efficient screening mechanisms in public places for pre-symptomatic people (since temperature screening only detects individuals with symptoms of the virus), continue to develop effective and efficient diagnostic and serological tests, estimate the effectiveness of early aggressive testing and contact tracing in reducing or eliminating the need for lockdowns, and explore the causes of disease spread both to newly infected individuals and within the human body.

In the longer term, that research should address not only new approaches, but also efficacy of methods in use and human factors that govern the success or failure of contact tracing and

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36 The $75 billion in the bill is for coordinated testing, contact tracing, surveillance, containment, and mitigation. The bill contains no explanation of how that amount is calculated. It includes both diagnostic and serological tests, and social services for infected individuals and underserved populations. There is no mention of digital contact tracing tools. The funding goes through FY21 and beyond.

The cost of diagnostic testing and contact tracing depends, in part, on the number of new cases, so we can only estimate the actual cost through the end of 2020. At the Medicare rate of $51/test, 3 million tests per week for 26 weeks will cost roughly $40 billion. Current prices are often more than the Medicare rate; future prices might drop if the actual cost of the tests drop. Roughly 300,000 contact tracers (number estimated by former CDC Director Tom Frieden) at $70,000 per tracer (estimate by CDC Director Robert Redfield) would cost roughly $21 billion. There would be additional costs to deploy digital contact tracing and serology testing. More funding will be needed beyond 2020.
related methods. It should also address security and privacy considerations and their interplay with policy directives in times of emergency.

The organization established in Recommendation 2 should coordinate this research program. The Secretary of HHS should provide an annual report to Congress on the needs determined by that program and the progress in finding solutions to those needs.

**Conclusion**

It is not too late to strengthen the Nation’s attack on the COVID-19 pandemic and its preparedness for future pandemics. Better testing, contact tracing, and methods for controlling the spread of this and other infectious diseases are essential.
Update to the Contact Tracing Report (12-11-20)

Since our report on contact tracing appeared in June, much scientific evidence has showed that although there is a delay between exposure and infection, it is likely that an infected person is contagious (that is, emits viral particles) days before symptoms appear. Some highly infectious people, especially those who are younger, remain asymptomatic throughout their infectious period. Since contagion precedes potential symptoms, the only way to determine quickly whether a person is infected is by testing that person. Our report emphasized the importance of widely available reliable RT-PCR testing, which was still not in place when the report appeared in June, and recommended that the increase in funded testing deployment have high priority. As the update to our testing report explains, rapid RT-PCR testing availability is still lagging.

Since contact tracing requires resources, the tracing process is overwhelmed if the prevalence of new cases is too high. When the report appeared, the number of new cases per day appeared to be stabilizing, or even decreasing, suggesting that aggressive testing and contact tracing, together with the use of masks and social distancing, would allow public access to many businesses. Since early October, the number of new cases per day has skyrocketed, necessitating other more burdensome public health interventions.

Examples of successful use of testing and contact tracing in controlled settings

Since the publication of our report in June, contact tracing in the United States has been successful in controlled settings such as universities and colleges, professional sporting teams, and communities that have started contact tracing while numbers of new cases were low. In effect, all of these groups create boundaries around their communities by testing the people who enter; then they augment social distancing and mask-wearing with frequent testing and assiduous contact tracing.

The most successful university and college programs test campus residents upon arrival and twice a week while in residence; they test people routinely entering the campus at least once a week; they require all people entering campus to report symptoms electronically; they do contact tracing and testing of contacts following determination of an infected individual; and they quarantine contacts.\(^1\) That degree of testing and contact tracing costs money, of course. Many New England institutions have availed themselves of the low-cost testing support provided by the Harvard-MIT Broad Institute. Some other institutions have gotten support from medical schools and research facilities. But, as a recent study by the California Institute of Technology demonstrates, in the absence of national leadership and funding, many higher education institutions are unable to carry out these kinds of programs.\(^2\)

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The National Basketball Association created a “bubble” for its summer playoff season, confining all personnel from 22 teams to Disney World in Orlando, Florida, requiring quarantine and testing for anyone who entered, monitoring contacts of those within the bubble, digitally, testing frequently, and monitoring symptoms. Nobody within the bubble tested positive for the duration of the containment. Implementing the bubble cost $190 million, which was easily covered by revenue of more than $1 billion from the playoffs.³

The Cherokee Nation succeeded in controlling spread of the coronavirus by setting up a COVID dashboard, mandating mask wearing, stockpiling PPE, and instituting testing and contact tracing programs early in Spring 2020. According to the dashboard, they had only 4560 cases and 33 deaths as of November 17, 2020 out of a population of 141,000 people. Their senior director of public health worked around the lack of guidance from the CDC by studying the WHO Ebola-response protocols for contact tracing.⁴

**Digital Contact tracing**

Traditionally, the contacts of an infected person are discovered by interviewing that person. The report explored the nascent techniques for identifying the contacts of infected people using smartphones. The report describes the introduction of a platform developed jointly by Apple and Google to enable phones to record the proximity and duration of other phones using Bluetooth communication mechanisms. The subsequently named Google-Apple Exposure Notification (GAEN) contact collection app can be accessed only by authorized public health organizations.

Initially, users were required both to download the GAEN tool and to enable data collection. As we had recommended, now the GAEN app is installed on the phone automatically. User action is required to enable collection, but states using the tool can send “push” notifications to encourage user activation. In addition, the need for each public health organization to develop an app to work with GAEN was an inhibitor to using digital contact tracing. In September, Apple and Google released Exposure Notification Express, a framework for public health authorities that they can customize to create their own apps, rather than having to start from scratch.⁵

As of December 10, nineteen states and the District of Columbia have rolled out public health apps using GAEN.⁶ Most of them have interoperability with other states using GAEN. At least two more states have stated the intention to participate. California introduced pilot projects at the

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University of California San Francisco and San Diego campuses (each of which has a medical school) on September 29, extended the pilot to the other University of California campuses in early November, and then rolled out a statewide app on December 10.

In addition to the challenge of developing the software for digital contact tracing, another concern has been the rate of adoption. When the idea of digital contact tracing was first introduced there was much talk about threats to privacy. Those fears have never been dispelled, despite the fact that, as we explained in our report, the GAEN design is privacy-protecting. The GAEN-based digital contact tracing tools pose far less threat to privacy than most of the online shopping, streaming, social media, and search capabilities used by billions of people every day. As states roll out their apps, there continues to be a need for more consistent, positive, and persuasive messaging.

Like so many other aspects of the U.S. response to the pandemic, if there had been leadership and adequate funding from the Federal government, digital contact tracing and the testing that is essential part of its use could have been deployed on a national scale months ago. Encouragement for the rapid development of tools such as GAEN and Exposure Notification Express, assistance to jurisdictions in customizing their own apps and services, and authoritative messaging via advertising and communication with the public, would have strengthened the nation’s ability to control the spread of Covid-19.

**Providing Trained People**

Whether determining and notifying contacts is done by human interviews, by digital tools, or by some combination, skilled workers are needed for the follow-up steps. In October 2020 the Pew Research Center published a study summarizing the challenges facing contact interviewers. In May 2020, the Johns Hopkins Bloomberg School of Public Health introduced a free 6-hour Coursera course that provides a training opportunity for new contact tracers. In many communities, furloughed workers are available to do that work. Although some workers have volunteered and others have been “loaned out” by their employers, however, most of the workers need to be paid. This is yet another demand on the inadequate funds that are available for testing and tracing.

**Additional Recommendation**

Our original report recommended (1) Federal leadership in the form of a unit within the Department of Health and Human Services (HHS), (2) appropriation of the $15 billion for contact tracing (along with $60 billion for testing) from the House HEROES Act, and (3)

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funding for short- and long-term research on the many aspects of controlling and reducing the spread of infectious disease. None of those recommendations have resulted in action. Their importance has not diminished.

Given the progress that has been made on digital contact tracing, we add the following recommendation:

**Recommendation 4.** The Federal government should institute digital contact tracing in all of its major facilities, including military bases, agency buildings and campuses, the White House and executive office buildings, and judicial facilities. Digital contact tracing should be integrated with diagnostic testing and human contact-tracing programs in every facility, as well as with state and international programs where they exist.
Strengthening the Public Health Infrastructure: The Role of Data in Controlling the Spread of COVID-19

By an Ad Hoc Pandemic-Response Subgroup of Former Members of President Obama’s Council of Advisors on Science and Technology

July 28, 2020

Introduction

The national response to the COVID-19 pandemic has exposed weaknesses in the United States public health system and has highlighted inadequacies in the nation’s ability to anticipate, to prepare for, and to respond to serious infectious disease epidemics. Comprehensive preparedness includes prevention, and it also includes sound plans for responding to a pandemic. A large part of an effective response depends on infrastructure that is in place ahead of the onset of illness and spread of infection. An effective public health response depends on information based on reliable and timely data. The experience of the past few months has demonstrated the need to strengthen substantially the infrastructure for the collection, analysis, and sharing of those data.¹

Inadequacy of data is not the only weakness exposed by the pandemic. The United States health care system has long been correctly characterized as costly, inefficient, inequitable, uncoordinated, and, thus, in need of improvement.² The underlying structural causes of these problems include the complexity of the combined public and private payment models, payment for volume rather than value, less than universal coverage, and separate silos of public health management and health care delivery. Our report focuses exclusively on the issues contributing to data availability, but many of these data problems impede needed improvements in the health system overall.

This report reviews the shortcomings of electronic data capture and use for public health purposes, outlines the recent history of changes in platforms and policies for digital health and health care data at CDC and in the broader health delivery system, and makes recommendations about immediate and mid-term policy changes that could accelerate the progress to a state-of-the-art, digital, data-science capability.

Establishing Electronic Health Records

Calls for better data collection for public health purposes are not new. About a decade ago, the United States made a push to digitize medical records from hospitals and doctors’ offices. As part of the massive federal response to the 2008 financial crisis, Congress passed the American Recovery and Reinvestment Act of 2009 (ARRA), part of which was the Health Information Technology for Economic and Clinical Health Act (HITECH Act). The HITECH Act was intended to spur implementation of electronic health records (EHRs) by providing incentive payments to providers to transition to digital records systems and demonstrate their meaningful use in clinical practice. The 2010 PCAST Report to the President on Health Information Technology observed, in this vein, that “If real time concurrent clinical data about every healthcare encounter were collected electronically, such data could be combined, without personal identifiers, from both regional and national perspectives to track public health developments and create timely prevention and amelioration strategies.”

The HITECH Act established a National Coordinator for Health Information Technology. One of the goals for the nationwide health-information-technology infrastructure for which the national coordinator is responsible is that it “improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks.” The strategy that the Office of the National Coordinator (ONC) introduced was to implement Meaningful Use in three stages. Stage 1 was to set the standards for the electronic capture of clinical data and the electronic access by patients to their personal health information. Later stages extended the scope to Health Information Exchanges (HIEs). HIEs are entities set up to share data among a local or regional group of health provider organizations. They have been described as a complex web of bilateral trade agreements. Some HIEs were much more effective than others, but all required significant resources to sustain the ability to exchange patient data. As the initial HITECH funding ran low, and the program moved more slowly than anticipated, the goal of providing all currently available electronic information on a patient from any source suffered.

Various attempts have been made over the years by the Office of the National Coordinator

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4 Ibid., Division A, Title XIII—Health Information Technology.
5 The program was renamed in 2019 as the Public Health and Promoting Interoperability Programs, https://www.cdc.gov/ehrmeaningfuluse/introduction.html
6 Realizing the Full Potential of Health Information Technology to improve Healthcare of Americans: The Path Forward, Report to the President, President’s Council of Advisors on Science and Technology, December 2010, pg. 21, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf
7 P.L. 111-5, Division A, Title XIII, Subtitle A, Sec. 3001 (b)(7).
8 Meaningful Use, as defined in the HITECH Act is now often styled as a proper noun.
9 Realizing the Full Potential, pg. 40
(ONC), the Centers for Disease Control (CDC)\textsuperscript{11}, and state and local public health organizations\textsuperscript{12} to graft public-health data systems onto legislatively mandated EHR systems to achieve later stages of Meaningful Use. Some organizations have used other sources, such as hospital admissions records, to gather population-level data. These efforts have been inadequately funded, and there has been insufficient coordination between federal efforts and those of other jurisdictions. As recent events have demonstrated, the nation cannot continue to do without a robust public-health data infrastructure. It is time for the United States government to act to create one, in coordination with state and local jurisdictions.

**How Does the Public Health System Use Data?**

Using data to discover and monitor the presence of disease

An essential first step in managing the response to any epidemic is the ability to identify early cases and clusters or outbreaks of disease. Ideally, centralized public health authorities would be able to spot outbreaks of characteristic symptom patterns even before diagnosis of identified cases occurs; then, identified cases would be reported immediately as the test results are returned. Information systems exist that would make this possible, but the United States is still not able to make optimal use of available digital science in the interest of public health in a pandemic situation. Traditional public health methodology is still too often manual – it depends on individual clinicians recognizing an unusual transmissible infection and then voluntarily reporting it by email, fax or phone to public health authorities. The transmission is electronic, but the reporting is manual. In a known epidemic situation, some hospitals and health systems will aggregate the data from a day, a week, or a month and then transmit the data to public health authorities. Electronic data retrieval and exchange has been enabled by a number of developments at local and state public health departments as well as at CDC, but these developments are widely variable in quality and far from universal.

As recently as May of 2020, the White House Pandemic Task Force was requesting Excel spreadsheets of COVID-19 cases from hospitals by fax or email.\textsuperscript{13} On July 10, 2020, the White House announced a controversial plan to have hospitals bypass CDC and send all COVID-19 patient information to a central database in Washington daily, still mostly by manual means.\textsuperscript{14} The HHS guidance states that “The following data will greatly assist the White House Coronavirus Task Force in tracking the movement of the virus, identifying potential strains in the healthcare delivery system, and informing [sic] distribution of supplies.” Concern has been expressed that the change places an additional burden on hospitals, that it politicizes data collection, that it weakens CDC, and that it risks withholding information from the public.\textsuperscript{15}

\textsuperscript{11} Both are organizations within the Department of Health and Human Service (HHS).

\textsuperscript{12} In this report phrases referring to state and local public health entities encompass tribes, territories, and community organizations.


\textsuperscript{15} Sheryl Gay Stolberg, *Trump Administration Strips C.D.C. of Control of Coronavirus Data*, New York Times, July 14, 2020, [https://nyti.ms/309Xisi](https://nyti.ms/309Xisi); Amy Goldstein and Lena H. Sun, *Hospital officials, experts say new federal rules...*
This reliance on antiquated data-entry and communication technology, along with burdensome clerical work from individual clinicians, is not how the United States should be retrieving such essential information in 2020. These antiquated approaches are fraught with shortcomings: incompleteness, errors, time lags, reporting bias, and added staff work and costs. Most importantly, they don’t give health authorities the information they need to respond optimally to protect public health and reduce the economic impact of the kinds of major personal restrictions now in place.

Modern digital technology can provide a more complete, more timely, more efficient, and less onerous approach to creating a data environment adequate for local, state, and national leaders to make appropriate policy decisions and, thereby, reduce infections risk and deaths. Modern data systems will allow immediate tracing of symptoms as people seek help in doctor’s offices, retail clinics, or emergency departments. This sort of syndromic surveillance becomes possible when the information from clinical encounters now recorded in EHRs is aggregated and automatically surveyed by regional, state, and national public-health offices. While a National Syndromic Surveillance Program (NSSP) already exists, it does not directly use EHR data and is limited in what symptoms are reported (as discussed below).

A significantly stronger syndromic surveillance would have allowed specific clusters of COVID-19 symptoms (such as dry cough, fever, lethargy, anosmia\(^\text{16}\)) to be identified early, even if the clinicians did not make the right diagnosis or were not yet aware that COVID-19 was in their area. The traditional public health model is that clinicians report cases of an infectious disease, which means they must have correctly identified the cause of illness in their patient and taken the time to send a report to the local public health authorities. Syndromic surveillance, by reporting encounters rather than cases, allows more rapid identification of trends, and provides more rapid useful situational information to clinicians. Influenza, which has some symptoms similar to but also different from COVID-19 in its early phases, could be differentiated from COVID-19 in seasonal outbreaks, leading to different treatments and different implications for isolation policies.

This kind of surveillance is not just possible in theory. NSSP is a primitive implementation, but better systems are already used in other countries that have comprehensive health-data systems, including ten European nations.\(^\text{17}\)

Using data to contain the spread of disease

In addition to data about symptoms, timely and complete information about testing prevalence (how widely diagnostic testing has been done) and test outcomes is essential to disease control. The United States has lagged behind other countries in the availability of diagnostic testing.\(^\text{18}\) In

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\(^{16}\) The loss of the sense of smell

\(^{17}\) Guerrisi et al., “Participatory Syndromic Surveillance of Influenza in Europe,” The Journal of Infectious Diseases, Volume 214, Issue suppl_4, December 2016, Pages S386–S392, [https://doi.org/10.1093/infdis/jiw280](https://doi.org/10.1093/infdis/jiw280)

\(^{18}\) Testing issues will be treated in more detail in a forthcoming report by our Ad Hoc Subgroup.
addition, reliable information about testing prevalence and test outcomes has not been efficiently transmitted to public health authorities. The best databases on testing for COVID-19 were created by research universities and by news organizations, not by public health authorities, and they are limited to aggregated counts derived from a patchwork of inconsistent reporting by counties, states, and commercial labs, with unknown validity and reliability.\textsuperscript{19} Other countries, such as Australia, South Korea, Germany, Denmark, Singapore, and Taiwan used a combination of widespread testing and contact tracing to make decisions to institute nonpharmacological interventions (NPI) such as social distancing, school and business closures, hand hygiene, and masking to limit the spread of the disease early and reduce case numbers and deaths.

If clusters of cases and regional outbreaks can be identified early, then NPI measures can be instituted in focused areas to limit spread and prepare for needed healthcare capacity, without requiring widespread shutdown of businesses and schools. Lacking this situational awareness, the United States has had to make public health decisions while “flying blind”.

Data scientists use modeling to forecast trends and outcomes, in realms from weather to economics. The use of a diversity of models to forecast the spread and impact of COVID-19 has produced widely divergent predictions, ranging from tens of thousands to more than two million deaths during the first months of the United States epidemic. These wide variations have led some to be skeptical of any predictive analytics and have reinforced the apparent inevitability of flying blind. But statistical models and predictions are only as good as the data and assumptions on which they are based. Most modelers are quite expert, but their assumptions necessarily have been based on the data available, which were insufficient and often of uncertain validity.

Clear understanding is still lacking about the transmissibility, clinical course, and lethality of the SARS-CoV-2 virus that causes COVID-19, and about the impact of different approaches to NPI. Access to timely and reliable population-level data could enable much more reliable and accurate forecasts. Using whatever data and forecasts were available, states variably instituted use of NPI, some mandating closure of businesses and gatherings of people, others remaining more lenient—sometimes with dire subsequent consequences. Strong NPI measures slow the rates of spread of COVID-19 and lower fatality rates, but because of adverse economic and social consequences of strong NPI, all states struggle with the decisions of when and how best to loosen restrictions. With better data and awareness of specific outbreaks, more rational decisions about the pace and process of reopening would be possible.

**What Are the Barriers to Using EHRs for Public Health?**

EHRs have been designed for clinical use

EHRs in the United States were not designed to provide data for syndromic surveillance and other population-level public health purposes. They were developed primarily to capture the data necessary to document clinical services in order to issue bills to insurers and to issue

prescriptions. In addition, the record systems are sold and maintained by several large commercial vendors, whose software is proprietary and who have been allowed to block information sharing with other entities. EHRs are able to aggregate data within a given system, for analyses of preventive services for patient panels\textsuperscript{20} or to identify patients with particular kinds of clinical needs. But with only a few exceptions, data from EHRs have not been able to be used directly for public health surveillance of an entire city, county, or state. Recently, workaround attempts to use other sources of data are being created, but none is likely to have the accuracy and completeness of EHRs.

The HITECH Act of 2009 focused on the export of data from EHRs. The enabling legislation and subsequent laws established a set of data elements that had to be accessible electronically. For example, Stage 1 of Meaningful Use measured data such as medications prescribed, vital signs, and smoking status. The legislation laid the groundwork for HIEs (see above) so that hospitals could access the data to send to CMS for Meaningful Use bonus payments, but the data flow is one-way – from the EHR to a client such as a billing system. Stage 2 required being able to share data with another local provider such as an emergency room and it too only required a limited scope of data transfer. Only in Stage 3 is there a provision for a trusted client to add information, such as a Summary of Care from a different health provider.

As regards public health, HITECH’s vision for communication with public health organizations is modest, consisting mostly of the issuance of predefined reports. For example, Stage 3, which became mandatory in 2018 but is not universally implemented, requires that periodically the provider generate and share at least two out of these five reports: immunization registry, syndromic surveillance reporting, electronic case reporting, public health reporting (but only of so-called reportable conditions), and clinical-data registry reporting. In times of emerging health crises such as pandemics, much more than periodic predefined reports is needed. Access to the entirety of the EHR is needed, since, clues to the nature and spread of the pandemic may emerge from data such as co-morbidities, vaccination, medication, or family history, or other information contained in the EHR that cannot be anticipated in advance. Data from EHRs needs to be available without delay (i.e. in real time) so that public health organizations can respond to pandemics quickly.

Health information exchange, as called for in Stage 3, requires the transfer of a Summary of Care record and the reconciliation of clinical information from multiple records. To enable that, independent records systems must be able to exchange data (so-called interoperability). Lack of interoperability has been a barrier to coordination of care, since patients may see providers who cannot access the records of other specialists, sometimes even in the same healthcare delivery system.

A more dynamic exchange of electronic information would be multi-directional, both for multiple health providers and for public health organizations. Conceptually, think of all the EHRs as a large distributed data base. Subject to privacy and security protections, authorized

\textsuperscript{20} In some healthcare practices, each patient is assigned to a particular primary care physician who coordinates care of that patient. The group of patients assigned to a particular physician is known as a patient panel.
users should be able to make queries into that database, rather than waiting to receive a predetermined set of reports.

EHR access must conform to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA required the Secretary of the U.S. Department of Health and Human Services (HHS) to develop regulations protecting the privacy and security of certain health information. To fulfill this requirement, HHS published what are commonly known as the HIPAA Privacy Rule and the HIPAA Security Rule. The Privacy Rule, or Standards for Privacy of Individually Identifiable Health Information, establishes national standards for the protection of certain health information irrespective of the form in which it is held. The Security Standards for the Protection of Electronic Protected Health Information (the Security Rule) establishes a national set of security standards for protecting certain health information that is held or transferred in electronic form.

The HIPAA Privacy Rule allows the disclosure of protected health information to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease. Hospitals are required to limit the protected health information disclosed to the minimum amount necessary to accomplish the public health purpose. The interpretation of this rule leads to the possibility of a patchwork of accessible and inaccessible data, or even “malicious compliance” with the narrowest legal interpretation of a stated request hiding data that is needed and reasonably implied. The HIPAA Privacy Rule also specifies standards for the de-identification of data “alone or in combination with other reasonably available information”, which many technologists believe to be unachievable given today’s capabilities in data analysis, including artificial intelligence. Changes in the HIPAA Rules are needed to make protected disclosure more robust and more appropriate for electronic interchange and to make de-identification standards consistent with current technological reality. Public health, as a collective good, should require only best-practice measures that are not insurmountable roadblocks.

**Advances in EHR technology are slow to be adopted**

There has been continuing progress in technology for the accessibility, sharing, and use of EHRs for clinical care. Health Level 7 International (HL7) is a not-for-profit membership organization founded in 1987, whose mission is to develop a platform and standards for the exchange, integration, sharing, and retrieval of electronic health information. Beginning in 2011, HL7 developed and has evolved the Fast Healthcare Interoperability Resources (FHIR) specification for the electronic exchange of healthcare information.

In October 2015, the HHS Center for Medicare and Medicaid Services (CMS) and the HHS Office of the National Coordinator for Health IT (ONC) published the final rule on Meaningful...
Use Stage 3, which became mandatory for all participants in 2018\textsuperscript{23}. The rule requires that Summary of Care reports be transmitted using the Consolidated Clinical-Document Architecture (C-CDA) specified by HL7.

Meanwhile, the 21\textsuperscript{st} Century Cures Act was signed into law in 2016\textsuperscript{24}. Title IV of that Act requires that patients have access to their electronic health information. It mandates interoperability, specifically that Application Programmer Interfaces (APIs) be available “without special effort” (basically, compelling open APIs rather than proprietary ones)\textsuperscript{25}. It also prohibits information blocking, the restricted availability of electronic health information. The National Coordinator is responsible for overseeing the implementation of those requirements.

Draft ONC rules to implement the Cures Act were finally issued in the fall of 2019, and the Cures Act Final Rule was issued in May 2020\textsuperscript{26}. The API certification criterion requires the use of FHIR release 4. The rule has still not taken effect, however.

The long delay is an indication of the complex web of vested interests underlying the limitations of the EHR system. Originally scheduled to take effect in November, 2020, the law’s implementation has regrettably been delayed even more in response to the COVID-19 pandemic, ostensibly because the changes necessary would cause additional burdens on the nation’s hospitals and health-care delivery infrastructure. The national crisis we now face ought instead to be a reason to move more quickly, once and for all, to make the changes preparing our nation for a stronger, more data-capable future. The recent ONC rules are focused on opening the information for clinical and patient use but can be easily extended to public health, as we recommend below.

In the last two decades, CDC has experimented with several different models for the collection of public health data. None has achieved the scope that is now needed, but valuable lessons have been learned.

A surge of interest in bioterrorism defense followed the terrorist attacks on 9/11 and subsequent threats of anthrax being weaponized. Leaders at the time wisely combined bioterrorism planning and resources with efforts to prepare for a naturally occurring pandemic, which experts predicted was inevitable. These efforts led, among other steps, to the creation of the Strategic National Stockpile.\textsuperscript{27} Leaders also understood the importance of data for biodefense, and CDC invested approximately $300M in BioSense, a “top-down”, contractor-designed, HIE sentinel network.\textsuperscript{28}

\textsuperscript{23} Stage 3 Program Requirements for Eligible Hospitals, CAHs and Dual-Eligible Hospitals Attesting to CMS, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage3_Requirements
\textsuperscript{25} APIs are the protocols for the interaction with software components such as data repositories or programs. They are often used to create user-level applications (“apps”) that invoke system-level services and data access. For example, a capability that gives a patient access to personal health information uses an API to access the EHR.
\textsuperscript{27} http://adhocresponsegroup.org/OPCAST_Ad_Hoc_Subgroup_Stockpile_Recommendations_05-20-20.pdf,
\textsuperscript{28} Public law 107-188, June 12, 2002, https://www.govinfo.gov/content/pkg/STATUTE-116/pdf/STATUTE-116-
The use of BioSense required a considerable amount of work and commitment by hospitals, requiring that data actually be transferred to a central entity. As reported in a paper by Gould *et al.*, by 2007 only 10% of civilian-hospital emergency departments (EDs) were participating.\(^{29}\) Likely also relevant to its limited success was that BioSense bypassed local and state public health departments, who were thus disinclined to advocate for it.

In 2008, CDC embarked on a four-year plan to redesign the BioSense network. *BioSense 2.0* allowed state and local health departments to access data that supported expansion of their syndromic surveillance systems in accordance with the *Meaningful Use* program. Rather than hospitals’ sending all data directly to CDC (as was the case with the original BioSense), under *BioSense 2.0* most data were sent to state and local health departments. Still, *BioSense 2.0 lacked a sustainable governance model with buy-in from all parties.* It appears that challenges in CDC’s collaborations with state and local health departments, together with changes in personnel, caused some disruption to the Biosense 2.0 program. In 2014 the BioSense 2.0 program became the National Syndromic Surveillance Program (NSSP). NSSP replaced the Biosense 2.0 system architecture with a system called *Essence*, created by Johns Hopkins Engineering School, which had a more modern user interface but more limited capabilities, something of a return to a “top-down” architecture.\(^{30}\)

**What is the Path Forward?**

A 21st century infrastructure for health information is a necessity for the United States. We believe that a national multi-app platform (defined below), federally funded but with collective governance involving state and local public health departments, should now be a top priority.

**Platform and Applications**

The distinction between platforms and apps is important. A *platform* is the software and communications infrastructure necessary for desired data flows to take place. The platform needed for public health data would take advantage of Application Program Interfaces (APIs) already being provided to their clients by EHR vendors to comply with *Meaningful Use* Stage 3 and *Cures Act* requirements. While these APIs have been designed for use in healthcare delivery, not for public health, a public health platform could utilize them as well. That platform would include *middleware* (software invisible to the end-user) that, depending on the platform’s design, may run on local systems, federated systems, or in the cloud.\(^ {31}\) In addition to infrastructure for

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\(^{31}\) The *cloud* refers to large data centers that provide data storage and services accessible to multiple clients over the Internet.
data flows, the platform must also provide infrastructure for security and the authentication of authorized users and programs.

The end-user exploits the public health platform through apps—software that presents a user interface designed for a specific purpose with corresponding convenience and functionality. In so-called closed platforms a central authority dictates, and generally itself develops, a single app, or small number of apps, for the user. Open platforms are designed to host apps written by more than one developer or entity (for example, state public health agencies or authorized private-sector companies), as long as their apps conform to the platform’s security and governance policies.

The idea that U.S. public health needs would be best served by an open platform (subject to security and governance limitations) is not new. A 2013 report prepared for the Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ) by the JASON advisory group proposed a platform to support the robust exchange of electronic health information. The JASON proposal advocated interoperability and the implementation of apps that could enable the use of health data not only by hospitals and clinicians, but by public health organizations, researchers, and patients.

Some earlier efforts to provide systems for public health data embraced some aspects of the open platform approach. Beginning in autumn 2006, the Distributed Surveillance Taskforce for Real-time Influenza Burden Tracking and Evaluation (DiSTRIBuTE) project built a distributed system using a new model in which an individual’s data were retained locally but aggregated data were reported centrally for activities such as syndromic surveillance. This was a move to an open platform model with de-centralized (i.e., distributed) data. In spring 2009, as the H1N1 influenza pandemic emerged, the system was deployed nationwide under the auspices of CDC. By early 2011, the network had 43 reporting sites and captured over 40% of all emergency department visits. DiSTRIBuTE was a pilot project and was discontinued in 2012 after six flu seasons.

As part of the HITECH Act, ONC funded the Strategic Health IT Advanced Research Projects (SHARP) program in 2010. One of the projects funded under SHARP was an award to Harvard Medical School and Boston Children’s Hospital to create the SMART (Substitutable Medical Application, Reusable Technologies) API to support a platform for apps that can be used on smart devices such as iPhones and Android phones. The SMART API uses the FHIR platform. The SMART project continued even after the end of the SHARP program. Technical support for the SMART API is provided by major EHR and Cloud vendors.

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34 The SMART API and services are described on the project website, SMART HealthIT, https://smarthealthit.org
CDC’s 2002-vintage BioSense system, mentioned above, used an Internet-based, but not cloud-based, software architecture. This was a closed-platform model with centralized data. That is, CDC both held the data and provided the user-level interface. In the BioSense 2.0 program, however, CDC funded the Association of State and Territorial Health Officials (ASTHO) to host the BioSense 2.0 cloud-based infrastructure and application and to develop data use agreements with participating state and local health departments. Most data were sent from hospitals to a secure, cloud-based, data-storage facility managed by ASTHO. The BioSense 2.0 platform provided a web-based user interface and embodied some aspects of an open-platform design.

Essence, the successor to BioSense 2.0, is cloud-based and has strong support for data analysis and visualization, but it appears to be a return to a single-app, closed-platform model, rather than a platform capable of supporting multiple applications. While the decision to return to this earlier model may have been justified at the time it was made, we believe that this model is inadequate to the needs highlighted by the COVID-19 pandemic. This public health emergency as well as future ones, will require a national data network that is more flexible, dynamic and versatile.

A recent project based in Chicago exemplifies the feasibility of an expandable collection of apps built using modern technology. The Chicago Department of Public Health (CDPH) and academic partners at the Rush University Medical Center have created their own platform, using a locally designed, cloud-based system that looks like Biosense 2.0 but is built on modern APIs, using components of the EPIC EHR platform. Using the FHIR specification, the team was able to bring together analysis of clinical, lab, and capacity data in just a few days to support the COVID-19 response. The Chicago platform uses publicly available open-source software tools to convert proprietary data formats to or from FHIR formats.

Using a common FHIR representation, the platform’s apps provide visualizations and downstream analytics that enable rapid connectivity of data and interoperability across multiple hospitals. With strong leadership from the CDPH and Rush Medical Center, all the major hospitals in the Chicago area agreed to share real-time capacity data to allow hospitals with overwhelmed ICUs to know immediately where they could transfer a patient who needed critical care or intubation and mechanical ventilation. They can use the same technology to share case numbers, prevalence of testing, results of testing, and other key information electronically. The Chicago experience demonstrates that a high technology-readiness level for the underlying necessary technologies already exists.

**Governance**

Previous attempts at achieving a national public health platform—whether closed or open—have often foundered on governance issues. First of all, it is the states, not the federal government, that

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35 Association of State and Territorial Health Officials website [https://www.astho.org](https://www.astho.org)
37 According to an October 2019 report from EHR in Practice, a small number of for-profit vendors provide most of the EHR systems in common use. Epic and Cerner control over 50% of the U.S. acute care hospital market. Epic also controls over 25% of the ambulatory care market and 6 companies share most of the remainder. [https://www.ehrinpractice.com/largest-ehr-vendors.html](https://www.ehrinpractice.com/largest-ehr-vendors.html)
are primarily responsible for public health. Yet, while we recognize that states are constitutionally responsible for public health law within their state, there is also an important role for national standards and guidance, especially in a major epidemic. For this reason, the nation’s public health effort would be much strengthened by consistent and interoperable data systems that include federal participation.

States’ data and practices are incomplete, uneven, and inconsistent. States too often collect public health data from manual reports from hospitals and clinics. The federal government collects public health data from the states and from regional entities through manual surveys and voluntary reporting of certain conditions by physicians and hospitals. The timeliness and completeness of these reports vary widely by municipality, by county and by state. Aggregated data from social networking and internet search add somewhat to this capability but are also subject to multiple sources of bias and data gaps. Real-time clinical data that would provide the best capability to respond optimally to national infectious public health threats are lacking.

While states have a statutory responsibility for public health in their jurisdiction, only the federal government has the (potential) capacity to coordinate data and accelerate collection for national planning and response to emergencies. CDC is the central federal agency responsible for this role. Even with the shortcomings described above CDC has until recently been the acknowledged national leader in the science of population health, respected globally, and a major source of both expertise and reliable data. This administration has significantly weakened CDC, but considerable expertise remains. CDC’s strengths can be restored, and its shortcomings can be addressed to create the unitary national resource that the nation and the global community need. The need for public health leadership will continue at both the national level and the state level, and for the organizations to work together closely and effectively. It is time for a national reinvestment in public health skills at both levels and in building bridges between them.

The development of a national public health infrastructure requires careful consideration of what its governance model should be. It is clear that top-down models, where CDC interacts directly with hospitals, bypassing state and local authorities, do not work. CDC itself has recognized this reality, for example by working more collaboratively with ASTHO and other stakeholders in the development of the now-defunct Biosense 2.0 program.

A more recent example of a workable governance model is the Digital Bridge Initiative, a collaboration among public health organizations, healthcare delivery organizations, and industrial healthcare information technology providers founded in 2016. Its initial focus has been on electronic case reporting. Using existing EHR services, potentially reportable disease cases are sent electronically to a central decision support service managed by the Association of Public Health Laboratories (APHL) and the Council for State and Territorial Epidemiologists (CSTE).

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Reportable cases are forwarded to public health organizations from one of the seven pilot sites.\(^{40}\)

The Initiative has paid careful attention to its governance structure and the process by which decisions are made. The CDC Office of Public Health Science and Surveillance is an active participant in Digital Bridge. Alas, while possibly offering lessons on governance, the pilot programs appear hobbled in technology, for example, not implementing any of the technology used in the Chicago project, the SMART platform, or other such efforts, and choosing instead to use software developed by APHL and the EHR vendors in seemingly a closed fashion.

A satisfactory governance model, coupled with a suitable platform-architecture design and adequate incentives for the development of apps, is a necessary prerequisite for the success of a national public-health infrastructure. Given the inherent turf issues and conflicts of interest among many of the stakeholders (e.g., CDC, states, EHR vendors), a dispassionate study of governance by a neutral party such as the National Academy of Medicine seems desirable.

**Information Technology Expertise**

Many public health departments do not have the level of technology expertise that the Chicago project enjoys, nor does it make sense for every organization to implement its own solutions. Federal, as well as state, leadership is needed. Even if a shared platform supports multiple apps, there is an immediate need for a co-developed single app with a high-quality user interface that all public health organizations can readily use. This is both a public health issue and a national security issue.

As part of the restoration of a strong collaborative Federal, state and local public health infrastructure. HHS and the Congress need to ensure that technical personnel are embedded in all levels of HHS, and included in the highest-level policy discussions, and that expertise is provided to state and local public health organizations that may not have that expertise within their own ranks.

**Short-term and Long-term Funding**

The CDC and state and local jurisdictions have all been hampered for decades by underfunding.\(^{41}\) In the shadow of the financial dominance of the medical-care system, including CMS, and the congressional excitement generated by the biomedical research mission of the National Institutes of Health (NIH), public health has long been undervalued at both the national and the state level.\(^{42}\) Relatively little of the funding that is allocated for public health is used for infectious diseases. Recent years have seen public health budgets go from small to smaller, as parts of the public health mission became political targets in the context of a more general devaluing of scientific expertise.\(^{43}\)

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\(^{40}\) Digital Bridge website, [https://digitalbridge.us/about/](https://digitalbridge.us/about/)


\(^{43}\) Michael D. Shear, ‘*They Let Us Down*’: 5 Takeaways on the C.D.C.’s Coronavirus Response, New York Times,
Federal funds, mostly from CDC and the Department of Agriculture (USDA), are the largest source of funding for state public health departments. The funding is almost always targeted to specific programs – particular diseases, maternal and child health, and food insecurity are examples. There is little core funding that might be used for infrastructure development or for emergencies such as the COVID-19 pandemic.

Funding for CDC’s Public Health Emergency Preparedness (PHEP) cooperative agreements, which support core public health capabilities in states, territories, and local areas, have decreased from $940 million in FY 2002 to $675 million in FY 2020. The 2010 Affordable Care Act established the Prevention and Public Health Fund (PPHF) and funded it with a permanent appropriation that was to rise to $2B per year in 2015. The Middle Class Tax Relief and Job Creation Act of 2012 (P.L. 112-96) reduced PPHF appropriations for FY2013 through FY2021 and the 21st Century Cures Act reduced PPHF appropriations for FY2018 through FY2024, each time diverting the appropriated funds for other purposes. The Fund reached $1B in FY 2012 and again in FY 2020; it is not expected to reach $2B until FY 2025.

It appears that funding by state governments, which typically comes from allocations from General Funds, has decreased at an even faster rate than Federal funding over the last decade. Exact figures are not available, however; there is little quantitative data that documents state public health expenditures. There is little consistency among states, moreover, in part because states use their public health funds for differing purposes. Some state funding for specific purposes such as immunizations is acquired through state taxes on public and private health insurance.

Given the inadequate and fluctuating funding, it is no surprise that both the Federal government and the states fail to invest in preparedness and infrastructure, choosing instead to use their limited funds for more immediate needs. Congress must take the lead in ensuring that the nation creates and maintains modern infrastructure and is well-prepared to respond to the present pandemic and the inevitable future public health emergencies.

**Recommendations**

**Cures Final Rule**

**Recommendation 1.** The Office of the National Coordinator (ONC) should rescind its announced delay in implementation of the Cures Act Final Rule on interoperability, and, during the COVID-19 pandemic, seek to accelerate its implementation.


Recommendation 2. In light of the COVID-19 pandemic, EHR vendors should accelerate their programs to support the ability to connect any authorized app to their systems, using the FHIR specification, as required by the Cures Act Final Rule.

Technology Improvements

Recommendation 3. The recent CARES act appropriates $500M to CDC to upgrade its IT systems. A major focus of that spending should be the planning, at a national level with collaboration by the states and localities, of a platform for real-time access by public health organizations to data from EHR records, mortality records, demographic data, and other electronically available information that can be used for pandemic preparedness. Such a platform should support multiple apps and decentralized data. The plan should be presented to Congress by June 2021.

Recommendation 4. CDC should lead the creation of the platform, drawing on the expertise provided by Recommendations 8 and 9, and funding appropriated by Congress.

Data Availability

Recommendation 5. To exploit the platform at the earliest possible time, including appropriate participation in its development and the development of apps for its use by public health officials, states and localities should develop individual policies for which public health data should be accessed by the platform from hospital/clinician EHR systems and which should be held in data repositories under state or local control. Regardless of location, however, the data must be available for authorized uses by national-scale apps on the platform.

Recommendation 6. The Centers for Medicare and Medicaid Services (CMS) and the Veteran’s Administration (VA) should seek to accelerate the collection of public health data, from hospitals and providers in their respective patient bases, using the mechanisms of the Cures Act Final Rule, even before that rule takes final effect. Congress should appropriate funds that can be allocated to hospitals and providers under supervision by CMS and VA for this purpose.

Recommendation 7. HHS should issue clarifying guidance (or if necessary amend) 45 CFR Section 164.515 to clarify that, for purposes of the HIPAA Privacy Rule, (i) determinations by CDC on “minimality” for the release of EHR records to state and local public health authorities should be considered sufficient for their release, and (ii) for public health purposes, a combination of reasonable de-identification and good cybersecurity practices in data storage will be deemed sufficient to satisfy the rule.

Information Technology Expertise

Recommendation 8. CDC, ONC, and HHS should make use of existing hiring authorities, significantly increased by the Cures Act, to strengthen agency information technology leadership and expertise.

Recommendation 9. The Office of the National Coordinator (ONC) should establish immediate workforce programs designed to bring needed IT technical expertise to the states and
localities. This might include hiring a pool of experts at the federal level and deploying them under the Intergovernmental Personnel Act (IPA) to states and localities on short-term assignment as “IT Tiger teams” under temporary state control. The pool should include high-level executives and managers with systems expertise as well as an IT service corps. Congress should appropriate funds for this purpose.

Infrastructure Governance

Recommendation 10. HHS should ask the National Academy of Medicine to convene a consensus study on governance issues associated with a national public-health data infrastructure under several scenarios, considering the views of all stakeholders. The study should be specifically tasked to recommend an actionable governance model.

Funding

Recommendation 11. Congress should pass legislation that restores funding for the Prevention and Public Health Fund to $2B per year from FY 2021 onward and provides for inflationary increases.

Recommendation 12. States should explore sources of funding for public health other than allocations from the General Fund. Taxes on health-insurance providers to support public health, for example, might actually decrease the provider’s net expenditures as a result of better disease prevention.

Recommendation 13. Congress should ask the National Academy of Medicine to convene a consensus study on funding issues associated with a national public-health data infrastructure under several scenarios, considering the views of all stakeholders. The study should be specifically tasked to recommend an actionable and stable funding model.

Conclusion

A strong national public health resource is necessary to help the states when needed, provide national guidance where it is essential, and coordinate technical capabilities for the nation to respond to epidemics and pandemics as well as bioterrorism threats. Abundant, accurate, and real-time data are essential to evidence-based decision making in times of pandemics, as well as in the ongoing responsibility of government for the health of its residents. The United States has fallen behind in its access to data and the technology to provide decision-support. Catching up must be a very high and immediate priority.
### Appendix: Glossary of Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACA</td>
<td>Patient Protection and Affordable Care Act of 2010, known colloquially as the Affordable Care Act, or Obamacare.</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality. Federal Agency that supports research about how health care systems work and its impacts on patient care.</td>
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<td>API</td>
<td>application programming interface. A specification of possible interactions with a computer program, allowing other programmers to use it without needing to know its internal details.</td>
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<td>ASTHO</td>
<td>Association of State and Territorial Health Officials. Private professional association of state and territorial health officials.</td>
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<tr>
<td>C-CDA</td>
<td>Consolidated Clinical-Document Architecture. Software providing the ability to generate industry standard clinical summary, transitions of care, and other documents that meet HL7 standards.</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention. Federal Agency that supports public health, including data collection from states and municipalities.</td>
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<td>CDPH</td>
<td>Chicago Department of Public Health. Municipal agency responsible for public health of the city of Chicago.</td>
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<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services. Federal agency within HHS that administers the Medicare and (partnering with the states) Medicaid programs.</td>
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<tr>
<td>Acronym</td>
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<tr>
<td>ED</td>
<td>emergency department of a hospital</td>
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<tr>
<td>HER</td>
<td>Electronic Health Record. Software platform for recording data about patient healthcare, including notes of doctor visits, lab tests, and hospitalizations.</td>
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<td>EPIC</td>
<td>One of the major companies selling and supporting electronic health records.</td>
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<tr>
<td>FHIR</td>
<td>Fast Healthcare Interoperability Resources. A standard developed by HL7 for exchanging healthcare information electronically.</td>
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<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services. Cabinet level federal agency focused on health, it includes CMS, CDC, NIH, AHRQ, ONC and other agencies.</td>
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<tr>
<td>HIE</td>
<td>Health Information Exchange. Regional organization set up to allow bilateral exchanges of health information by local providers.</td>
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<tr>
<td>HITECH</td>
<td>Health Information Technology for Economic and Clinical Health Act. Part of ARRA focused on accelerating adoption of electronic health records by bonus payments to providers.</td>
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<tr>
<td>HL7</td>
<td>Health Level 7 International. Voluntary organization that sets standards for electronic health care data formats and exchange protocols.</td>
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<tr>
<td>ICU</td>
<td>intensive care unit. Special unit in a hospital caring for extremely sick patients using breathing machines and other high technology.</td>
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<tr>
<td>IPA</td>
<td>Intergovernmental Personnel Act Mobility Program. Program providing for the temporary assignment of personnel bidirectionally between the federal government and state and local governments, universities, and certain nonprofit research organizations.</td>
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<tr>
<td>IT</td>
<td>Information Technology</td>
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<tr>
<td>JASON</td>
<td>Longstanding independent group of scientists that advises the federal government on matters of science and technology, especially national-security related.</td>
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</table>
NIH  National Institutes of Health. Federal agency that supports basic and clinical research in human biology and health.

NPI  nonpharmacological interventions. Behavioral ways to prevent the spread of infectious illnesses, including social distancing and wearing face masks.

NSSP  National Syndromic Surveillance Program. Use of electronic data for early identification of people with symptoms of an illness that might be infectious.

ONC  Office of the National Coordinator. Office within HHS responsible for overseeing electronic health records.

OPCAST  Obama Administration PCAST. Scientists who advised the president during the Obama Administration, now acting in their individual capacities.

PCAST  President's Council of Advisors on Science and Technology. White House office comprising a group of scientists who formally advise the president.

PHEP  Public Health Emergency Preparedness cooperative agreements. CDC program of financial assistance to state and local public health departments for emergency preparedness.

PPHF  Prevention and Public Health Fund. Appropriations funding stream to CDC for a range of purposes, established as part of ACA.

SARS-CoV-2  Severe Acute Respiratory Syndrome Coronavirus 2. The virus that causes Covid-19. Related to SARS and MERS, previous epidemics causing respiratory illness.

SHARP  Strategic Health IT Advanced Research Projects. Former university grants program for the development of advanced health information technology administered by ONC.

SMART  Substitutable Medical Application, Reusable Technologies. Open source software that allows developers to create secure apps to access authorized healthcare data directly within an EHR using FHIR protocols.

USDA  U.S. Department of Agriculture. Cabinet level agency overseeing agriculture.

VA  U.S. Department of Veterans Affairs. Cabinet level agency overseeing Veterans Affairs, including a major health care program for veterans.
Update to the Data report (12-08-20)

The challenges around a national pandemic-data capability, as described in the OPCODEST Report of July 28, 2020, have not materially changed, even with several months of dramatic increases in case numbers, deaths, and stresses on the nation’s hospitals and healthcare workforce. Significant advances in biomedical knowledge about treating COVID-19 have occurred, and early data on vaccine trials are very promising, but there has been less progress in broad application of the relevant data science.

Opportunities are being missed for modern data science to track spread and identify early trends in risk determination, prevention, and treatment. Lost or delayed are chances to use data analysis to augment the promising biomedical advances while the nation is fighting COVID-19 as well as to lay groundwork for a better response to future epidemics. The recommendations of our previous report are even more relevant at this time, with a new administration preparing to launch major federal efforts to address the pandemic.

We think that two efforts that have emerged since our report emerged are particularly worthy of being built upon, one led by CDC and one by NIH.

CDC launched the Pandemic-Ready Interoperability Modernization Effort (PRIME), a multi-year collaboration between CDC and the US Digital Service (USDS) to “improve data quality and information technology systems for COVID-19 and beyond”. This effort is intended primarily to help strengthen IT systems in state and local health departments. It supports pilot projects to streamline local data flow, to collect data in a cloud-based data hub, and to allow data input from mobile devices. These steps address important needs, but they do so with an incremental approach, with a timetable that is far too slow, and without the necessary transformational steps to open clinical information at a national level as recommended in the OPCODEST report.

NIH launched the National COVID Cohort Collaborative (N3C) to provide access to clinical data for COVID-19 researchers. It leverages the extensive existing network of Clinical Translational Science Awards (CTSA) Hubs and the National Center for Data to Health (CD2H) to build a centralized national data resource on COVID-19. Currently 72 sites are contributing Electronic Health Record (EHR) data amounting to 2.1 million patients, of whom almost 300,000 are COVID-19 positive. The data are stored in secure NIH repository, and users must agree to a strict data use agreement about not making attempts to reidentify individual data sources.

N3C is able to be implemented quickly because of NIH’s preexisting relationships with the clinical centers. Even so, it requires each institution to agree to share their EHR data, and several

1 The Health and Human Services (HHS) Protect Program has not met its goals. See Federal hospital data system falters at tracking pandemic, Charles Pillar, Science, 4 DECEMBER 2020 • VOL 370 ISSUE 6521
https://science.sciencemag.org/content/sci/370/6521/1148.full.pdf
2 https://www.cdc.gov/surveillance/pdfs/PRIME_1-sheet_single-page.pdf
large academic institutions are facing resistance from patients and community members concerned about the privacy and security of the data. In reality, however, in addition to the data-use agreements, the data being shared have very few identifiers—only zip code and dates of hospitalization/treatment. But public mistrust about sharing of health care data, especially for potential use by commercial entities such as drug companies, requires attention.

This issue is another opportunity for proactive federal action. Building public support and trust will require explicit engagement of public entities in data policy, transparency about data sources and uses, and strong national leadership with both technical and ethical credibility. Some have referred to the concept of “social license” drawn from the experience of environmental impact industries and the general public trust required to enable progress. N3C is attending carefully to this need to sustain public trust, and it may prove to be a model for the more aggressive federal actions needed.

One approach to data security is a new technology called “synthetic data” which will be piloted using the large data sets of N3C. Synthetic data are fictional patient profiles that, collectively, match very closely the statistical properties of the true data sets. This approach only works if the training data set is large enough and representational enough—which N3C has the potential to be. Its use will only mirror the results that would be obtained from real data if truly representational diversity exists in the data being submitted by the different sites. Thus the success of the synthetic data model will require significant social license to be able to assemble large data sets adequate to serve as the basis for the synthetic data.

The 13 recommendations in the OPCAST report, synthesized in the following list, are even more urgently relevant now than in July:

1. Accelerate implementation of Interoperability requirements for EHRs to allow data sharing with public health authorities. This step could be accomplished easily through ONC regulatory changes initiated in the 21st Century Cures Act.
2. Initiate and support effective shared governance between states and the CDC. The COVID-19 experience is a burning example that ought to motivate the key players to get this step done.
3. Use some of the COVID-19 recovery funding to build up the digital expertise and infrastructure at CDC and at the state level. There is already $500 million in the CARES Act that could be used for this purpose.

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Testing for the Pathogen during the COVID-19 Pandemic and Future Ones

By an Ad Hoc Pandemic-Response Subgroup of Former Members of President Obama’s Council of Advisors on Science and Technology

August 18, 2020

Introduction

The United States has failed to deploy adequate testing for the presence of the coronavirus SARS-CoV-2 during the Covid-19 pandemic and has been unable to avoid continued spread of the virus. In this report, we explain why such testing is an essential factor in efforts to control the pandemic, why adequate testing has been difficult to achieve, and why the United States has not met the challenge. We conclude by recommending ways to provide more extensive testing in this and future epidemics.

Why testing in the Covid-19 pandemic is both essential and difficult.

The United States has now been in the midst of the Covid-19 pandemic for about half a year. The effects on the nation have been appalling, with dramatic losses of life, health, social well-being, and economic stability.

Some of this disaster can be attributed to the inherent characteristics of the infectious agent, the coronavirus SARS-CoV-2. Because it is novel, there is no vaccine to block infection, there are no therapies to significantly reduce the morbidity of the disease it causes, and no segment of the population has been rendered naturally immune because of prior exposures. Because the virus spreads efficiently from one infected person to another, apparently by multiple routes, and can do so even when an infected person has no symptoms of the disease, it is difficult to slow transmission sufficiently to avoid epidemic growth of the disease.

These traits are innate to the virus, wherever it appears. Yet the United States has fared among the worst of all nations—large and small, rich and poor—that have faced the pandemic, despite the country’s wealth and scientific prowess and despite its traditional standing as a nation well-prepared to combat disease.

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1 S Lee; T Kim, E. Lee et al. Clinical Course and Molecular Viral Shedding Among Asymptomatic and Symptomatic Patients With SARS-CoV-2 Infection in a Community Treatment Center in the Republic of Korea, JAMA August 6, 2020 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769235


Why has this happened? And how can the country change its course in this pandemic and act more effectively in future ones? These are questions that our Subgroup, composed of former members of President Obama’s Council of Advisors on Science and Technology (PCAST), has been asking over the course of the past few months. We have previously examined the federal stockpiles of medical equipment⁴, methods for tracing contacts of infected individuals⁵, and management of pandemic-relevant public health data.⁶ In all three settings, we have found systemic deficiencies and proposed remedies.

Here we explore the role of testing—mainly for the virus, but also for the host responses to it—and offer additional explanations for why the United States has done so poorly during the Covid-19 pandemic. These include confused messages from political leaders about the significance of testing, shortcomings in test design and certification, inadequate financing of tests, deficiencies in the availability of tests, and failures to test as broadly, frequently, and equitably as possible. Of course, the problems with testing do not, by themselves, complete the list of explanations for the U.S. failures.

The issues we raise here cannot be viewed solely as matters that concern the technology of testing; they must be considered in the light of the other elements of a public health response and in the context of a complex society. It is widely recognized that a test revealing the coronavirus in an ailing patient allows accurate diagnosis and guides the therapeutic strategy for that person.⁷ But, with respect to control of an epidemic in a community, a test will be of little value if not linked to rigorous practices of public health, so that contacts are identified, interviewed, tested themselves, and, if found to be infected, properly isolated to prevent further spread of the virus⁸. Careful management and interpretation of test data are also required to design strategies for effective control of the pandemic.⁹

The tests must be accurate, widely accessible, rapidly performed, efficiently reported, and used extensively for surveillance as well as diagnosis. And, generally, they should be subsidized. Achieving all this can be especially difficult in this country’s heterogeneous society, with its many ethnicities, religions, and social classes; its diverse climates, geographies, and population densities; its uneven distribution and quality of health care, delivered in so many different ways; the premium that many of its citizens place on individualism and resistance to behavioral directives; and its complicated systems of governance at the federal, state, and local levels.

⁴http://opcast.org/OPCAST_Ad_Hoc_Subgroup_Stockpile_Recommendations_05-20-20.pdf  
Methods to test for the presence or past history of infection are especially important in situations like the current pandemic, in which the infection may not produce symptoms, the disease is difficult to diagnose even when symptoms appear, and no preventive vaccines or highly effective therapies are yet available.

There are three broad categories of tests. **Viral tests** are designed to identify the microbe directly for three main purposes: to make a definitive diagnosis of the disease that the virus causes (**diagnostic tests**), to ascertain whether those known to have been exposed to infected people are infected (**contact-based tests**), and to monitor the distribution of the infectious agent in populations of asymptomatic people (**surveillance tests**). **Serological tests** are designed to document and characterize host immune responses to the infectious agent. **Prognostic tests** appraise the severity of individual cases. An expanded account of the nature, purpose, and status of these tests in the context of Covid-19 is provided in the Appendix.

As we argue below, to curb the spread of the coronavirus in the current pandemic, surveillance testing will need to be massively increased, achieving a far greater scale than the diagnostic and contact testing that have accounted for the majority of viral tests administered in the United States to date. Serological testing will likely play an important role at a later stage in the course of the pandemic and its aftermath, but for now emphasis must be placed on widespread viral testing to detect those currently infected, so that they may be isolated and their contacts traced, tested, and isolated when appropriate.

**How to bring a pandemic to an end without treatments or vaccines.**

Without an effective vaccine, without pre-existing herd immunity, and without effective antiviral drugs, public health measures to control a viral outbreak must be focused on methods that restrain spread of the virus—impeding further progress of the pandemic and ultimately ending it. The most effective means to block further transmission of a virus in this situation is to identify all people who are infected so that they can isolate themselves, for as long as they remain infected, from those who are not infected. This extreme method can rarely be implemented perfectly, but it can be supplemented by using equipment (face masks, shields, gloves, and other protective gear) and virus disinfectants (to wash hands and contaminated surfaces) to further constrain spread of the virus.

If there were no tests to determine who is and is not infected, the physical separation strategy could be implemented successfully only by separating everyone from everyone else—an approach that is socially, economically, and emotionally unacceptable. But if it were possible to know at all times who is and who is not infected, any pandemic could be ended by using that information to limit isolation only to those who are infected and to limit its duration only to the period of infection. The availability of tests to detect the presence of the virus is thus critical for management of the pandemic, and the speed, cost, accuracy, extent, and frequency of use of those tests will determine how effectively transmission can be controlled by isolation methods alone.¹⁰

¹⁰ DB Larremore, B Wilder, E Lester, et al. Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance. [https://doi.org/10.1101/2020.06.22.20136309](https://doi.org/10.1101/2020.06.22.20136309)
Hypothetically then, if every person in a given region were tested for virus *every* day—currently a logistically untenable proposition, but perhaps achievable in the future—we could know who should remain completely isolated until their infection disappears, while others could interact with other uninfected people at work or at school, in social or commercial activities. In theory, if done accurately and efficiently, this approach would rapidly eliminate the virus from that region—at least until an infected person appeared from elsewhere.

Less far-reaching but more realistic strategies for ending the Covid-19 pandemic can be measured against this rigorous but currently infeasible standard. The impracticality of testing every person can be at least partially offset by the other methods designed to protect against virus spread. These strategies include several already in use: the identification and quarantining of people who have been in contact with others known to be infected (“contact tracing”) and the practices of mask-wearing, hand-washing, and social distancing.

The scale of surveillance testing can also be reduced by focusing on those most likely to be exposed to infected people. Currently, the tests most often used to detect SARS-CoV-2 are diagnostic tests of symptomatic people or contact-based tests of asymptomatic people known to have been exposed to infected individuals. Testing more broadly and strategically—especially by surveying those who are at higher than average risk because they encounter large numbers of people in daily life or at unusual events—should reduce dependence on the other transmission-blunting measures, which have their own costs, difficulties of enforcement, and limited efficacies. But any effort to expand surveillance testing depends on a commitment to lower barriers, such as cost, inconvenience, and slow return of results, and to provide appropriate contact-tracing and other public health measures quickly and effectively when a test is positive for the virus.

**The dilemmas of testing for virus during COVID-19**

Because of their central role in efforts to control the pandemic in the absence of an effective vaccine, tests for the virus have been the subject of extended, vociferous public debate about their availability, turn-around time, accuracy, appropriate use, cost, and reimbursement. Indeed, the nation’s inadequacies in controlling Covid-19 can be attributed in large measure to deficiencies in testing in all of the aspects of testing described below.

The first cases of Covid-19 in Wuhan, China, in December 2019, were followed by the rapid isolation and identification of the causative coronavirus, SARS-CoV-2, and by the swift determination and dissemination of the sequence of the viral RNA genome in January, 2020. Once that information became available, only a few days were required to develop a relatively simple PCR-based test that could detect the coronavirus RNA in a matter of hours. (It is instructive to recall that tests for the causative agent of AIDS, the retrovirus HIV, were not available until a few years, rather than a few weeks, after the first report of the disease in 1981, which highlights the power of new technologies that allow the rapid identification and characterization of novel viral pathogens and the development of specific molecular tests to detect them.)

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11 PCR-based tests are explained in the Appendix.
As has been widely reported, the swift identification of SARS-CoV-2 and the rapid design of molecular tests to detect it were followed by a multiplicity of problems that have impaired the ability of many countries, including the United States, to make testing widely, easily, and cheaply accessible for the diagnosis of individuals and for monitoring the spread of infection in broad populations.

Why has this happened? According to multiple reports, soon after the first case of Covid-19 was reported in Seattle WA, on January 20th, the agency responsible for providing materials for and guidance about microbial tests, the Centers for Disease Control and Prevention (CDC), began distributing small numbers of test kits, some of which were flawed because they included inappropriate control samples. In addition, the agency did not endorse the use of tests for virus detection available from other countries. As a result, U.S. national testing capacity was initially woefully small.

Over the ensuing months, testing capacity in the United States has gradually grown, using a variety of sampling kits and laboratory-based methods, supplied mostly by private companies, but also by academic institutions and government agencies, and approved by the Food and Drug Administration (FDA) under Emergency Use Authorizations (EUAs). As this is written, about 730,000 tests are performed in the US per day (about 20 million per month). It appears that the vast majority of these tests are diagnostic, with a smaller number being contact-based; the number of surveillance tests is not known, but they are likely to be relatively uncommon. Further, officials in many states and cities continue to bemoan the difficulties of obtaining tests for SARS-CoV-2 for any purpose and the efficacy of much of the surveillance testing is undermined by the slow return of results.

As a result, the number of people who have been infected with SARS-CoV-2, with or without symptoms, remains uncertain, but probably ranges from 2- to 10-fold more than the number of documented cases, a number that can only be determined more accurately by widespread deployment of serological tests to identify those who have been infected in the past.

Although it is not known how many people are tested repeatedly or how many tests are performed for surveillance rather than diagnosis, about 1.5 percent of the US population is tested per week for all purposes (about 0.2 percent per day), with the frequency of surveillance testing

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14 The COVID Tracking Project. [https://covidtracking.com](https://covidtracking.com)


17 Presuming that the serological tests are accurate and that detectable amounts of anti-viral antibodies remain.
being probably 5- to 10-fold lower. If it is assumed that about 10 percent of the population is at a relatively high risk of exposure to the virus—because of work, school, or other factors—and that they should be tested on at least a weekly or bi-weekly basis, then the country is underusing surveillance testing by a factor of about 10- to 100-fold. Or put another way: adequate surveillance testing would require nearly five million tests per day, an order of magnitude more than the number of all people currently being tested, who are mainly symptomatic patients and identified contacts. These estimates inform our recommendations for expanded surveillance testing.

Many reasons have been advanced to explain the deficiency in the use of virus testing. The prices of the tests, although controlled by Congressional legislation and the Center for Medicare and Medicaid Services (CMS), are significant (generally about $100 per test) and reimbursable by Medicare, Medicaid, or private insurers only when used for established indications (symptoms or contacts), not for surveillance. Access to testing sites appears to be limited in many places, especially for some of the most severely affected populations (including underserved minorities, and uninsured, poor, and rural populations). The methods of obtaining samples from the upper respiratory tract are not standardized, are often uncomfortable (discouraging some from seeking tests), and do not always provide material from infected regions of the mucosa, discouraging some from seeking testing.

The value and attraction of the tests are further reduced by slow return of results—which often take as long as five to ten days from sampling to reporting in the case of some commercial vendors\(^\text{17}\) meaning that infected subjects are unaware of their status and capable of transmitting the virus to others for several days before they are quarantined and interviewed by contact tracers. Such lags make contact tracing nearly useless. And, despite extensive efforts to improve the efficiency of testing through research on the underlying technologies, nearly all tests for the three primary purposes, including surveillance testing, are still performed individually in central laboratories, using standard PCR-based methods, rather than newer, potentially faster, cheaper, and more convenient technologies, including protein- rather than RNA-based tests, as described further below.

Without sufficient surveillance testing to identify a large fraction of infected asymptomatic individuals, most of the country has had to resorted to other methods that are less specific, more costly, and less effective. The most extreme has been the shutting down of all but the most essential activities in our society, which has brought economic disaster for many, made life difficult for all, and failed to protect essential workers, who must remain at their jobs, from high risk of infection. The most acceptable and simplest methods, but still not uniformly adopted, reduce virus transmission with masks, gloves, disinfection, and safe distancing. Other methods include inherently inaccurate diagnostic surrogates for viral testing (temperature-sensing devices and symptom-reporting, often used at workplaces, meeting centers, and airports) and prompts to get tested (e.g., via contact-tracing that informs people that they have been exposed to an infected person).

\(^{17}\) Testing Results Take Too Long, U.S. Official Concedes
Clearly, though, the totality of measures that have been used in this country has fallen short of controlling Covid-19. The tsunami of new cases occurring in most states several months after the pandemic began offers grim testimony for the need to expand testing so that a much larger fraction of infected people will know that they are virus carriers and can be separated from others. The case for much wider testing and a more precise plan to find and isolate infected individuals has become especially compelling at a time when restrictions on commercial and social life are being lifted, schools and colleges are trying to reopen, and people are tiring of the emotionally draining isolation strategies justifiably imposed by state and city governments during the first months of the pandemic.

**A closer look at the challenge of widespread surveillance testing for the virus**

Why has it been difficult to provide an inexpensive, accurate test with a rapid return of results so that many more people might be monitored for the presence of virus on a regular basis, perhaps even daily, weekly, or bi-weekly? To understand the difficulties and to consider means to overcome them, especially as this country attempts to reopen in this country, it is useful to analyze the testing process step-by-step, revealing its complexities, costs, recent failures, and opportunities for improvement.

**Deciding to be tested**

Testing begins with a decision to have a test done. That decision is now made in a variety of ways that reflect the unevenness of U.S. testing practices. The primary reasons for obtaining a test fall into three categories: (i) an individual has symptoms suggestive of Covid-19 and decides (often after a recommendation from health care personnel) to have a diagnostic test for SARS-CoV-2; (ii) an asymptomatic person learns about a recent contact with an infected individual and is requested (or volunteers) to have a contact-based test; and (iii) a presumably healthy person undergoes surveillance testing as part of an effort to reduce the number of carriers present in a workplace, school, or large event or in response to a request to participate in a survey designed to determine the prevalence of virus carriers.

Unfortunately, these three sets of circumstances are often not considered separately when considering how much testing should be done, what testing methods should be used, how they should be financed, or even where and how they should be performed. Moreover, the results are not usually tracked separately when public health information is compiled. As a result, the total number of tests performed over time in any location and the fraction of tests that yield positive results may be misinterpreted. (For example, a higher percentage of positive tests is expected from diagnostic tests of symptomatic people than from surveillance tests of well people, but it is typically not possible to disaggregate these different circumstances.)

The frequency at which people decide to obtain tests that are not mandated (e.g. by an employer, school administrator, or event organizer) will depend on a number of factors: the location of sampling sites, the mode of sampling, the way in which the significance of the test has been communicated, the time required for return of results, and the cost and the likelihood of reimbursement. At present, public and private health insurance will reimburse virus tests for diagnosis (when a patient has symptoms of Covid-19) or for evaluation of contacts with an
infected person. Virus surveillance requires additional financial support since the tests are not generally eligible for reimbursement. The problems of cost are magnified by the need for repeated surveillance: those with a negative test today may become virus-positive tomorrow.

**Taking the sample**

The second steps are physical: getting to a sampling site and having a sample taken for viral testing. With few exceptions, samples for viral testing of all three types are obtained by trained personnel at sites outside homes and workplaces. Although the number of such sites has grown, they are still inequitably distributed, sometimes depleted of necessary personal protective equipment (PPE), swabs, or tubes, and often inconvenient because they are far away or require long wait-times. Since the motivation is greater for a symptomatic person to obtain a diagnostic test than for an asymptomatic person to obtain a surveillance or contact-tracing test, inconvenient testing sites will disproportionately discourage the latter. Expansion of viral testing would be facilitated by greater attention to the distribution and efficiency of sampling sites or by greater use of test kits that allow self-sampling at home or work.

Although the coronavirus grows in many cell types and can be found at many sites in the body, the conventional approach is to sample the upper respiratory tract where the virus appears to be most abundant and transmissible. There is, however, still no consensus about the best method for procuring the sample. Initially, nearly all sampling was performed by inserting long swabs through the nose to obtain material from the posterior pharynx. For several reasons—the discomfort of this procedure, early shortages of the swabs, and the apparent ability of some laboratories to obtain reliable results from samples taken with less invasive approaches—sampling is now often performed in other ways: by swabbing the anterior nose or the oral cavity or by collecting saliva. These alternative sampling methods have obvious advantages; they are less uncomfortable, can be self-administered, and can obviate the requirement to travel to a sampling site. But it is distressing that, several months into the pandemic, there have been no large-scale, systematic studies and no consensus about which sampling procedure should be followed under which circumstances to achieve the most accurate results.

**Transporting the sample**

As most viral tests are currently performed at dedicated central laboratories, the samples need to be safely, securely, and swiftly brought from the sampling site (at home, workplace, or sampling facility) to the testing location. This step would be eliminated, of course, if tests could be performed at the site of sampling (see below), but currently most tests are performed in large laboratories using expensive equipment managed by trained technical staff. The reliability and speed of transit to the testing site are important variables in the process, requiring careful tracking, but no regulations currently mandate such tracking.

**Detecting the virus**

The molecular methods used to detect SARS-CoV-2 are at the heart of the testing process. Although the PCR-based test used from the start of the pandemic is now standard (see Appendix) and many versions have received FDA approval for emergency use, it is still inefficient, relatively expensive, and performed nearly exclusively at centralized laboratories.
(The variable cost per test is estimated to be about $20, but the price per test is generally at or near the Medicare rate of $100 per sample and occasionally much more.\textsuperscript{18}) Other potentially cheaper, faster, and simpler testing methods are under development in commercial, governmental, and academic laboratories, as discussed below.

Of special interest are tests for surveillance that can be conducted rapidly at the site of sample collection, since such tests could then be performed at the entry points at work places, schools, large meetings, or social or cultural events; in such settings, identification of even one infected asymptomatic person could prevent transmission to many susceptible people. Testing in those settings could be made cheaper and faster with methods that detect viral proteins (antigens) rather than viral RNA, in the manner used for existing tests (e.g. for pregnancy) that take only a few minutes to perform. This antigen testing may sacrifice sensitivity of detection for convenience and economy; but, importantly, the advantages of much wider and more frequent use could offset the loss of sensitivity and be as effective in suppressing viral spread.\textsuperscript{19}

**Returning result**

Regardless of the reason for testing, rapid return of results, especially positive results, is essential to ensure that the best course of treatment is pursued and that any infectious persons and all contacts are informed and appropriately counseled to minimize further spread of the virus. Tests performed at centralized laboratories typically require several hours to process. But the actual time from sample collection to delivery of results is often much longer, sometimes as long as 5 to 10 days, especially from commercial providers that are well compensated.\textsuperscript{20} During the delays, infected people can spread infection to many others and may themselves develop life-threatening symptoms of Covid-19.

The timely return of results is heavily dependent on the technical methods used for testing and the number of samples waiting to be tested, but also on the efficiency with which a testing pipeline operates and the administrative competence of the entity that performs the test. Moreover, the results must be sent to health care personnel and public health agencies with suitable speed (at least within 24 hours). Patients and health care providers should also receive appropriate statements about the documented frequency of false-negative and false-positive results and about the indications for repeated testing. Some of these issues will, of course, be obviated if very rapid tests (such as tests for viral protein) that can be performed at the site of sampling, including the home, come into common use.

\textsuperscript{18} Most Coronavirus Tests Cost About $100. Why Did One Cost $2,315?  

\textsuperscript{19} The Rockefeller Foundation, Covid-19 National Testing & Tracing Action Plan -  

DB Larremore, B Wilder, E Lester, et al Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance  
[https://doi.org/10.1101/2020.06.22.20136309](https://doi.org/10.1101/2020.06.22.20136309)

\textsuperscript{20} Testing Results Take Too Long, U.S. Official Concedes  
Acting on the results: tracing contacts and isolating infected individuals

After a positive result has been transmitted to and received by the subject and public health authorities, efforts must be made to identify, inform, and guide as many people as possible who are known or suspected to have been in contact with the infected person, as outlined in our Subgroup’s report on contact tracing. In addition, appropriate guidance about quarantining and medical care needs to be provided by someone with adequate time and knowledge to address a patient’s concerns. The CDC offers recommendations about such matters, but it is not known whether and how often the recommendations are followed.

As the foregoing discussion of these components of the testing process reveals, the process is complex, even when the molecular test for viral RNA is relatively simple in design and execution. Moreover, the path towards much more widespread use of surveillance tests—on a scale that would dramatically improve population-based strategies to control the pandemic, not simply diagnose and treat symptomatic individuals—is uncertain and not yet pursued with the urgency, attention, and rigor that would be expected for responses during other kinds of national emergencies, such as a military attack.

Strategies for improved testing: Medical Research, Technical Platforms, and Data Repositories

As noted above, numerous explanations have been proposed for the U.S.’s failure to test adequate numbers of people, including surveillance of asymptomatic people, for SARS-CoV-2 during the current pandemic: lack of political commitment and leadership, high costs and inadequate reimbursement, poor public communication about the purposes of testing, and a weak public health system for following up on positive results. These are barriers that other countries have been able to overcome with consistent, informed direction by governments and with support from well-organized public health systems. Still, if the tests were faster and cheaper, if they had greater capacity and accuracy, and if they could be performed on saliva in the home or workplace, the United States would likely be in much better shape at this time.

Opportunities for improved testing

Several commentators have noted ways in which testing for virus might be improved:

• Viral level. Although viral tests are almost always reported as simply being positive or negative, the quantitative level of virus present at a given time varies across individuals by 100 million-fold. Some of the variation is due to the stage of infection, with levels being higher soon after infection and declining thereafter, but much may be due to inter-individual differences. While it is reasonable to guess that an individual’s viral level would be related to their

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infectiousness, with the highest levels perhaps being more likely to give rise to super-spreading events, there is little empirical evidence on this point. Systematic collection, analysis, and understanding of the role of viral levels might inform both regulatory and public health strategies, including trade-offs between test cost and sensitivity and how to deploy resources to limit spread.

• **Pooling.** One obvious possibility is to increase testing capacity by pooling multiple samples in a single test reaction, especially for surveillance testing when the prevalence of virus carriers is low\(^\text{23}\). If the pooled test reveals no virus, the individual samples need not be tested. Some institutions (including intramural NIH and Stanford University) have used such pools of tens or hundreds of samples to survey employees for virus, and the FDA recently granted Emergency Use Authorization (EUA) to a commercial vendor (Quest Diagnostics) to pool samples for virus tests, but only four per tube. Of course, whenever a pool includes at least one positive sample, substantial extra work and time is required to identify the infected person.

• **Barcoding.** Another approach to enlarging testing capacity involves equipping each sample with a unique molecular barcode so that thousands or tens of thousands of samples could be evaluated at once\(^\text{24}\). Such technology is widely employed in DNA and RNA sequencing experiments but has not yet been fully validated for viral testing. To enhance sensitivity, the tests would be performed with rapid DNA sequencing methods after DNA amplification with PCR. The wide variation of viral levels across infected individuals may offset the efficiency of barcoding, because it will be necessary to perform very deep sequencing to reliably detect barcodes present at levels differing by 100 million-fold.

• **Testing for viral protein.** There is widespread interest in developing viral tests, especially for surveillance, that detect viral proteins (which can be specifically identified as antigens, using well-characterized antibodies) as a cheaper, faster, and simpler substitute for current tests that detect the coronavirus by measuring its RNA. Such tests are already in use in other countries and the FDA is beginning to grant them EUAs. They have the potential to lower costs to well under $10 per test, can be performed at the place of sampling (even as self-administered tests at home), and could identify more infected individuals than RNA-based tests, despite their lower sensitivity, simply by more frequent and more widespread use\(^\text{25}\). Large-scale systematic studies are still needed to compare the time course and levels of viral protein and viral RNA, as well as the sensitivity and specificity of different antigen tests.

• **Testing at sampling sites.** Options other than antigen-based tests are under development to make molecular tests suitable for use at the site of sampling, even at home or in a workplace.

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\(^{23}\) How to Test More People for Coronavirus Without Actually Needing More Tests

https://www.theatlantic.com/ideas/archive/2020/05/lack-testing-holding-science-back/611422/

\(^{25}\) The Rockefeller Foundation, Covid-19 National Testing & Tracing Action Plan

DB Larremore, B Wilder, E Lester, et al Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance. https://doi.org/10.1101/2020.06.22.20136309
These methods include DNA amplification that does not require cumbersome thermocycling machines\textsuperscript{26} and detection techniques based on properties of certain gene-editing systems.\textsuperscript{27}

- \textit{Testing entire communities}. Other approaches to population-based evaluation of virus prevalence are currently being used to detect virus particles in sewage or other pooled community effluvia as a means to sense the presence of non-infectious remnants of pathogenic viruses like SARS-CoV-2 in entire neighborhoods.

\textbf{Research on testing}

The federal government has a number of tools at its disposal that might accelerate such improvements. The first and most obvious is to expand traditional mechanisms for supporting goal-oriented programs through grants and the use of government laboratories staffed by agency scientists. Some programs of this type have recently been launched. Funds provided to the National Cancer Institute (NCI) by the CURES Act in April, 2020, are being used to establish a Serological Sciences Network (SSN), based at the NCI’s Frederick National Laboratory, to improve serological and related testing and to address underlying features of the host response to infection with SARS-CoV-2 \textsuperscript{28}. In addition, the NIH has used funds appropriated under the CURES Act to establish an important initiative (called Rapid Acceleration of Diagnostics or RADx) to improve testing methods for SARS-CoV-2.\textsuperscript{29} Although it is moving as swiftly as possible with traditional program planning, calls for proposals, and expedited peer review, RADx has just begun select grantees, several months after the enacting legislation.

These programs—and related scientific work that may be in even earlier phases, when the applicability of basic science to testing may not yet be apparent—are essential means to improve national testing capacity over the long term. But part of the problem has been a failure to use the technology that already exists in an effective manner. Many companies are working diligently and competitively to improve virus and serological testing, and they could be further encouraged during the pandemic by administrative incentives, such as fast action on patent applications and tax incentives.

\textbf{Technical Platforms}

The government could take advantage of developments in academic and commercial science: the recognition that certain kinds of investigation can be markedly accelerated by the organization of “\textit{technical platforms}”—units with specialized machines and highly trained staff that expedite

\begin{footnotes}
\item[27] The US already has the technology to test millions of people a day \url{https://www.technologyreview.com/2020/04/28/1000671/covid-tests-millions-per-day-crispr-biotechnology-advances/}
\end{footnotes}
experiments in which large numbers of samples are swiftly processed, often with the help of robotics and sophisticated data analysis, to approach a specific goal\textsuperscript{30}. In the usual conduct of medical research, such goals include the identification of small molecules that block a disease-promoting factor or the discovery of genes that have roles in the development of a disease. The critical concept is that the methodology is generic and can be rapidly adapted to study a novel problem when enough is learned to apply the platform specifically to that problem. For instance, the discovery of a novel agent responsible for a pandemic and determination of the sequence of the agent’s genome would allow the swift use of existing platforms to produce diagnostic tests, optimize serological assays, and develop vaccine candidates.

Data repositories

During the Covid-19 pandemic, the public has been most effectively informed about the dynamics of the pandemic through efforts to compile and analyze public data by academic institutions, like Johns Hopkins University, and by major news outlets \textsuperscript{31}. Also illustrative of the poor performance in informing the public, some government-held data have been released for public viewing only after challenges under the Freedom of Information Act. More recently, case reporting to the federal government has recently been redirected exclusively to HHS (which has hired a private contractor to handle the flow of information), rather than to the CDC, as in the past. This shift has created uncertainty about the use, reliability, and accessibility of the data, as reviewed in an earlier report from our Subgroup.\textsuperscript{32}

An improved, government-supported, national public registry of available tests, accompanied by a comprehensive presentation of the results in accord with the purpose of the tests, would enhance the ability of state and city public health departments and other non-governmental entities to analyze the data and to adjust plans for the control of the current outbreak and any future ones. Key components of the relevant data sets, especially the number of ascertained infections, should be based on reliable tests for the virus and for serological responses to it. A database of this scope and quality would also encourage the sharing of research results and reagents and the formation of research collaborations.

Recommendations

Although a comprehensive history of the Covid-19 pandemic cannot yet be written, it is apparent that the United States has fared poorly by many criteria, in significant part because the nation has lacked effective, centralized, scientifically based oversight of the response, including testing\textsuperscript{33}. A full accounting will require more time and a deeper evaluation—the kind of study that can be

\begin{thebibliography}{99}
\bibitem{The COVID Tracking Project} The COVID Tracking Project. \url{https://covidtracking.com}
\end{thebibliography}
done only by a suitably staffed and financed “national commission” on Covid-19 established after the pandemic has run its course. A commission of this type should be directed to identify the causes of failure during the pandemic and to propose the functional and structural changes that would allow a more effective response to pandemics (and perhaps other health emergencies) in the future.34

But, even now, it is possible to recommend some changes that could improve control of the current pandemic and better prepare us for the next one. With the country experiencing the extensive economic, social, and medical consequences of a severe pandemic, Congress and the public should be convinced by now of the need to pay the costs of effective testing and many other aspects of pandemic control—no less a commitment than the public would demand to confront an invasion by foreign troops.

**Recommendation 1.** Congress should expand Federal financial support for viral testing immediately, mandate wider surveillance testing, and enhance reimbursement for appropriate use of viral and serological tests during epidemics. As a first step, Congress should pass and the President should sign legislation that provides at least $60 billion for viral testing over the next eight months, with an additional $15 billion provided to support contact tracing. The legislation should also require a nation-wide plan for expanded testing.

According to our calculations, the amount we recommend would allow an approximately 10- to 20-fold increase in surveillance and contact-based testing, focused on individuals at high risk of exposure, and would also support contact tracing itself, an obligatory accompaniment to achieve the goals of testing. These sums align with the $75 billion designated for testing and contact tracing in the version of the HEROES Act recently passed by the House of Representatives and awaiting consideration by the Senate. The amount is also consistent with the recommendations by others35 and with a recommendation in our Subgroup’s recent report on contact tracing 36. Since continued improvements in testing technologies and costs are likely, and since the course of the pandemic has been difficult to predict, the situation should be reevaluated in about six months.

Decisions about allocation of funds to states and localities for testing and contact tracing should be administered by the Office of the Secretary (OS) at the DHHS, with guidance primarily from the Centers for Disease Control and Prevention (CDC) and also the Office of the Assistant Secretary for Preparedness and Response (OPR), the Biomedical Advanced Research and Development Authority (BARDA), and the Center for Medicare and Medicaid Services (CMS). These decisions should be presented to Congress within 30 days of the signing of the legislation, in the context of a national plan, developed in conjunction with


states and localities, to detect SARS-CoV-2, especially in populations at high risk of infection; to quarantine all those found to be infectious; and to recognize variations in the prevalence of infection in different locations and among those with different occupations and behavioral patterns.

**Recommendation 2.** CDC should establish a national testing website and registry to ensure effective communication about the appropriate use, value, and results of laboratory tests.

The CDC has traditionally been assigned the responsibility for informing states, localities, and the general public about the availability, uses, interpretations, and outcomes of tests designed to detect microbial pathogens, to assess host responses, and to monitor spread of infection in the population. For reasons that have yet to be fully investigated, the agency was widely judged not to have fulfilled that critical role successfully during the current pandemic\(^37\), and its role as recipient of healthcare data has recently been reassigned to DHHS by the White House, sowing significant confusion.\(^38\)

To rectify matters, the DHHS should work with the CDC and other departmental components to improve the public information that the CDC provides about tests relevant to the current and future pandemics and to accelerate the delivery of such information. That information should include the nature and number of tests performed in the context of the pandemic, and the CDC should work with the Office of the National Coordinator at DHHS to improve electronic data collection and presentation. The informatics infrastructure at the CDC should also be enhanced, in accord with our recently released report on data management.\(^39\)

In our view, it will be faster and more efficient to identify and repair the weaknesses in the CDC, rather than to empower a different or new institution with some of the CDC’s responsibilities.

**Recommendation 3.** As part of its authorization and appropriations processes, Congress should re-examine the roles assigned to three major Public Health Service (PHS) agencies for the development, approval, implementation, and analysis of testing during public health emergencies.\(^40\)

Historically, the NIH has been expected to perform the basic and applied research required to produce improved tests for diseases, the FDA has had responsibility for evaluating and


\(^{40}\) The U.S. Public Health Service is comprised of eight of the eleven divisions of the DHHS; three of the largest are relevant to several aspects of this report: the NIH, the FDA, and the CDC.
approving new tests, and the CDC has been assigned the tasks of guiding the use of the tests and reporting and analyzing the results, in conjunction with state and local public health authorities. In view of the country’s failure to control the Covid-19 pandemic, Congress should determine whether the powers and budgetary resources provided by the Federal government are sufficient for them to carry out their responsibilities in national public health emergencies. If it concludes that they are not, the Congress should augment them.

Special consideration should be given to the CDC, in view of the widespread perception that it was unable to provide strong Federal leadership of the nation’s response to the Covid-19 pandemic. The standards by which the FDA accords EUAs for tests should also be re-examined to determine whether such authorization is being allocated too readily or too slowly.

Recommendation 4. The agencies of the PHS should use current authorities to strengthen the nation’s preparedness for testing during this and future epidemics. These measures should include: building versatile, efficient, and low-cost technical platforms and point-of-care devices that can be used in routine healthcare and rapidly adapted for specific situations, such as national or global infectious disease emergencies; providing clear criteria for swift approval of novel tests; and creating an informatics infrastructure for nation-wide deployment of tests and interpretation of the results.

By many accounts, the United States has failed to adapt existing technologies and to provide tests at the speed and scale required to diagnose and control the spread of SARS-CoV-2 at many stages of the current pandemic, despite the widely acknowledged strengths of U.S. biomedical science.

The NIH should build upon its new programs in viral and serological testing to create and maintain advanced technical platforms that promote the provision of reliable testing programs during public health emergencies, while also continuing to support basic science programs with their inherent potential to improve methods used for testing. As mentioned under Recommendation 3, the FDA should examine its criteria for issuance of EUAs, especially to ensure that appropriate criteria are provided for evaluation of novel low-cost viral tests that can be performed at sampling sites. And the CDC should guarantee that its

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41 E. Yong, How the Pandemic Defeated America - The Atlantic, Sept.2020


recommendations to (and communications with) public health authorities are responsive to the varied status of the current pandemic in different states and localities and aligned with our prescriptions for better management of relevant data, including data concerning the results of testing, as described under Recommendation 2.

Appendix 1: Types of Tests and their Functions

1. Viral Tests

Tests that detect the causative agent of any infectious disease are based either on the growth of the organism (requiring that the agent retain biological activity) or on some chemical or physical attributes, regardless of viability. Tests for infectious SARS-CoV-2 are available—performed mostly with cultured cells, sometimes with experimental animals—and are often used for research purposes, especially in studies of host immune responses and viral disease-causing mechanisms. But virtually all tests used in clinical practice to diagnose Covid-19 and to track epidemiological patterns for public health purposes measure an essential chemical component of the virus—the SARS-CoV-2 RNA genome or one or more of the proteins present in virus particles.

Such molecular tests are generally cheaper, safer, faster, and often more sensitive than tests for infectious virus. Nearly all FDA-approved tests currently in use measure viral RNA and depend upon a common two-step process: copying the coronavirus RNA into DNA, with the enzyme called reverse transcriptase, then amplification of parts of the resulting viral DNA many times over, using the polymerase chain reaction (PCR). Other methods for measuring viral RNA are available for research purposes or under development for surveying larger numbers of healthy individuals, as discussed in the text and elsewhere.

Tests that detect virus by measuring viral proteins, using antibodies specific for known proteins, are potentially faster and cheaper than most tests for viral RNA and may prove amenable to self-administered use. Such tests are being pursued commercially, as well as in the public sector, but only two have been granted an EUA by the FDA.

As described in the text, virus tests may be diagnostic (used to establish the cause of disease), contact-based (used to seek evidence of infection in persons believed to have been in contact with an infected person), or a means of surveillance (for infected, asymptomatic people in populations without known contacts with infected people). Identification of the causative agent is essential for a specific diagnosis of any infectious disease in an individual patient; in its absence,
diagnosis is presumptive. Surveillance tests must be available in large quantities and to all sectors of the population; relatively simple, rapid, and inexpensive. They can achieve their purpose of infection control even if not as accurate as tests used for diagnostic purposes or for contact-tracing.

The reliability of tests for SARS-CoV-2 depends on the timing and mode of sampling, as well as the sensitivity and specificity of the method. False-positive tests are generally rare, but sometimes occur due to poor test design or contamination of samples with viral RNA or DNA. (Since a false-positive result can lead to unnecessary quarantine, contact tracing, or treatment, even a low error rate is problematic.) Negative results for persons who have been infected most commonly occur if the sample is taken before the virus has multiplied to produce amounts that allow detection or if the sampling of material from the upper respiratory tract has been ineffective. The sensitivity of PCR-based tests for viral RNA is generally great enough to detect even very low concentrations of virus. Antibody-based tests for viral proteins, however, are inherently less sensitive and may fail to detect a significant minority of virus-positive subjects—a trade-off for simplicity, speed, and lower costs. A report by the JASON group explores the significance of false-negative findings in greater detail, and others have argued that the simplicity, speed, and low cost of antigen-based tests for virus can outweigh the virtues of the high sensitivity of RNA-based tests, when tests are used for surveillance.

2. Serological tests

Tests that ascertain the host’s immune response to the infectious agent depend largely on immunological methods to detect antibodies that bind proteins found in virus particles. Immune responses to SARS CoV-2 are most commonly sought with tests for either of two viral proteins: the spike (S) protein, which is on the surface of the virus particle, comprises its predominant halo (or “corona”), and mediates entry of virus into cells by binding to a specific host receptor protein (called ACE2); or the nucleocapsid (N) protein, which is an essential component of the internal core of the virus.

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47 This issue has been dramatically illustrated in the current epidemic. Although over 99% of Covid-19 patients in whom coronavirus RNA was detected were later shown to have made virus-specific antibodies, validating the diagnosis, less than 40% of patients with a presumptive diagnosis of Covid-19, without testing for viral RNA, produced antibodies against SARS-CoV-2. Thus, in over 60%, the symptoms were likely produced by another condition. F Wajnberg, F Amanat, A Firpo et al SARS-CoV-2 infection induces robust, neutralizing antibody responses that are stable for at least three months. medRxiv 2020.07.14.20151126; doi: https://doi.org/10.1101/2020.07.14.20151126

48 False positives in reverse transcription PCR testing for SARS-CoV-2 | medRxiv https://www.medrxiv.org/content/10.1101/2020.04.26.20080911v2


When properly designed and performed, these tests can provide definitive evidence that the individual has been infected by the relevant microbe at some time in the past—at least several days or a few weeks before a sample (usually blood) is taken for testing—since the relevant cells in the immune system require time to produce sufficient antibody for detection. Many versions of such tests for antibodies against the S and N proteins have been designed, approved by the FDA under Emergency Use Authorization (EUA), and deployed in epidemiological studies to determine the fraction of a population that has been infected by SARS-CoV-2 or in medical practice to ascertain whether an individual patient has been infected in the past.

The general utility, regulation, demand for, and pricing of such tests are unresolved issues. Although detection of antibodies ascertains that the subject was once infected, it does not reveal whether virus is still present. Whether naturally infected persons acquire truly protective immunity can be established only by ascertaining resistance to subsequent infection; this can be difficult to document unless a cohort of individuals who have been naturally infected is closely followed for re-infection while infection rates remain high in the general population. But the detection of neutralizing antibodies, especially at high levels, offers presumptive evidence for immunity and suggests that development of a successful vaccine is possible. The persistence of the state of immunity after natural infection, however, remains uncertain and that too will have important implications for the success of vaccination programs.

The presence of neutralizing antibodies in sera from patients convalescing from Covid-19 also signifies the potential utility of such sera for treatment of severely ill patients, and it provides motivation for the generation of neutralizing monoclonal antibodies as therapeutic agents. Clinical trials of these immunologically-based therapies are in progress. Finally, other more specialized tests of immune cell function, including tests for the reactivity of T cells against virus-infected cells, can provide additional information about the host immune response, but they are still generally confined to research settings.

3. Prognostic tests

Tests that indicate the severity of the clinical course of the disease and predict its outcome measure various kinds of host responses, such as immune cell factors implicated in tissue inflammation or in signaling between cell types in the immune system. (One FDA-approved example is a test for the cytokine, IL-6.) Such tests are being developed during the Covid-19 pandemic to predict which patients are likely to manifest the severe syndromes (profound respiratory distress, renal disease, vascular disorders, and a Kawasaki-like syndrome in children) that arise in a subset of infected individuals and require specialized treatment. Identification of such “biomarkers” may prove to be important to devise new therapies, use them appropriately, and reduce the case mortality rate; tests to do so will require an extensive research effort; fortunately, such work is currently underway in government, academic, and commercial laboratories throughout the world.

51 Equally important, more specialized tests—for antibodies that inactivate (“neutralize”) the infectivity of the virus—are required to gauge whether the individual is likely to be resistant to infection (immune).
Update to the Testing Report (12-08-20)

The status of testing for SARS-CoV-2 in the US

A modest increase has occurred in the number of tests for the novel coronavirus conducted per day—from about 730,000 per day at the time of our report to over 1.5 million per day in late November\(^1\)—driven largely by the marked increase in the number of newly diagnosed cases during the past two months. The nation still lacks a plan to increase testing to the levels recommended in our report (to about 5 to 10 million tests per day), however, especially for surveillance to detect contagious asymptomatic people.

Testing of asymptomatic employees at institutional workplaces now occurs at only about 17% of facilities, and only half of those are testing at least once a week.\(^2\) The institutions that have not adopted such testing attribute their decision to the costs, the logistical complexities, the slow return of results, and (least often) unavailability of tests. Despite a failure to increase substantially the frequency of testing for virus in asymptomatic people overall, such tests have been beneficially employed in some circumscribed subpopulations. For instance, all members of largely isolated groups on some college campuses and in some professional athletic organizations have been tested multiple times per week to identify and quarantine infected individuals, with remarkable success, although the vast majority of colleges have not developed testing programs for students on campus.\(^3\)

The failure to reach the levels of testing recommended in our report can be attributed, at least in part, to the failure of Congress to pass the HEROES Act, which, in the version passed by the House of Representatives several months ago, proposed $60 billion for testing, as well as $15 billion for contact tracing.

Changes in testing methods

Prospects remain for making tests more rapid, more efficient, and less costly through research, but the nature and prices of tests for virus detection that remain in common use have not significantly changed. High throughput tests, such as those that employ new DNA sequencing methods and “bar-coding” or those that employ the nucleic-acid editing function called CRISPR, remain under investigation but have not received FDA approval. Limited pooling of samples for PCR-based tests is employed in a few settings and has the potential to reduce costs by as much as ten-fold (from approximately $20 per test to about $2 per test\(^4\)), but this strategy becomes less effective when the frequency of positive tests rises, as is happening in many places currently.\(^1\) A

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1. [https://covidtracking.com/data/national](https://covidtracking.com/data/national)
test (developed by Lumira), based on a PCR method that does not require thermo-cycling machines in centralized laboratories, has recently received an EUA from the FDA for use and rapid interpretation at home, but it is too early to know how widely this test will be used, in part because of its significant cost. The vast majority of tests continue to be performed at centralized laboratories, not at places of work, at social gatherings, or at home.

The federal government has encouraged the use of rapid (and less costly) viral-antigen-based tests for infection, through the purchase of 150 million tests by the Department of Health and Human Services. But widespread adoption of such tests has not occurred, despite their advantages in efforts to restrain spread of the virus, presumably because of their inherent lower sensitivity compared with PCR-based tests, as well as reports of false positive results. The NIH has issued several awards for studies to improve testing methods through its RADx program, but it is too early to expect results that would lead to significant changes in current practice.

Our earlier report on testing advocated greatly expanded testing of asymptomatic people for virus. But, a few days after the report was released, the CDC revised its guidance in a surprising direction—arguing that tests should be used primarily for diagnosis of symptomatic people. The altered guidelines were widely and swiftly criticized and rescinded shortly thereafter. Still, the hoped-for massive increase in testing of asymptomatic individuals—especially those known to have had recent contacts with infected people and those participating in group activities in which virus transmission is likely—has not materialized

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8 https://www.propublica.org/article/rapid-testing-is-less-accurate-than-the-government-wants-to-admit
9 https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-phase2-awards
Recommendations for the Coming COVID-19 Commission

By an Ad Hoc Pandemic-Response Subgroup of Former Members of President Obama’s Council of Advisors on Science and Technology

September 21, 2020

Introduction

The United States confronted a succession of biological threats over the first two decades of the twenty-first century. These included the 2001 anthrax attacks, the 2002-2004 SARS coronavirus (SARS-CoV-1) pandemic, the 2009 H1N1 influenza pandemic, the 2012 MERS-CoV coronavirus epidemic in the Mideast, the 2014 Ebola outbreak in Africa, and the 2015-2016 mosquito-borne Zika virus epidemic in the Americas.

This pace of emerging disease outbreaks had been anticipated by leading microbiologists and epidemiologists in the late twentieth century. In 2004, the National Intelligence Council in its report *Mapping the Global Future*, noted that “Some experts believe it is only a matter of time before a new pandemic appears, such as the 1918–1919 influenza virus ... Such a pandemic... would be devastating and could spread rapidly throughout the world.” In 2008, a careful accounting catalogued the emergence of 335 infectious diseases into humans between 1940 and 2004. While a small number of these spread widely or even became established (for example, the HIV virus that causes AIDS), nearly all subsided quickly. But it was clear to microbiologists that the threat was ever-present, and likely increasing.

The executive branch first put a national strategy in place for pandemic disease outbreak surveillance and response with Presidential Decision Directive PDD NSTC-7, issued by President Clinton in 1996. Since then there has been a series of U.S. strategy documents related to biodefense, including defense against naturally occurring disease. Since 2001, the U.S. Government has spent billions of dollars annually to protect the country against both intentional biological attacks and emerging infectious diseases.

Now the United States is in the midst of the COVID-19 pandemic, due to another emergent coronavirus, SARS-CoV-2. Despite decades of warning and strategy documents, and billions of

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3 Over 60% of these were zoonotic, i.e. of animal origin. K. E. Jones, N. G. Patel, M. A. Levy, A. Storeygard, D. Balk, J. L. Gittleman, and P. Daszak, “Global Trends in Emerging Infectious Diseases,” *Nature* 451 (21 February 2008), pp. 990-993; [https://www.nature.com/articles/nature06536](https://www.nature.com/articles/nature06536).


dollars of funding, the United States has fared among the worst of all advanced nations that have faced the pandemic, with over 190,000 Americans dead as of mid-September 2020 and about a thousand more dying each day. Why and how has this happened? And how can the country ensure that it acts more effectively in future pandemics? Over the past months there have been proposals in the press and in Congress to create a commission to investigate and provide comprehensive answers to these questions. Here the Pandemic Response Subgroup of President Obama’s Council of Advisors on Science and Technology (OPCAST) makes comprehensive recommendations for the topics that should be examined by a COVID-19 commission.

Legislative Background

On July 1, 2020, Senators Diane Feinstein (D-CA), Amy Klobuchar (D-MN), and Bob Casey (D-PA) introduced legislation to create a ten-member bipartisan commission on the United States’ handling of the COVID-19 pandemic. The Senate legislation is similar to draft legislation introduced in the House of Representatives in April by Adam Schiff (D-CA). The legislation calls for an examination of U.S. government preparedness prior to the pandemic, its response during it, and recommendations to improve the United States’ ability to respond and recover in future pandemics. The proposed Commission is explicitly modeled after the National Commission on Terrorist Attacks Upon the United States (the “9/11 Commission”).

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7 Johns Hopkins University Coronavirus Resource Center, https://coronavirus.jhu.edu

8 These are questions that our OPCODE Pandemic-Response Subgroup, composed of former members of President Obama’s Council of Advisors on Science and Technology, has been asking over the course of the past several months. We have previously examined the federal stockpiles of medical equipment, methods for tracing contacts of infected individuals, management of pandemic-relevant public health care data, and testing. In all four settings, we have found systemic deficiencies and proposed remedies. Our reports on these topics may be accessed at http://opcast.org.


The COVID-19 Commission proposed in the legislation would:

• Be composed of ten members who are not current federal officials, with backgrounds including public health, epidemiology, emergency preparedness, armed services, and intelligence. Members would be chosen by Senate and House leaders, with the Chair chosen by the President;
• Have sufficient staffing and resources to complete the task thoroughly and quickly;
• Have subpoena power to compel cooperation by relevant witnesses;
• Not be required to comply with the Federal Advisory Committee Act (FACA);13
• Report to the American People, the Congress, and the President on the circumstances related to the outbreak in the United States, including preparedness as well as the intelligence and public health information available before the virus reached the United States, and to assess how federal, state, and local governments, as well as the private sector, responded to the crisis;
• Make specific recommendations to Congress and the Executive Branch on how to improve U.S. preparedness for future pandemic disease outbreaks;
• Be established in February 2021 and report in August 2022.

The legislation anticipates that the February start date would prove to be subsequent to the end of the pandemic. This prediction is likely to be overly optimistic, however.

The 9/11 Commission

The bullet list in the previous section giving the attributes of the COVID-19 Commission proposed in current legislation parallels the characteristics of the 9/11 Commission. A sense of the scale of that earlier effort is instructive in considering what would be appropriate for a COVID-19 Commission. With a $15 million budget, the 9/11 Commission had 10 Commissioners and over 80 members of staff (some of whom held the security clearances necessary to review highly classified material), together with subpoena power, so was able to conduct extensive investigations.14 It interviewed over 1,200 people and reviewed millions of pages of documents. Although the Commission was not a FACA committee, it nevertheless held about a dozen sessions in which public testimony was given. Those who testified to the Commission, some in private and some publicly, included every relevant cabinet official of the Bush and Clinton administrations, as well as the President and Vice President of both administrations.15

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13 In general, any advisory group established by a federal agency must comply with the 1972 Federal Advisory Committee Act (FACA), and must, among other requirements, hold open meetings that are announced in the Federal Register with sufficient advance notice. See https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/advice-and-guidance/the-federal-advisory-committee-act-faca-brochure


15 The testimony of the then-former President (Clinton) and Vice President (Gore) was recorded. The COVID-19 Commission may wish to follow this precedent. See NBC News, “9/11 Commission Finishes Bush, Cheney
The 9/11 Commission was established in November 2002 and spent almost two years in its work, publishing its 567-page final report in August 2004. The report begins with the events of September 11th, describes the rise of Al Qaeda and previous attempts at grand terrorism, then describes efforts, and failures, by the United States executive and legislative branches to adapt to these new threats. There follows a sequence of chapters describing past antiterrorism efforts, Al Qaeda planning, and the failure to detect and circumvent the 9/11 plot. The report then analyzes government actions on 9/11 itself, before turning finally to recommendations for what should be done substantively and organizationally to prevent another such successful attack.

The Select Committee on Katrina

There is another extensive recent report analyzing the failure of the United States to adequately respond to a major threat and the resulting catastrophe: *A Failure of Initiative: Final Report of the Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina*. Hurricane Katrina made landfall in New Orleans on the morning of August 29, 2005, leading to over 1,800 deaths and causing over $100 billion worth of damage.

The House Select Bipartisan Committee had sixteen members and 34 members of staff, and it had subpoena power. The Select Committee was established by the House of Representatives on September 15, 2005, only two weeks after Katrina hit New Orleans. It delivered its final 364-page report to the full House in February 2006, a 5-month effort. It held nine hearings, “conducted scores of interviews and received dozens of briefings from local, state, and federal officials; non-governmental organizations; private companies and individuals who provided or offered external support after Katrina; and hurricane victims. The Select Committee also requested and received more than 500,000 pages of documents from a wide array of sources.”

The Select Committee’s report provides an overview of the national framework for emergency management, examining the history of the Federal Emergency Management Agency (FEMA) beginning with its creation in 1979, the much later creation of the Department of Homeland Security (DHS), and the incorporation of FEMA into DHS. The complicated “push-pull” relationship between the federal government and the states for emergency preparation and management is discussed. and current federal, state, and local, as well as private, capabilities are summarized. The report then describes pre-landfall preparation, including lessons learned from previous hurricanes, and “Hurricane Pam,” a July 2004 FEMA-funded disaster simulation exercise in which a fictitious hurricane hit the New Orleans area. The report details failures of the exercise process and also a failure at state and local levels to address major problems identified by the simulation. It examines a series of critical infrastructure and planning issues and identifies failures of federal, state, and local actions on each of these topics.

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18 Select Committee report, p. 11.
Recommendations for COVID-19 Commission Structure and Focuses

The Congressional Research Service has usefully compared the characteristics of five proposed models for a COVID-19 Commission, albeit without making a recommendation. On the key question of the basic structure for the Commission, our OPCODE Pandemic-Response Subgroup favors an independent bipartisan commission (the 9/11 Commission model) over a select bipartisan congressional committee (the Katrina Commission model). The 9/11 Commission model provides a level of resources, dedicated members and staff, authority, independence, and credibility that the select congressional committee would be unlikely to be able to match. As with the 9/11 Commission, at least some members of the COVID-19 Commission should have the clearances necessary to read, and receive briefings on, highly classified intelligence.

Our recommendations for the topics that should be examined by the coming COVID-19 Commission follow; they move from broad background issues to specific questions regarding U.S. preparations and response.

Gleaning Insights from Previous Commissions

An early step in the Commission process likely will be interviews with 9/11 Commission members and staff for the purposes of hearing lessons learned from that experience and the Commissioners’ insights into important issues to examine in the COVID investigation. The 9/11 Commission framework provides a powerful structure for the COVID Commission, but many of the broad substantive issues raised by the House Select Committee investigating the Katrina catastrophe provide closer echoes to the COVID response: failure despite long-standing strategic warning and on-point previous experience; tardy exercise of federal authority; complicated relationships between the federal and state governments; and many others. It will therefore be equally important to interview Committee members and staff on the Katrina Select Committee, who may have insights that complement those serving on the 9/11 Commission.

The Threat of Emerging Infectious Diseases

Just as the 9/11 Commission examined the rise of Al Qaeda in order to go beyond merely proximate causes for the 9/11 attacks, so the COVID Commission should survey the causes and frequency of emerging zoonotic disease outbreaks, for which there is, of course, an extensive literature. Major outbreaks of the past two decades, and successes and shortcomings of the U.S government response in these cases, should be examined, including avian influenza (e.g. H1N1), Ebola, Zika, and other coronavirus outbreaks (SARS, MERS).

Attention should be paid to whether there is a pattern of increased urgency and funding subsequent to an outbreak that is then not maintained, only to be followed by another burst of attention at the time of the next outbreak. If this pattern does in fact exist, the Commission


should consider mechanisms to mitigate this start/stop pattern of attention and resource commitment to what is clearly an ever-present threat.

**Origins of SARS-CoV-2 and Strategic Warning**

The Commission should summarize the expert consensus, including disagreements and uncertainties, on the origin of SARS-CoV-2. Did the virus jump from an animal into the human population, leading to the Wuhan outbreak? Is there a credible possibility that the virus escaped from the Wuhan Institute of Virology, perhaps having been brought there after efforts to sample and track dangerous viruses in the wild? Is there any credible evidence that the virus was a human-engineered virus? There is value in definitively assessing and, as warranted by the evidence, supporting or rebutting these speculations.

When, or in what stages, did the United States receive warning of a novel coronavirus outbreak in Wuhan and indications of the level of threat it might pose? To what extent, if any, did the previous drawdown of CDC and/or other U.S. personnel in China affect the U.S. warning time? How did this information move through the United States government, and how and when did it reach the White House and the President?

How forthcoming and timely was China in providing information to the United States? Was there appropriate and timely communication among U.S. health, diplomatic, and other agency personnel?

**The Role of the World Health Organization**

The World Health Organization (WHO) has launched an independent review, the “Independent Panel for Pandemic Preparedness and Response,” of the international response to the COVID-19 pandemic. The Panel is to deliver an interim report in November 2020 and a complete report to the World Health Assembly in May 2021. The U.S. COVID-19 Commission should, of course, make use of this review, but nevertheless should conduct its own investigation into a number of long- and short-term questions about WHO’s role, as well as into issues that are unique to the United States.

Following the 2002–2004 SARS outbreak, the WHO’s International Health Regulations (IHRs), binding on 196 countries, were modified with the intention of improving global health security, including countries’ timely reporting of significant disease outbreaks and giving the WHO Director the authority and responsibility to declare a Public Health Emergency of International Concern (PHEIC) when necessary. The Commission should review the effectiveness of the IHRs in outbreaks subsequent to SARS and in the current pandemic, in particular, with special

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21 Gentry and Gordon define “strategic warning” as the “communication to senior national decision-makers of the potential for, or actually impending, events of major significance to national interests and recommendations that leaders consider making policy decisions and/or taking actions to address the situations.” John A. Gentry and Joseph S. Gordon, *Strategic Warning Intelligence: History, Challenges, and Prospects* (Georgetown Univ. Press, 2019).

attention to China’s fulfillment of its IHR responsibilities and to WHO’s timing of its PHEIC declaration.

The Commission should examine the role the United States has played in the WHO since the SARS outbreak and whether this role has been sufficiently effective or could have been improved. Among other issues in this connection, the Commission should inquire into the circumstance that the U.S. seat on WHO’s executive board was left empty for more than two years and only filled in May 2020. What are the reasons for this absence, and did it have significant consequences?

In late May 2020, President Trump announced that the United States would end its membership in the WHO effective July 6, 2021, citing the WHO’s handling of the pandemic. The Commission should understand the basis of this decision and consider whether it is in the interests of the United States. If the United States ultimately stays within the WHO, the Commission should consider recommendations for improving the WHO’s performance in disease outbreak detection, notification, and response.

The Commission should also examine, specifically, WHO’s ability to make decisions in the interest of global health even if those run against the wishes of powerful member states. De facto as well as de jure constraints on WHO decision-making should be considered.

Evolution of U.S. Infectious Disease Surveillance and Response Since PDD NSTC-7

As noted in the Introduction, above, the first U.S. national strategy for pandemic surveillance and response was Presidential Decision Directive PDD NSTC-7, issued by President Clinton in 1996.23 The Commission should review this document and the subsequent succession of national studies of biodefense and assess, in that context, the adequacy of U.S. national pandemic planning prior to the COVID outbreak. Specific questions to be addressed should include:

Has the emphasis on preparations for bioterrorism or biological attack from a state adversary significantly detracted from preparedness for naturally occurring disease? At the same time, the country does not want to be in the position in a decade’s time of suffering a bioengineered attack from an adversary and asking the exact opposite question. The Commission will wish to critically consider the optimal balance between defense against natural occurring disease and defense against biological attack, as well as dual-use approaches.

The incoming Trump Administration was provided with the National Security Council’s 69-page “Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents.”24 Why was the Playbook created by the Obama administration? How was it presented to the incoming Trump administration? What efforts were made to follow its prescriptions? Were the Playbook’s prescriptions flawed or inadequate?

The Department of Defense established its Global Emerging Infections Surveillance program in 1997. Did this program play a role in addressing some of the significant outbreaks of the past two decades, and is it appropriately funded and staffed to do so? The same questions should be asked of the Global Disease Detection Centers within the CDC’s Global Disease Detection program.

The role of the Centers for Disease Control and Prevention (CDC) in international disease surveillance should be examined. Since 2017, more than 30 staff members have been pulled out of the CDC’s office in China. In July 2019, the Administration ended funding for a U.S. epidemiologist embedded in China’s equivalent to the CDC. Why were these steps taken? Could these personnel have played a significant role in providing more warning to the United States about the origins or nature of the COVID outbreak in Wuhan? How many personnel does and should the CDC have in place in other countries, and how effective has been their role?

Executive Branch Structure, Preparedness, and Response

In May 2018, the White House disbanded the Directorate for Global Health Security and Biodefense, which had been created by the Obama Administration in 2015, within the National Security Council staff. The head of the directorate left the Administration, while some members of the team were merged into other NSC directorates. How consequential was this reorganization with respect to the U.S. ability to anticipate and respond to the COVID pandemic?

The Commission should examine how decision-making and responsibility were apportioned during the COVID-19 pandemic among the various parts of the Department of Health and Human Security (HHS)—including the CDC, the Food and Drug Administration (FDA), the office of the Assistant Secretary for Preparedness and Response (ASPR), and the Secretary)—the Department of Homeland Security (DHS), the NSC staff, the OSTP staff, and formal and informal White House task forces. Were structures and lines of command in place to enable rapid but informed decision making? If not, what changes should be made?

More specifically, on January 29, 2020 President Trump announced the formation of the President’s Coronavirus Task Force, to be chaired by HHS Secretary Azar and coordinated through the NSC. Twelve subject-matter experts from the White House and government agencies were appointed to the Task Force. On February 26, 2020 Vice President Pence was named to chair the task force, and Dr. Deborah Birx was named the response coordinator. The task force’s mandate was to “lead the Administration’s efforts to monitor, contain, and mitigate the spread of the virus, while ensuring that the American people have the most accurate and up-to-date health and travel information.”

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There were daily meetings and press briefings until late April. Since then, there have been infrequent press briefings and an unknown number of regular meetings. On May 5, five new members with expertise in the field of vaccines and getting Americans back to work safely were added to the Task Force. How effective was this group in the initial phases? Did its effectiveness change after the expansion and change of emphasis in May? Was there conflict between the White House and the participating agencies regarding decisions and public announcements? What would have made the task force more effective? In the early months, respected scientists participated actively in the briefings; their public roles at the briefings were diminished beginning in May. Why was this? What was the interaction of the task force with governors and mayors? Personal protective equipment (PPE) suppliers? Public health officials?

Special consideration should be given to the CDC, in view of the widespread perception that it was unable to provide strong Federal leadership for the nation’s response to the COVID-19 pandemic. The evolution of the CDC since PDD NSTC-7 was issued should be documented, with particular attention to budgets, staffing, the quality of personnel and leadership, adequacy of information technology, capacity to collect and analyze data, and communications with public health organizations and the public.

With respect to the Department of Homeland Security, a former DHS chief of staff has written that “Years of DHS planning for a pandemic threat have been largely wasted.” The Commission should examine DHS pandemic planning and investigate this claim.

The invocation of the Defense Production Act (DPA), and its utility, should be investigated. Did invoking the DPA have significant impact, or if not, why? Could it have been more expansively and/or effectively employed?

**The Strategic National Stockpile**

The Commission should survey the history of the creation and maintenance of the Strategic National Stockpile (SNS). The SNS was depleted during the H1N1 epidemic in 2009. In March 2013, Congress enacted the Pandemic and All-Hazards Preparedness Reauthorization Act of

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2013; Section 403 of the Act’s Title IV “Reauthorizes the Strategic National Stockpile for FY2014-FY2018.” One result of the failure to appropriate and carry out the funding and actions authorized in Public Law 113-5 (as well as the failure to renew the authorization beyond 2018) has been that the United States was unprepared for the supply needs of the Spring 2020 COVID-19 pandemic. Why did the authorization of PL 113-5 not lead to appropriations? Why was the authorization not renewed?

The responsibility for stockpile shortcomings is not the Federal government’s alone. According to Greg Burel, who was Director of the SNS from March 2007 to December 2019, SNS planning assumed that state stockpiles would also be in place, as they had been in the past. For the most part, however, those stockpiles were not replenished and maintained after the 2008 financial crisis. The failure to replenish both the SNS and state stockpiles should be documented and understood, with lessons drawn for the readiness of the stockpiles in the future.

On October 1, 2018, the full responsibility for the SNS was transferred from CDC to the HHS ASPR. This decision, and its impact on preparedness and response to the COVID pandemic, should be examined. In particular, whether this move coincided with a change in emphasis from preparedness for naturally occurring disease to preparedness for biological attack should be examined, and the consequences of this change understood.

The role that supply-chain issues have played in the replenishment of the stockpile should be examined. Why was adequate surge capacity not in place? Is the United States too dependent on foreign manufacturers for the items in its stockpile, and if so how can this vulnerability be mitigated? What role did, could, and should the Defense Production Act have played?

The Commission should examine efforts, reportedly sometimes chaotic and resulting in the waste of hundreds of millions of dollars, to rebuild the stockpile subsequent to the start of the pandemic.

The mission statement of the SNS was changed on April 2, 2020, in the midst of pandemic-driven shortages of respirator masks and other equipment. The Commission should investigate

38 Prior to April 2, 2020, the Office of the Assistant Secretary for Preparedness and Response described the mission of the SNS as follows: “Strategic National Stockpile is the nation’s largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. When state, local, tribal, and territorial responders request federal assistance to support their response efforts, the stockpile ensures that the right medicines and supplies get to those who need them most during an emergency. Organized for scalable response to a variety of public health threats, the repository contains enough supplies to respond to multiple large-scale emergencies simultaneously.” The new mission statement reads: “The Strategic National Stockpile’s role is to supplement state and local supplies during public health emergencies. Many states have products stockpiled, as
the reason for this change, and consider whether the new mission statement is an appropriate one for the SNS. If not, the Commission should present its recommendation for a modified or new mission statement, or for reverting to the previous one.

The SNS and other stockpiles are intended to serve not only pandemic response but the response to other emergencies, as well, such as hurricanes and wildfires. In autumn 2020, several states found themselves having to cope with those natural disasters simultaneously with the COVID-19 pandemic. The Commission should examine how prioritization is done with the SNS regarding preparing and responding to these different challenges, and whether any changes in the SNS, its management, or the deployment of its resources need to be made as a result of this examination.

Public Health Funding in the United States

The CDC and state and local jurisdictions have all been hampered for decades by underfunding.\(^{39}\) In the shadow of the financial dominance of the medical-care system, as compared with spending on public health, and the congressional enthusiasm for the biomedical research mission of the NIH, public health has long been undervalued at both the national and the state level.\(^{40}\) In addition, relatively little of the funding that is allocated for public health is used for infectious diseases.

In addition to the more obvious casualties of underfunding, there is reason for concern about neglect of such important questions as the influence, on disease propagation, of human behavior and the character and operation of residential, commercial, industrial, and transportation infrastructure.\(^{41}\) The Commission should examine whether there is adequate focus and appropriate responsibility for these matters anywhere in the public health system and, if not, how the inadequacies can best be remedied. Where should such work be done (universities, national labs, industry labs?), who should fund it (DOE? NSF?), and who should be responsible for overseeing its implementation (CDC?).

Recent years have seen public health budgets go from small to smaller, as parts of the public health mission became political targets in the context of a more general devaluing of scientific expertise.\(^{42}\) Federal funds, mostly from CDC and the Department of Agriculture (USDA), are the largest source of funding for state public health departments. The funding is almost always targeted to specific programs—particular diseases, maternal and child health, and food insecurity are examples. There is little core funding that might be used for infrastructure development or for well. The supplies, medicines, and devices for life-saving care contained in the stockpile can be used as a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available.” See [https://www.phe.gov/emergency/events/COVID19/SNS/Pages/default.aspx](https://www.phe.gov/emergency/events/COVID19/SNS/Pages/default.aspx)


emergencies such as the COVID-19 pandemic.\textsuperscript{43} It appears that funding by state governments, which typically comes from allocations from General Funds, has decreased at an even faster rate than Federal funding over the last decade.

As a result, the COVID-19 pandemic arrived in a United States whose public health infrastructure was already weakened. Local health departments have lost 55,000 jobs, a quarter of their workforce, since 2009.\textsuperscript{44} The Commission should consider the effects of public health funding on the United States’ ability to prepare for and respond to the COVID-19 pandemic. It should examine, specifically, the impacts of personnel and funding shortfalls on the CDC’s preparation and response, as well as the impact that inadequate state and local public health personnel and budgets have had on the country’s ability to cope with the COVID-19 pandemic. Its recommendations should address not only how to repair shortfall in particular agencies and jurisdictions, but also, more broadly, how to place public health in the United States on a more appropriate and stable footing.

Infrastructure for Public Health Data

The management of public health data needs to be a specific focus of Commission attention. As noted in the OPCAST Subgroup’s recent report on data issues germane to this country’s COVID-19 response,\textsuperscript{45} traditional public health methodology for managing data is still often manual. As recently as March 2020, the President’s Coronavirus Task Force was requesting spreadsheets of COVID-19 cases from hospitals by fax or email.\textsuperscript{46} This reliance on antiquated data-entry and communication technology, along with imposition of burdensome clerical work on individual clinicians, is not how the United States should be retrieving such essential information in 2020.

Modern digital technology can provide a more complete, more timely, and less onerous approach. Modern data systems could allow immediate tracing of symptoms as people seek help in doctor’s offices, retail clinics, or emergency departments. This sort of \textit{syndromic surveillance} becomes possible when the information from clinical encounters now recorded in Electronic Health Records (EHRs) is aggregated and automatically surveyed by regional, state, and national

\begin{itemize}
\item \textsuperscript{43} Funding for CDC’s Public Health Emergency Preparedness (PHEP) cooperative agreements, which support core public health capabilities in states, territories, and local areas, has decreased from $940 million in FY 2002 to $675 million in FY 2020. The 2010 Affordable Care Act established the Prevention and Public Health Fund (PPHF) and funded it with a permanent appropriation that was to rise to $2B per year in 2015 (Public Law No: 111-148, https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf). The Middle Class Tax Relief and Job Creation Act of 2012 (P.L. 112-96) reduced PPHF appropriations for FY2013 through FY2021 and the 21\textsuperscript{st} Century Cures Act reduced PPHF appropriations for FY2018 through FY2024, each time diverting the appropriated funds for other purposes. The Fund reached $1B in FY 2012 and again in FY 2020; it is not expected to reach $2B until FY 2025. See NORC at the University of Chicago, \textit{An Examination of Public Health Financing in the United States}, March 2013, prepared for the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), https://www.norc.org/PDFs/PH%20Financing%20Report%20-%20Final.pdf
\item \textsuperscript{44} Ed Yong, “How Did It Come to This? Why the Virus Won” \textit{The Atlantic}, September 2020, p. 40.
\item \textsuperscript{45} “Strengthening the Public Health Infrastructure: The Role of Data in Controlling the Spread of COVID-19,” July 28, 2020, \url{http://opcast.org/OPCAST_Public_Health_Data_Report_07-28-20.pdf}
\end{itemize}
public-health offices. This kind of surveillance is not just possible in theory. As the OPCODE Subgroup’s data report cited above noted, while a National Syndromic Surveillance Program (NSSP) already exists, it does not directly use EHR data and is limited in what symptoms are reported.

Better systems are already used in other countries, including ten European nations that have comprehensive health-data systems. The division of public-health data functions and responsibilities in the United States across federal, state, and local jurisdictions and across public and private entities poses particular challenges, however. States have a statutory responsibility for public health in their jurisdiction, but only the Federal government has the (potential) capacity to coordinate data and accelerate collection for national planning and response to emergencies.

Historically, CDC has been the central federal agency responsible for this role. Even with the shortcomings described above, and the tensions attendant on managing relations with hospitals and state and local authorities, the CDC has until recently been the acknowledged national leader in the science of population health, respected globally, and a major source of both expertise and reliable data. On July 10, 2020, however, the White House announced a plan to have hospitals bypass CDC and send all COVID-19 patient information to a central database in Washington daily, still mostly by manual means, with the database to be managed by a private contractor.

Reaction to this move in the public health community has been largely critical. It was argued that the change placed an additional burden on hospitals, that it politicized data collection, that it weakened CDC, and that it risked withholding information from the public. At the time of this writing, it appears that data responsibility has been transferred back to CDC. But the proposal and the furor underscore the need for the careful consideration, by the Commission, of the structural arrangements for management of public health data in this country. What was the rationale for the Administration’s initial switch from CDC? Have CDC’s powers and capacities with respect to data collection been significantly weakened in recent years, and, if so, was that a factor in motivating the change? Is some other form of major restructuring of responsibilities the

answer, or would it be preferable to build up (rebuild?) CDC’s data management capabilities and clarify procedures for its interactions with hospitals and state and local authorities?

Testing for the Coronavirus

Tests that detect the novel coronavirus SARS-CoV-2 have been a critical element in the response to the current pandemic, and the use, availability, cost, and reliability of these tests have been hotly debated. These topics and related issues will be important subjects for investigation by a COVID-19 commission.

Tests for virus are used for at least three purposes: to make a definitive diagnosis of patients with symptoms of COVID-19; to ascertain whether persons who were in contact with diagnosed individuals are infected; and to screen selected groups of asymptomatic people for virus to prevent them from infecting others. The outcomes of testing in all three categories will be important matters for any commission to study.

Many entities—Federal, state, and local governments, and many private institutions and companies—have participated in the development, regulation, use, and interpretation of these tests. Historically, at the federal level, the National Institutes of Health (NIH) has been expected to perform the biomedical research that provides much of the fundamental knowledge required to produce such tests for this and other diseases, whereas the commercial sector has been responsible for designing, manufacturing, and supplying a variety of versions of the tests to be employed in a disease-specific fashion. The FDA has had responsibility for evaluating and approving new tests, and the CDC has been assigned the tasks of guiding the use of the tests and reporting and analyzing the results, in conjunction with state and local public health authorities.

In view of the country’s failure to control the COVID-19 pandemic more rapidly, the Commission should determine whether the powers and budgetary resources provided to the NIH, the CDC, and the FDA by the Federal government were sufficient for them to carry out their responsibilities in this national public health emergency and whether the authorities, funds, and responsibilities need to be adjusted to be better able to confront future pandemics.

It has been widely noted that long-term advances in basic science, especially in genomics and chemistry, have helped to develop tests for the new coronavirus with appropriate combinations of cost, speed in delivering results, sensitivity, accuracy, and amenability to high-volume production and use. Nevertheless, shortages of tests, inconsistent directions about their use, high costs, and restrictions on reimbursement for some purposes were observed to have been impediments to effective use of viral tests during the pandemic.

The failures of the CDC to facilitate testing early in the pandemic and to guide the use of available tests later in the pandemic have been well documented, but the Commission should

52 “The Unique U.S. Failure to Control the Virus,” https://www.nytimes.com/2020/08/06/us/united-states-failure-
provide a definitive history of what went wrong, and what factors may account for the lax laboratory standards that were evident during the early phase. In addition: Why and how was a decision made to reject internationally available tests? Could this decision have been reversed when problems with the CDC-produced tests became clear, and would it have made a difference at that point if it had been? If so, why was the decision not reversed?

The standards by which the Food and Drug Administration (FDA) accords Emergency Use Authorizations for tests should also be re-examined to determine whether such authorization is being allocated too readily (e.g. for the many polymerase chain reaction -based tests for viral RNA\textsuperscript{53}) or too slowly (e.g. for the newer, faster tests for viral antigen that may be held to an inappropriately high standard for sensitivity\textsuperscript{54}). Does the FDA need additional protection against politicization?

Contact Tracing

An essential element in the control of infectious diseases is the identification and tracing of the contacts of infected individuals, testing the contacts for the infectious agent, and quarantining of any who prove to be infected, until the infection is resolved. Many reports have alleged that the United States was poorly prepared to perform such contact tracing and that those deficiencies had a significant role in prolonging and failing to control the pandemic.\textsuperscript{55} The Commission should consider the basis and accuracy of these allegations. Was the United States sufficiently prepared to perform contact tracing in conjunction with diagnostic testing to slow the spread of SARS-CoV-2? How and where should contact tracing be conducted and who should be responsible for organizing such efforts? Should the Federal government establish a unit for testing and contact tracing in one of the agencies of the Department of Health and Human Services (HHS).

Travel Bans

In the early stages of the pandemic, in an effort to reduce the number of infected individuals in the United States, the White House announced three travel bans, prohibiting travelers from entering the United States from China on January 31, 2020, from Europe on March 11, 2020, and from the United Kingdom on March 14. U.S. citizens were exempt. No requirements for quarantine upon entry were imposed. The Commission should examine both the decision-making.
that led up to these bans and the public health effects of the bans themselves. Who made the decisions and on what basis? Were the bans effective in slowing the spread of COVID to or within the United States?

No travel restrictions were imposed within this country, although eventually some states required that visitors from other states needed to subject themselves to quarantine for as long as two weeks after arrival. Would interstate travel bans have made a difference? What lessons can be drawn for the use of travel bans in future outbreaks? Is there a role, and would it be constitutional, for U.S. states to impose travel bans affecting residents from other states? Could such bans be more effective than quarantining people entering states from elsewhere?

Providing Accurate Information to Health-Care Workers and the Public

Traditionally, the CDC has been assigned the authority to provide guidance to the states, localities, and the general public about many aspects of infectious diseases. The Commission should examine the consistency, adequacy, and consequences of announcements regarding COVID-19 issued by the CDC and by other components of federal and state governments. This examination should include guidance on mask use by the public, tests for the coronavirus and for the serological responses to it; prevention and treatment strategies; the timeliness of warnings concerning foreign travel and cruise ship vacations; and information regarding social distancing and lockdown. Particular attention should be paid to situations in which public health guidance changed during the pandemic; how well were such changes communicated to avoid confusion and loss of trust?

The role and effects of social media with respect to the spread of information, misinformation, and conspiracy theories regarding the pandemic should be examined. The Commission should consider producing a classified annex on the role of any Russian or other foreign nations’ misinformation campaigns targeted at the U.S. government, news programs, or the public.

On August 22, 2020, the President of the United States tweeted that “The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd.” This tweeted accusation was disputed by the FDA Commissioner. The Commission should investigate whether there is any evidence that the FDA intentionally delayed the development of vaccines or therapeutics in order to influence the November 2020 election.

Therapies for COVID-19

Scientists in the United States and many other countries became engaged in searches for effective therapies for COVID-19 very quickly after the disease was first described, and they were helped by the growth of knowledge about new therapies against the human immunodeficiency virus (HIV), hepatitis C virus (HCV), and other viral pathogens. New

methods for screening and evaluating new compounds and drugs previously approved by the FDA for other purposes were harnessed in massive, collaborative efforts to find effective treatments for COVID-19. And work was quickly initiated to determine whether antibodies against SARS-CoV-2—either those found in plasma from convalescent patients or those developed as mono-clonal antibodies in the laboratory—might provide benefit to severely ill patients.

Nevertheless, more than six months into the pandemic, no highly effective treatments have become available. One repurposed drug approved for other infections, remdesivir, received an Emergency Use Authorization (EUA) from the FDA based on evidence that it shortens the length of hospitalization. On the other hand, an initial EUA for hydroxychloroquine was rescinded, and some early, potentially promising results with convalescent plasma formed the basis for a controversial ruling by the FDA on its effectiveness.

The COVID-19 Commission should take a close look at the several aspects of the search for therapies during the pandemic. Was the research effort well-organized and monitored by the federal government? Did the FDA make sensible decisions about the issuance of EUAs? Were the components of the U.S. health care system properly informed about available therapies? In particular, U.S. government decision-making and public pronouncements regarding hydroxycholoquine, remdesivir, and convalescent plasma should be examined in detail.

Vaccines

From the first days of the pandemic, it was widely recognized that an effective vaccine could bring the situation under control, assuming public acceptance. Although experience with the development of vaccines against other coronaviruses was very limited, and despite the long timeline to approval of novel vaccines in the past (generally more than four years), the U.S. government quickly established a research initiative (Operation Warp Speed) and provided financial incentives to private industries in hopes of accelerating the development, testing, and production of a vaccine against SARS-CoV-2 at an unprecedented pace. From the outset, it was evident that progress in genomics, virology, gene therapy, and immunology was affecting the design of novel vaccines and that one or more effective vaccines might be available for widespread use in unprecedented time.

While the outcome is not yet known, it is certain that efforts in the United States and elsewhere to speed the development, testing, and distribution of a vaccine should be examined by a COVID-19 Commission, with lessons drawn for both future outbreaks as well as ongoing vaccine production under non-crisis conditions. Special attention should be given to the usefulness of the research collaborations organized by the federal government, to the effects of government subsidies and advance purchases of vaccines that had yet to be tested, and to the plans for phased distribution of vaccines in the United States, as well as plans to work with other agencies, including the World Health Organization (WHO), to distribute vaccines throughout the world.

On September 1, 2020, the Trump Administration announced that it would not be part of a global effort to develop and distribute a SARS COVID-19 vaccine, reportedly in part because of the
involvement of the WHO in that effort. The Commission should examine why this decision was made, assess whether it did or did not affect the timing and availability of a COVID-19 vaccine in the United States, and assess whether there were any significant international consequences of this decision.

State and Local Decision-Making

The Commission should perform a critical comparison and assessment of the variety of state and local responses to the pandemic, especially with respect to key public health decisions.

Numerous approaches short of complete lockdowns were imposed at different times by various states and localities, such as quarantines, temperature-taking on entry to buildings, limiting crowd size, requirements for masks and social distancing, and the closing (and re-opening) of schools, bars, movie theaters, and so on. To the extent possible, the Commission should evaluate the relative success of these different approaches and seek to identify best practices.

Disparate Demographic Impacts of the Epidemic in the United States

By mid-June 2020, 40% of deaths due to SARS-CoV-2 in the United States had taken place in nursing homes and long-term care facilities. The Commission should examine whether federal and state officials could have better protected the elderly, as well as staff, in these facilities. Lessons learned could be propagated prior to future pandemics. Similar questions should be asked about front-line workers in hospitals, essential workers in other professions, and prison staff and inmates.

The COVID-19 epidemic has had disparate demographic impacts in addition to the heavy toll on the elderly. As of August 2020, Black Americans had been twice as likely to die from COVID-19 than White or Asian Americans, for example. Indigenous people were also especially hard hit. Adjusting the data for age differences among different ethnic groups make the disparities even more severe. The Commission should present the most recent reliable final or near-final data on these disparities, probe the reasons for them, and offer suggestions about what governmental entities should be responsible for tracking these differential impacts and seeking to minimize them in the future.


58 Ed Yong, “How Did It Come to This?” The Atlantic, September 2020, p. 38.

Lessons Learned from Other Countries

There were disparate experiences with the pandemic in other technically advanced countries, though nearly all were more effective in their response than was the United States. The Commission should survey and contrast approaches taken by China, South Korea, Australia, Canada, and a variety of European countries, particularly the United Kingdom, Germany, Italy and Sweden. Why were the number of cases in Italy so much larger than those in its neighbors? How and to what extent did these countries reopen successfully?

Conclusions

After the terrorist attacks of September 11, 2001, Congress established the 9/11 Commission to examine U.S. preparedness and response to the catastrophe. After the 2005 Katrina catastrophe, the House of Representatives created a Select Committee with an analogous mandate. The hope was that such examinations would make catastrophe less likely in future disasters. By mid-September 2020, sixty times more Americans have already died from the COVID-19 pandemic than died in the 9/11 attacks. A bipartisan (or better, non-partisan) COVID-19 Commission to examine federal, state, and private sector preparedness and response, and to recommend ways to prevent such a catastrophe from happening again, is clearly needed.

Here the OCAST Pandemic Response Group has tried to lay out systematically the many questions that a future COVID-19 Commission should examine. The scope is necessarily broad, as was true for the 9/11 Commission. There will always be disease outbreaks, and the pace at which infectious agents emerge from animal hosts into the human population seems likely to increase in the coming decades. Preventing these events from becoming catastrophes must be the goal.

By an Ad Hoc Pandemic-Response Subgroup of Former Members of President Obama’s Council of Advisors on Science and Technology

September 28, 2020

Introduction

Many Americans’ first introduction to epidemiological modeling occurred via the media in the first months of the COVID-19 pandemic; and, like so much else associated with the pandemic response, the experience was not salutary. Although many were familiar with the idea of projecting future trends—for example the extrapolation of a company’s quarterly earnings growth into future years—here was something quite different: At a time when coronavirus cases in many places were increasing exponentially, some media and politicians showed projections—models—that had the pandemic rapidly peaking and then rapidly diminishing, while others predicted a series of cycles that might continue for several years. Models varied as to the effectiveness of “flattening the curve” to keep the demand for ICU beds and respirators manageable. Many graphs in the published media showed, as a likely forecast, the disappearance of the coronavirus within a few months.1

It was difficult for the public to understand how, with almost all indicators trending upwards, scientists could predict a near-future peak followed by a decline. Two explanations were frequently given: “herd immunity” that might occur naturally,2 and R₀ (the virus’ “basic reproduction number”) that might, by social distancing measures, be brought below the critical value of 1.0, slowing and ultimately halting virus propagation.3

These were difficult ideas to communicate. The dependence of the models on input data—which were scarce and often unreliable early on—was often glossed over. The models themselves were incomplete. Recognition of such real effects as asymptomatic transmission, aerosol transmission, and super-spreaders came only gradually. Scientific understanding was changing with time, communication channels to the public were cluttered with noise (not least from the Executive Branch), and the character and implications of continuing uncertainties were sometimes lost in translation.

The consequences of these shortcomings—especially the lack of clarity around genuine scientific

uncertainty—are not small. The public’s respect for science has been undermined in ways whose full damage has yet to manifest itself, for example, in people who will be reluctant to agree that a properly developed and tested future vaccine will be safe and effective, and who may thus refuse vaccination. It is also disheartening to see respected public health authorities backing away from epidemiological modeling as a useful tool in time of pandemic crisis (even if their statements are narrowly accurate),4 since, as we will explain, modeling is one of very few tools available for guiding policy responses.

The purpose of this report is to give our views on (i) what went right and what went wrong; (ii) what are the weaknesses in the field of epidemiological modeling, and in its federal support, that made its sub-optimal showing in time of crisis almost preordained; and (iii) what needs to be changed, so that in future crises modelers can be more effective in providing accurate models and estimates of model uncertainty, communicating more effectively to the public, and connecting more effectively to policy makers facing difficult real-time decisions. This is not a case of simply “send more money.” We will show that epidemiological modeling is, in a sense, an “orphan” field;5 and we will make specific recommendations for changes inside federal agencies and for new kinds of initiatives to support academic research on modeling.

This is not about finger-pointing. Rather, the coronavirus pandemic has exposed this deficiency (among many others) in how public health in the United States is organized, prioritized, and funded. If the nation takes necessary steps now, it will be better off during future pandemics.

Why Is Modeling Necessary?

With the goal of understanding how diseases spread in populations, epidemiology must rely on incomplete data from natural disease outbreaks—by definition such data are gathered in times when its meticulous curation may not be a high of priority. Epidemiology is an observational, not an experimental, science. Science advances by putting forth hypotheses that can be objectively evaluated. In experimental fields of science, for example molecular biology or accelerator particle physics, critical experiments can be designed to distinguish cleanly among new and old hypotheses. In observational fields, no single set of data plays the role of such experiments. Rather, there is a need for an intermediate construct—an evolving model—that, on the one hand, embodies a continuing set of hypotheses or assumptions; and, on the other hand, makes predictions that can be compared to new observational data that may become available.6 Observational fields advance less often by single “eureka!” observations (i.e., akin to critical

4 Dr. Anthony Fauci on Fox News: “Models are only as good as the assumptions that you put into the model…. When real data comes in, then data in my mind always trumps any model.” April 10, 2020, at https://www.foxnews.com/media/fauci-coronavirus-mitigation-programs-models-china-italy


experiments), and more often by combining the steady acquisition of new data with the steady improvement of models. The data must be robust, timely, and granular, as addressed in a previous report by our group.\(^7\)

Since it must make quantitative predictions, a model is, by definition, a mathematical construct. Simple models may be algebraic equations that can be solved “by hand”. Somewhat more complicated models may be “ordinary differential equations” whose left-hand-sides are the rates of change of quantities of interest with time (infections, cases, deaths, etc.), and whose right-hand-sides embody the effects that drive such change. Nowadays, models are often expressed algorithmically, i.e., as computer programs, sometimes highly complex and computationally demanding, requiring supercomputing capabilities. An example of complexity is so-called “agent-based modeling”, where the model may represent in a computer the individual daily activities of a hundred thousand or more simulated inhabitants of a city, keeping track of how often each interacts with others and infects (or is infected by) them.

Stepping back for a moment from epidemiology, the observational sciences astronomy and meteorology provide some useful perspectives on both the nature of modeling, and on how models can be practically harnessed. Models often contain a mixture of assumptions that are scientifically rigorous (like Newton’s laws of motion) and assumptions that simply describe empirical regularities in the data (like the “seasonal adjustments” that are applied to retail sales figures). Both kinds of assumptions are useful. The more empirical a model is, the more likely it is to be improved by new and better data—both to tune its parameters and also to guide the improvement of underlying theory. Astronomy provides an historical example. Ptolemy’s 2nd century *Almagest* expressed its geocentric model as detailed mathematical tables. Planets moved in epicycles (roughly, circles upon circles) inside the celestial sphere. The model’s geocentric assumption was of course completely wrong. But its quantitative predictions—exactly where each planet would be observed in the sky on a given date—were in fact quite accurate. Not until the 17th century did observations become precise enough to show discrepancies.\(^8\)

Another lesson, also from the history of astronomy, can be drawn from the rare transits of Venus across the solar face in 1761 and 1769. From the precise timing of these events, the absolute size of the solar system could be deduced—using a Keplerian model. Competing expeditions from multiple countries were launched. Not unlike the recent COVID-19 experience, the answers obtained were wildly discordant, and the whole enterprise was widely deemed a failure. Forty years later, the great mathematician C.F. Gauss improved the model and was able to get a single accurate result from the old, disparate data. How? Gauss invented the idea of a *statistical model*. Although Kepler’s model was (nearly) exact, the observations were not. Gauss first understood that data should be viewed as one instantiation of a statistical distribution (i.e., repeated observations of the same phenomenon will never be exactly the same), and that the model must

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\(^8\) Interestingly, Copernicus’ heliocentric model gave no more accurate predictions than Ptolemy’s, because Copernicus kept the faulty assumption of circles. It was not until Kepler’s introduction of elliptical orbits that the model’s predictions actually improved.
include properties of the appropriate distributions. Superior models are often more sophisticated in their application of statistical theory.

Meteorology (as a basic science) and weather forecasting (as its practical application) are also relevant examples. For a long time, the limiting resources were computer power, which determines the models’ smallest spatial resolution, and the availability of data. Weather prediction has improved significantly as computing power has grown and data have become more abundant. The challenge now is to master the complexity of the physics and chemistry of weather, and the ways in which even small inaccuracies in modeling present conditions are magnified as models predict further into the future. Below, we will also look to weather prediction as an example of how a field spanning basic research and operational mission can be organized at the federal level.

Epidemiological models today span a range from more empirical to more driven by well-established biomedical science, from more mechanistic to more statistical, from models that can be run on a laptop to those requiring a supercomputer. As continuing academic research, this diversity of approaches is a good thing—but only if there are institutional mechanisms for evaluating models for soundness and maturity, further developing those that show promise and also evaluating models for readiness for use in practice. In time of crisis, this diversity can also be a good thing—but only if there are institutional mechanisms for coordinating, summarizing, and communicating the most robust predictions of the ensemble of models to decision-makers in real time. It is those institutional mechanisms that critically need strengthening, and on which we will make recommendations.

**Types of Epidemiological Models and Their Different Uses**

As a rough taxonomy, epidemiological models may be divided into three classes: *compartamental* models, *network* models, and *statistical-empirical* models—noting that individual models may have elements of more than one type.

**Compartamental models**

Also called mass-action models, compartment models assume some degree of homogeneity within a population—for example that every infectious individual has the same probability of infecting every susceptible individual. Every individual is assigned to a “compartment”. The most famous compartamental models, SEIR (for Susceptible, Exposed, Infectious, and Recovered) and SIR (lacking the Exposed component) have been taught in every graduate school of public health and with precursors dating back to the 1920s. In the simplest formulations, ordinary differential equations (ODEs) describe the time history of the fraction of population in each compartment.

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Compartmental models contain adjustable parameters that are different for different diseases, and can be different in different populations (e.g., Italy vs. Germany). Early, and then continuing, data for a given epidemic must be used to fit for these parameters before useful predictions can be made. If the parameters are inadequately determined, or if their changes in time due to policy interventions or other effects are not accounted for, the model predictions can be wildly wrong.

Simple compartmental models can easily be implemented on a laptop by anyone with even modest epidemiological and mathematical skill. It is by now clear that much of the confusion about modeling in early months of the coronavirus pandemic was due to haste by well-meaning individuals of varying backgrounds in implementing simple compartmental models, seeding them with incomplete data of variable quality, and putting out predictions that ranged from reassuring to apocalyptic. The confusion was magnified by the (again, well-meaning) decision of many scientific journals to publish submissions prior to peer review, albeit so labeled, and further magnified by the lack of any U.S. nationwide institutional infrastructure with an accepted role for sorting out the confusion and giving authoritative advice.

More elaborate, state-of-the-art compartmental models replace simple ODEs by sometimes complex statistical models for how individuals transition between compartments; and by increasing the number of compartments (or subdividing existing ones) to mitigate the assumption of absolute homogeneity. So-called metapopulation models consider sets of local populations connected by migrating individuals. Models may also differ in the sophistication with which they incorporate initial or ongoing data, for example using machine learning (ML) techniques.

A recognized world center in predominantly compartmental, mechanistic, modeling is the Medical Research Council (MRC) Centre for Global Infectious Disease Analysis (GIDA) at Imperial College, London. Chartered in 2007 by the British government as a national center of excellence, GIDA has come to be regarded as the U.K.’s authoritative resource on epidemiological modeling. It has been able to establish close connections to the U.K.’s national public health authorities, and has “a seat at the table” in times of crisis management. The United States has no similarly authoritative, dedicated capability. GIDA will serve as a model for some of our recommendations, below, although we recognize some of its shortcomings as a single institution (thus without the advantages of multi-institution competition) serving two distinct missions (advancing science, crisis readiness), and with a single dominant methodology (elaborated SEIR).

Network models

This class of models breaks the assumption of population homogeneity in one of several ways. Agent-based models were already mentioned. These break homogeneity all the way down to single (if simulated) individuals with heterogeneous characteristics deduced from detailed census, social network, cell-phone mobility, or other fine-grained, data. Notably, these models then

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11 GIDA was formerly called the Centre for Outbreak Analysis and Modeling.

simulate “actual” daily lives of large numbers of these “agents” in their home-work transportation patterns, workplace densities, shopping, recreation, and so forth, in a specific, usually urban, setting, e.g., Wichita, Kansas. Multiple simulation runs may be made so as to estimate variability. Agent-based models have large numbers of parameters to set, but many of these can be set via data other than epidemiological, e.g., phone data, traffic density, retail sales, etc.

In contrast to agent-based network models, some other network models can be more abstractly statistical in construction, representing the contact patterns of individuals by a social graph whose vertices represent individuals and whose connecting lines represent, for instance, the probability that one individual will infect another. Social graphs can have multiple layers and multiple scales, embodying the nested and overlapping effects of families, friendship groups, social gathering sites, schools, socio-economic or ethnic communities, and so on. Models can be “run” by instantiating a graph with the desired statistical properties and then propagating the disease on it in simulation, or by inferring results from the underlying statistical features of the graphs using a combination of simulation and analytic methods.

In contrast to compartmental models, network models can model local outbreaks, “second waves”, and other dynamics due to disease propagation from community to community. Network models can distinguish variability due to public health interventions (social distancing, masking, etc.) from variability due to underlying population inhomogeneity. The additional potential of network models, as compared to compartmental (i.e., mass-action) models, can be especially important for forecasting the later stages of an epidemic: Mass-action models must generally predict rapid exponential decay when $R_0$ falls below one. Network models can show the more complicated dynamics of complicated social networks with pockets of disease. (Metapopulation models are an intermediate case.\textsuperscript{13}) For COVID-19, rapid exponential decay has been seen sometimes, but not always. In the United States thus far, it is the exception, not the rule.

\textbf{Statistical-empirical models}

Models of this type seek to predict disease dynamics by carefully curating an ensemble of experiences at various locales—for example, the rise and subsequent fall of coronavirus cases in individual cities in China, Italy, and Spain, and then finding the best statistical matches of the current data in a place of interest (e.g., New York City) to that ensemble. Efforts at utilizing this technique by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington attracted much attention early in the coronavirus pandemic, because of the model’s seeming ability to make predictions without any detailed knowledge about the underlying disease—how it was transmitted, what its infectious period was, and so forth.

The model’s defenders asserted that their underlying data—epidemiological curves—were more, not less, directly related to the desired predictions of cases and deaths than is the case with other model types. Unfortunately, IHME’s model predictions changed greatly as new data were

\textsuperscript{13} See, for example, a model description at https://wwwnc.cdc.gov/eid/article/26/10/20-1702-app1.pdf
incorporated; and they became politicized when the Trump Administration cherry-picked the more favorable results.\textsuperscript{14} Judgment on whether statistical-empirical models can play a useful role must thus await further research and calmer times.

\textbf{Varying uses for models}

In addition to there being different types of epidemiological models, each can be optimized for quite different uses. Here are four examples:

- For advancing the basic science of epidemiology, a model may be entirely retrospective, using the historical data of a past epidemic as well as properties of its disease known from basic biomedical research. Such a model need have no predictive ability at all. Data from late stages of an epidemic may shed light on its early stages—only possible after the fact.

- During an epidemic, fragmented and incomplete data are inevitable. From the raw data alone, it is hard to know what is the true, current state. Models can provide a unified situational awareness (sometimes called “nowcasting”). Here also, prediction/forecasting, other than from the immediate past to the immediate future, is not the purpose of the model.

- Forecasting is of course the most difficult application.\textsuperscript{15} Not only does a model embody assumptions about the past and present, it makes assumptions about the future (e.g., public health policy interventions and the reaction of the population to them) that may turn out to be different from what is anticipated. Even if its disease model were perfect, epidemic forecasting would be quite different from weather forecasting: When NOAA forecasts a hurricane, authorities may tell people to take shelter—but their doing so does not change the path of the hurricane! During an epidemic, the customers for forecasting include not only public health authorities, and the public at large, but also the pharmaceutical industry. Choosing the right time and place for drug and vaccine trials may rely on predictions of when and where cases are likely to occur.

- Closely related to forecasting, but distinct, is the use of models to support decision-making by federal, state, and local authorities.\textsuperscript{16} Sometimes called “counter-factual analyses”, these models are optimized for questions like, “if we do this, how many \textit{fewer} deaths will occur”. This application cares less about absolute predictions, more about differential predictions among sets of policy alternatives. In this application, a model may be embedded in a stochastic optimization program capable of answering a quantitative question like: “What combination of new case rate, testing positivity rate, and hospital ICU occupancy should be the threshold for relaxing lockdown restrictions from Stage 3 to Stage 2?”\textsuperscript{17}


\textsuperscript{15} Yogi Berra is inevitably here quoted: “It's tough to make predictions, especially about the future.”


\textsuperscript{17} Stochastic optimization is a methodology for trying many different parameter values until one finds an optimal
How Has Epidemiological Modeling Been Supported in the United States?

In recent years, a patchwork of federal agencies has provided resources in support of epidemiological modeling, both for research and development as well as for operational use in time of crisis. A partial list of model-supporting agencies includes: the National Institutes of Health (NIH), the National Science Foundation (NSF), the Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the Department of Homeland Security (DHS), the Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response (DHHS/ASPR), and the Defense Threat Reduction Agency (DTRA). There is little coordination among this alphabet soup of agencies. In the period leading up to COVID-19, moreover, the overall trend was towards decreasing support.

For much of the first part of the current century, NIH’s National Institute of General Medical Sciences (NIGMS) was a leader among federal agencies, with its program called Models of Infectious Disease Agent Study (MIDAS). Many practitioners whom we interviewed cited MIDAS as significant in the development of the field. Indeed, MIDAS seemed poised to effectuate many of the functions that we recommend as necessary, below. MIDAS once funded centers of excellence in epidemiological modeling at universities including Harvard University, the University of Pittsburgh, the University of Chicago, the University of Washington, Yale University, the University of Virginia, and Northwestern University. Unfortunately, a combination of budget cuts and retiring staff at NIH reduced MIDAS to a pale shadow of what it was (or could have been). While the program continues in name,18 functioning primarily as a communications hub for researchers and public health practitioners and facilitating the awarding of some small grants. There also exists within NIH a small effort in modeling cross-national epidemics (especially flu) in the Division of International Epidemiology and Population Studies (DIEPS) of the Fogarty International Center.

At NSF, some epidemiological modeling is supported by the program on Ecology and Evolution of Infectious Diseases (EEID) within the Directorate for Biological Sciences. The scope of this support is limited by two realities apart from budget: First, since NSF does not in general support the study of human disease (that being considered NIH’s domain), NSF’s program must focus on other useful but arguably peripheral aspects, for example the evolution of zoonotic diseases in animals. Second, as a matter of policy, NSF limits its salary support of most principal investigators to two months annually;19 but much of the research on epidemiological modeling (not NSF-funded) is conducted in medical schools and schools of public health that expect their faculty to bring in twelve-month salary support. NIH does allow twelve-month salaries (but with a cap on salary levels). Previously, there existed a level of cooperation between NSF/EEID and NIH/MIDAS, allowing for coordinated funding to some researchers; but apparently this cooperation has decayed with the decline of MIDAS.

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18 See https://midasnetwork.us/.
19 NSF Grant Proposal Guide section II.C.2g(i)(a) at https://www.nsf.gov/pubs/policydocs/pappguide/nsf09_1/gpg_2.jsp
Within DHS, there previously existed a pandemic response effort in the National Infrastructure Simulation and Analysis Center (NISAC). NISAC was started in 1999 as a collaboration between the Los Alamos and Sandia National Laboratories. Its oversight was later moved to DHS, but it continues to have access to DOE supercomputing facilities. NISAC’s scope included pandemic response as well as other kinds of natural disasters (hurricanes, earthquakes, etc.). NISAC’s Incident Response Fast Analysis and Simulation Team (FAST) connected policymakers to the national labs for immediate situational analyses. In 2016-2017, however, at the direction of senior DHS officials, NISAC’s effort in pandemic response was largely dismantled, with a sudden shift of priority to cyber-threat machine learning. A news report quoted a former official: “They’ve allowed a lot of capability to decay, including the pandemic models and transportation models and a whole bunch of other stuff in favor of chasing the soccer ball on different cyber things.”

Since 2013, CDC has supported the real-time curation of seasonal flu forecasts from multiple academic and private industry researchers. Twenty-four different teams participated in the flu forecasting initiative during the 2018-2019 flu season, and winners were declared, providing motivation for the cross-fertilization of best practices. Separately, the Intelligence Advanced Research Projects Agency, IARPA, also sponsors a flu forecasting competition. With the onset of the COVID-19 pandemic, CDC has partnered closely with the volunteer COVID-19 ForecastHub effort at the University of Massachusetts Amherst to maintain a COVID-19 Mathematical Modeling portal. The portal curates and displays the model predictions of dozens of geographically and methodologically scattered forecasting efforts with respect to deaths, hospitalizations, and cases. This effort is a fruitful example of academic-government partnership, especially for the speed in which it has been stood up under crisis conditions. Such “ensemble modeling” is, in other fields, a proven method for getting more accurate predictions, and also for advancing state-of-the-art.

Noteworthy, however, is that the “data” for this useful effort, namely the outputs from the multiple models, flow from outside CDC to inside. Historically, relations between CDC and the academic forecasting/modeling community have been difficult at times, because the necessary

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22 “FluSight: Flu Forecasting” at https://www.cdc.gov/flu/weekly/flusight/index.html . “Los Alamos National Laboratory, led by Dr. Dave Osthus, provided the most accurate national-, regional-, and state-level influenza-like illness forecasts. … The Delphi group at Carnegie Mellon University, led by Dr. Roni Rosenfeld, provided the most accurate national-level hospitalization forecasts.”
data flow to advance the field of epidemiological modeling is in the other direction, from CDC to outside research groups; and CDC has not been seen as being supportive of that. In the case of flu, CDC is the recipient of vast amounts of data from state and local public health authorities. The data are (or can easily be) aggregated so as to avoid patient privacy issues. Several leading academic investigators expressed to us their frustration at being unable to obtain these data for retrospective research purposes at city level of aggregation. The problem appears to be less the existence of any formal policy forbidding it, and more that the support of basic epidemiological research in this way is not seen by CDC as a mission priority. That needs to be changed.

Within the Department of Defense, DTRA’s Technical Reachback program provides 24/7/365 capabilities for combatant commanders to get immediate technical advice relating to battlefield environmental hazards, including biological releases. The program has funded some research in epidemiological modeling.

USAID’s PREDICT program of epidemiological research, while not specifically aimed at modeling, supplied large amounts of data of value to epidemiological modeling, including the identification of more than 160 novel coronaviruses. The program was curtailed in 2019 by the Trump administration and terminated in March, 2020. In response to criticism from Senators Angus King and Elizabeth Warren, the program was then extended for six months with a small amount of funding.

The coronavirus pandemic has prompted increased interest in modeling by the pharmaceutical industry. Clinical trials of drugs require that there be enough diagnosed cases of the disease to enroll a statistically sufficient number in the trial. Trials of vaccines require enough natural cases of disease in the unvaccinated control group. Forecasts of when and where outbreaks may occur are thus important. In the present pandemic, as one example, Johnson & Johnson systematically reached out to a number of academic and other modeling groups to create, in effect, its own ensemble model, which it is using to guide decisions about when and where to activate trial sites and set enrollment levels. It is salient that this was an impromptu effort within one company—that there was no pre-existing government or academic infrastructure in place to support this important application.

**What needs to be done?**

Two points should by now be evident: (i) that epidemiological modeling can and must play an important role in pandemic response, and (ii) that, within the federal government, it is an orphan field. Before we suggest remedies, let us step back and consider a quite different, yet in many ways analogous field, namely weather forecasting and the fundamental research behind it.

Meteorology, and closely-related climate science, are, like astronomy and epidemiology, observational sciences, relying on the fusion of data and models to advance. Meteorology relies

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on an undergirding foundation of basic science, but (unlike most astronomy, say) the field also has a critical operational mission. The nation (and world) depend on timely, accurate weather forecasts. The economic value of such forecasts, some tens of billions of dollars annually, justifies government and private investment in an entire value chain consisting of (i) basic atmospheric research, (ii) the development of large-scale (supercomputer) climate and weather models for research, (iii) the operationalization of those models (and combining ensembles of independent models) for 24/7 weather forecasting and longer-term forecasts of climate-change impact, (iv) the distribution of forecasts, in formats of practical utility, to policy-makers, private-sector companies, and consumers.

In the United States, this value chain is predominantly coordinated by two federal agencies. A somewhat simplified description is this: NSF supports basic science as the lead research agency, in large part through its National Center for Atmospheric Research (NCAR) in Boulder, Colorado. Managed by a consortium of universities, NCAR integrates model development, observations, and supercomputer facilities. The National Oceanic and Atmospheric Administration (NOAA), as the lead mission agency, conducts more-applied scientific research and operates weather and other environmental satellites and their data flows. Then, NOAA’s National Weather Service (NWS) operationalizes forecast codes, ingests voluminous data, produces forecasts, and particularizes these forecasts to user needs through 120 local weather-forecast offices.

The analogies are clear. In times of pandemic, the economic value of good epidemiological forecasts would be large—potentially saving trillions of dollars. Even in the case of annual flu epidemics, savings in the billions might be attainable with targeted public health measures. Advancing the state-of-the-art of epidemiological modeling requires long-term, robust basic research (NCAR-like). It also requires coordinated mechanisms for operationalizing and communicating this research to decision makers, the public, and the private sector (NWS-like). Above all, it requires a clear assignment of responsibility to appropriate federal agencies, along with budgets that allow them to meet those responsibilities.


declarations

We make three high-level and then four more-specific recommendations. Our high-level recommendations are these:

**Recommendation 1.** The National Science Foundation should be the lead research agency with primary responsibility for supporting basic and initial translational research in epidemiological modeling, with new Congressionally appropriated funding.

NSF, especially through NCAR, has extensive experience in large-scale modeling in support of basic research. It also operates national supercomputer centers. In addition to basic biological sciences, NSF has outreach into fields necessary for the success of the

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interdisciplinary field of epidemiological modeling, for example, evolutionary and environmental biology, computer and computational science, and data science. No other basic science agency has this scope.

**Recommendation 2.** The Centers for Disease Control and Prevention should be the lead mission agency, with primary responsibility for operationalizing the research results of NSF’s research program.

CDC would be the epidemiological analog to NOAA and NWS. Only CDC has the ability to gather data from state and local public health agencies and to distribute back to them actionable recommendations. We define this role further below.

**Recommendation 3.** The National Institutes of Health and the Department of Energy should have defined (and funded) partnering roles with NSF and CDC in epidemiological modeling.

Both NIH and DOE have experience in operationalizing translational research that augments that of NSF and CDC. In addition, both agencies bring necessary subject-matter strengths.

NSF is not, by charter, well-suited for emergency response, while both DOE and NIH are combined research and mission agencies able to meet operational needs in real time. Among all science agencies, DOE leads in the use of large-scale modeling in support of its missions. DOE has a long history of expertise in and support for supercomputing, primarily through many of its national laboratories, which provide the most powerful U.S. supercomputing capabilities in the public sector. DOE’s national laboratories can play a crucial role in the computational aspects of epidemiological modeling. NIH has primary responsibility for the study of specific disease states and supports the scientists most knowledgeable about those diseases. Both NIH and NSF have previously successfully partnered with DOE. A “blueprint” for such collaborations in biomedical areas, and testimony as to their success, was recently briefed to Congress.

Involving DOE in the provisioning of computing and data resources (especially surge and operational capacity) across research needs (partnering with NSF) and operational needs (partnering with CDC) will facilitate the translation of research models to operational use.

Since NSF lacks a mandate in human health science, its partnering with NIH in supporting the basic biomedical science of modeled diseases is essential. NIH engagement will help to tether the work of modelers to the biological realities of the particular disease being modeled. NIH also has the benefit of the experience of its previous MIDAS program. While NIH lacks

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32 In Congress, on the House side, DOE has the same authorization committee (Energy and Commerce) as NIH. On the Senate side, it is overseen by the Committee on Energy and Natural Resources.

a well-developed culture in mathematical modeling in general, and in the provision of supercomputing facilities for modeling in particular, partnering between NSF and NIH will help to build such a culture, so that successor efforts to MIDAS can be more sustainable.

Both DOE and NIH are able to fund the twelve-month academic salaries of individual principal investigators, and they should commit to co-funding epidemiological modeling researchers in institutions requiring twelve-month salary funding.

Our more specific recommendations are these:

**Recommendation 4.** Starting immediately, the National Academies of Science, Engineering, and Medicine (NASEM), with funding from NSF and NIH, should establish a series of workshop conferences on modeling, with the aims of creating a community of modeling researchers, benchmarking the field, and facilitating the transition of models from research to operational settings.

These workshops should bring together practitioners from different modeling communities, including the private sector, representing a wide range of model types and applications as well as a range from basic research to operational use and decision support. The workshops should explore such themes as how to benchmark models against each other and against data, both in real time and retrospectively; how to transition models from research to operational settings; how model results can best be communicated to the public; what kinds of products are most useful for decision-makers; and so forth.

Currently, the remaining parts of the MIDAS program perform some similar functions; but the greater convening power and influence of NASEM is now warranted. It is time to create a broad community of modeling researchers who can cross-pollinate advances in modeling research.

**Recommendation 5.** Approximately five university-based national centers for epidemiological modeling research should be chartered by NSF by competitive selection, with funding funded from a new Congressional appropriation at approximately $10-$15 million per year each for five years.

These centers collectively would be the analog of NCAR. In today’s world, however, it makes more sense to have a larger number of distributed centers, not a single one. It is important to get the selection criteria right. Each center should have an empowered director, an external advisory committee, and a coherent program for research, education, and outreach. The U.K.’s GIDA (discussed above), with strong collaborations between modelers and disease experts, is a useful model; but our centers should not take on the roles that we describe as better suited for CDC as the lead mission agency.

A center should not be a loose association of principal investigators pursuing their own unrelated programs, and it will be essential to enforce this requirement during the selection process. Each center should have a specific focus and a coherent program of research, without unduly constraining the creative exploration of individual researchers. Because public health is a state and local responsibility, the centers should be geographically diverse.
Partnering relationships with state and local public health organizations, as well as partnering with researchers at other universities should be an essential requirement, as should be programs for training the next generation of modelers and receptive decision-makers, for example, at summer institutes.

Centers should be free to use part of their funding to support collaborating researchers at other institutions. Collaborations with the private sector should be encouraged. An understanding of the ways epidemiological modeling is used in industry should help to inform the modeling topics addressed by the Center. Models of use to industry may be different from other models. A vaccine trial may, for example, have as a defined endpoint reduction of “moderate to severe infection,” which is different from the more-often modeled reductions of “cases” or “deaths”.

Within their universities, the centers should be interdisciplinary organizations able to draw on expertise in departments spanning biomedical science, evolutionary and environmental biology, computer and data science, etc. Sitting a center wholly within a school of public health would not, in our view, harness broad enough perspectives and thinking “outside the box”.

**Recommendation 6.** CDC should create, and Congress should fund, a new “Office of Epidemic Forecasting and Analytics” (or an equivalent name) responsible for implementation of CDC’s role as the lead mission agency.

This office would be responsible for operationalizing the research result of the university-based centers, developing epidemiological data streams to be fed back to researchers on a continuing basis, preparing for epidemic crises, and, in time of crisis, generating and authoritatively communicating model forecasts and their uncertainties to federal, state, and local decision-makers, to the public, and to industry. By policy, this office would be represented (“have a seat at the table”) in the specific incident command structures activated by CDC for particular emergencies.  

An analysis by C. Rivers and D. George suggests a budget level of about $80 million per year for this office.

Patterning on NSF’s so-called “rotators”, the office should make use of hiring authorities under the Intergovernmental Personnel Act of 1970 (IPA) to bring into CDC members of the research community for periods of up to two years. It should partner with DOE for the provision of supercomputer resources.

The office should have engagement with the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE), and

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34 “CDC Emergency Operations Center (EOC)” at [https://www.cdc.gov/cpr/eoc/eoc.htm](https://www.cdc.gov/cpr/eoc/eoc.htm).
35 Ref. 31 above and additional unpublished communication.
work to build key capacity—specifically, the ability to integrate model results into decisions—at state and local levels. The office should also develop, in advance of any epidemic, protocols for the rapid use of its ensemble of models by pharmaceutical companies in their planning and executing of clinical trials and other time-critical applications.

**Recommendation 7.** DOE, with new funding from Congress, should create a new subprogram of its Advanced Scientific Computing Research (ASCR) program and assign it responsibility for supporting the missions of both the NSF and CDC in epidemiological modeling.

DOE and ASCR should consider how best to be the “bridge” between research and operations (including emergency operations). We view this as a crucial role that only DOE can fill. Beyond supplying bulk computer capacity (as, for example, at its Oak Ridge Leadership Computing Facility), DOE should actively engage researchers at its national laboratories in support of this mission, including preparing them to be rapidly available scientific resources in time of emergency.

**Conclusion**

Epidemiological modeling is an important but under-supported field of science that lacks a clear home among the federal science-funding agencies. Additional basic research and translational work in the field is needed between pandemics, and greater operational capabilities are needed during epidemics. We have identified here a series of actions that can strengthen modeling efforts and their operationalization, to make the country better prepared for the next pandemic.

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