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Positioning America's Public Health System for the Next Pandemic

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HEALTH PROJECT

Under the leadership of former Senate Majority Leaders Tom Daschle and Bill Frist, M.D., the Bipartisan Policy Center's Health Project develops bipartisan policy recommendations that will improve health care quality, lower costs, and enhance coverage and delivery. The project focuses on coverage and access to care, delivery system reform, cost containment, chronic and long-term care, and rural and behavioral health.

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Executive Summary

The COVID-19 pandemic has made clear that the nation's safety, health, and economic prosperity are dependent on a robust public health system.

Federal public health agencies and state and local public health departments have long been severely underfunded. They have lacked the workforce and modern data systems to support surveillance, contact tracing, testing, guidance on mitigation measures, administration of vaccines, and clear communication that is needed to stop infectious diseases from spreading across the country. In the beginning of the current pandemic, the federal government did not provide effective testing kits or clear and timely guidance to states, localities, tribes, and territories on COVID-19 mitigation measures, resulting in a delayed and fragmented national response. In addition, many Americans have chronic underlying health conditions such as obesity and heart disease, leaving them more likely to develop severe illness from the virus that causes COVID-19. Public health agencies and departments lack the resources to support prevention programs that might have reduced the prevalence of these conditions. Further, there are long-standing racial and socioeconomic inequities with respect to health and health care access.

Had these shortcomings not existed, the United States death toll might have been smaller. It is also true that if vaccine development had been delayed further, the death toll would have been higher. As of the end of May 2021, the U.S. has the highest mortality numbers in the world, with more than 592,000 deaths from COVID-19.[1] Communities of color disproportionately represent these deaths. Tens of thousands more Americans are living with the persistent and debilitating symptoms from COVID-19, including brain fog, headaches, and shortness of breath.

Halfway into 2021, the United States is on better footing. There has been a whole-of-government response to the pandemic along with clearer federal guidance issued to public health departments. Congress has appropriated additional resources to the public health sector, which is engaged in a historic national vaccination effort. As of the end of May, more than half of adults received at least one dose of a COVID-19 vaccine and deaths are at the lowest level in 11 months. The economy is recovering, and Americans are expecting a return to a more normal life.

But even as the pandemic is easing, the United States must prepare for possible additional waves of disease from this pandemic, potentially caused by new virus variants, as well as plan for future public health emergencies.

The nation remains vulnerable to myriad threats, including from another dangerous infectious disease, a widespread natural disaster, or a potential bioterrorist attack, each of which could impact almost every sector of the economy, disrupt social connections, and have significant long-lasting health impacts. Equipping the public health system with an adequate and prepared workforce, data systems, and medical countermeasures will enable the country to better withstand not only a pandemic, but any number of other public health emergencies.

Shoring up the system will take years of consistent effort by public health officials and policymakers. In the past 20 years, the nation has responded to every public health crisis with temporary funding measures that have not provided state and local public health departments with the people and the information technology tools needed to build enduring programs which address Americans' poor health and adequately prepare for a future emergency. This moment must be different. There is heightened appreciation for the critical role of public health. A May 2021 survey from the Harvard Opinion Research Program and the Robert Wood Johnson Foundation found that over 70% of adults "favor substantially increasing federal spending on improving the nation's public health programs," and the same proportion believe public health agency activities are very or extremely important to the nation's health.[2]

Since August 2020, the Bipartisan Policy Center's Future of Health Care Initiative leaders have been developing and supporting recommendations to improve the resilience of the nation's health care and public health systems to address the threat of COVID-19 and beyond. In January 2021, the Future of Health Care leaders released a report outlining high-priority immediate actions that the administration and Congress should take in combating COVID-19. In this report, the leaders have developed additional recommendations to ensure that the public health system, specifically, not only continues to respond to COVID-19, but that it is well-prepared to respond to and mitigate the consequences of a future pandemic.

Our recommendations focus on three areas: 1) creating clarity and accountability in federal leadership and operations during a pandemic; 2) improving public health information technology and data systems; and 3) committing the United States to more and consistent funding of public health to prepare for inevitable public health crises.

There are 10 overarching recommendations in this report:

1. Clarify and strengthen federal operational roles and responsibilities during a federal response to a pandemic.

To improve the nation's federal response to emergency events such as a pandemic, the White House and Congress should clearly define roles, responsibilities, and authorities for all relevant governmental entities. Because

only the White House has the authority to direct federal departments to work with one another and coordinate their efforts, the president should appoint a White House Deputy National Security Advisor for Pandemic and Biothreats Preparedness to provide leadership to prepare and respond to national public health emergencies and conduct joint pandemic planning efforts including exercises to refine roles and responsibilities. White House leadership and coordination of agency preparedness should be supplemented by congressional evaluations of roles and responsibilities to ensure federal entities have the necessary authorities and resources to execute emergency pandemic response efforts.

2. **Incentivize states to participate in a coordinated response to national public health threats.**

The patchwork of state responses to COVID-19 raises salient concerns about barriers to a coordinated national response during public health emergencies. States and localities have the flexibility to appropriately tailor public health activities to their community needs. However, it is still vital for states and localities to follow federal evidence-based guidelines for disease mitigation during a pandemic. Congress and the executive branch should create incentives to encourage states and localities to follow these guidelines and best practices. These incentives could involve additional financial resources beyond core funding, such as providing supplemental public health funds, to enhance a state's pandemic response.

3. **Establish a National Board on Pandemic Preparedness to provide oversight and ensure the United States is equipped to respond to future public health threats.**

There is no congressionally chartered oversight mechanism for evaluating the state of America's pandemic preparedness system, which is reliant on the capacity, capabilities, and coordination of federal, state, and local agencies. This lack of oversight leaves the nation vulnerable to a suboptimal response to public health emergencies and future pandemics. To ensure the United States is equipped to respond, Congress should create an independent National Board on Pandemic Preparedness that will establish a set of metrics and benchmarks for evaluation of federal and state pandemic preparedness capacity and capability; gauge how the nation is faring against these metrics; and develop an annual report to Congress on the state of pandemic preparedness with specific recommendations. The Board will be supported by independent career staff in a new Office of Pandemic Preparedness located in the executive branch.

4. **Establish federal data collection and reporting standards to improve consistent collection of core public health data across data systems, with a prioritized focus on race and ethnicity data.**

The Office of the National Coordinator for Health Information Technology (ONC) recently established a Public Health Data Systems Task Force that should consider defining a "core public health dataset," developing additional standards for data collection, and developing a plan for implementing those standards, including linking them to funding mechanisms. Core public health data should include information for public health surveillance and response, such as demographic information, electronic laboratory data, travel health data, genomic sequencing data, and electronic vital records data. The health disparities in the COVID-19 pandemic have revealed the urgent need to set standards around race, ethnicity, and other demographic data, and should be treated as a priority. To ensure accountability, Congress should require the Department of Health and Human Services (HHS) to submit a report on current streams of funding, activities, and program requirements related to data collection and standardization.

5. **Improve data sharing and interoperability by establishing integrated platforms for detection and surveillance of public health threats, clarifying privacy standards during public health emergencies, and encouraging data exchange between clinical and public health organizations.**

The U.S. public health system relies on an outdated, patchwork data system that does not allow data to flow freely between public health, clinical and other entities. To improve early detection of public health threats, the CDC should establish an integrated infectious disease surveillance system that would strengthen surveillance efforts currently conducted by multiple data systems and agencies. This system could be modeled like the CDC's existing influenza surveillance system and be expanded to detect other novel pathogens. To improve situational awareness during public health emergencies, Congress should direct the HHS secretary to ask the National Academy of Medicine (NAM) to propose a design for a national interoperable data platform to improve access to health data and other relevant data needs during ongoing public health emergencies. Considering the volume and type of data sharing required during public health emergencies, patient privacy and security must be prioritized. Finally, as the United States updates electronic health record (EHR) standards, a priority should be made to include public health data, and to facilitate data sharing between health systems and public health officials.

6. **Build upon data collection and sharing efforts during COVID-19 to strengthen vaccination data systems for use during future infectious disease pandemics.**

The CDC recently issued guidance that fully vaccinated individuals can resume certain activities, but—despite demand from private businesses—there is not currently a reliable system in place to identify who has been fully vaccinated. Several private companies are working on platforms that an individual could use to digitally access their vaccination information. The federal government has a key role to play in promoting the development of a vaccination credential system by ensuring that credentials protect privacy and are synchronized, secure, and high quality. In addition, HHS should build on technology it is using to collect states' COVID-19 immunization tracking data to inform national response efforts and improve interoperability between states and enhance states' collection of demographic data, such as race and ethnicity.

7. **Assess existing federal funding of pandemic preparedness and response activities for opportunities to increase coordination and efficiency and improve equity. For programs deemed highest priority to prevent, detect, and address infectious disease threats, create a permanent budget designation named Biodefense Interagency Operations outside annual 302(a) allocations, and should they be established by future legislation, outside overall budget limitations.**

Congress should form a Joint Select Committee including members representing the relevant authorizing and appropriating committees to evaluate existing federal funding, identify mission-critical investments, and produce legislative recommendations with stakeholder feedback on how interagency funding can be better coordinated and optimized. Those programs deemed mission critical would receive a Biodefense Interagency Operations (BIO) exemption, allowing them to be exempt from budget caps, including any future discretionary spending limits set after the expiration of Budget Control Act of 2011 limits in fiscal year 2021, and federal departments and agencies should be allowed to independently request the BIO exemption for their programs to ensure the country remains vigilant and primed for pandemic threats.

8. **Allocate funding to the Public Health Emergency Fund for use immediately following a Public Health Emergency declaration and use it as the primary vehicle for supplemental appropriations funding.**

To enable the federal government to rapidly deploy funding as a stopgap measure in a public health emergency until Congress can pass emergency supplemental appropriations, Congress should add funding to the Public Health Emergency Fund and consider passing future supplemental appropriations through the fund in future emergencies. When the pandemic began, there were

zero dollars in the fund, requiring the HHS secretary to draw upon the transfer of funds from other executive programs to pay for emergency response, arguably adding to the initially disorganized response to COVID-19.

9. Allocate $4.5 billion in permanent annual mandatory funding to a new Public Health Infrastructure Account to support state, local, tribal, and territorial foundational public health capabilities.

To enable state and local health departments to develop the minimal, cross-cutting capabilities that are needed to support their delivery of public health programs, the federal government should build on investments made by the administration through the American Rescue Plan. Congressional appropriations committees would still appropriate this money annually, but the money would not be subject to Committee 302(b) allocations. The HHS secretary would award the appropriated money in grants to accredited jurisdictions based on population size, level of health disparities, level of health risk and chronic disease burden in the community, and public health governance structure to bolster foundational public health programs. Part of the funding would be tied to the set of metrics and benchmarks created by the National Board on Pandemic Preparedness for evaluation of federal, state, and local pandemic preparedness capacity and capability.

10. Reform and increase annual funding to the existing Prevention and Public Health Fund from its current level of about $900 million to $4 billion to bolster inadequately supported public health programs and meet local needs.

Congress should direct funds from the Prevention and Public Health Fund, created under the Affordable Care Act, to state and local health departments to support public health programs, and the Preventive Health and Health Services Block Grants that gives health departments "the flexibility to solve problems unique to their residents, while still being held accountable for demonstrating the local, state and national impact of the investments." Public health programs include chronic disease prevention and communicable disease control programs that aim to improve community health.[3] Statutory language should be added to the law to prevent Congress from using the Prevention Fund to offset other activities as Congress has done since 2014. Research shows investment in prevention reduces long-term illnesses in a population. With a healthier population, the United States will be less vulnerable to an infectious disease outbreak, and individuals will live longer with a higher quality of life.

The $7.6 billion called for in Recommendation Nos. 9 and 10 would be funded by a public health excise tax.

Introduction

The U.S. public health system is a complex and intricate network of governmental agencies, local boards of health, and private health organizations that collaborate to promote and protect Americans' health. Its foundation includes a mix of 50 state (and the District of Columbia) health departments, 2,794 local governments, 565 federally recognized tribal agencies, and five U.S. territories.[4]

Even prior to the pandemic, the sprawling system of administrative bodies faced challenges from decades of inadequate federal funding.[5] The system's workforce has been stretched, and its data systems antiquated. There continue to be disparities in national health outcomes from chronic diseases and other illnesses, across racial, ethnic, and income groups.

COVID-19 exposed these flaws, underscored by a staggering death toll. As of the end of May 2021, over 592,000 Americans have lost their lives to the SARS-CoV-2 coronavirus that causes COVID-19, with Black and Latino populations making up a disproportionate number of deaths.[6]

The pandemic has begun to recede in the United States, as more than half the adult population has been vaccinated. But progress could be short-lived as new, more contagious strains of SARS-CoV-2 are circulating the globe. In the spring of 2021, a wave of new COVID-19 cases erupted in India and South America, providing more opportunities for the virus to mutate into new strains, spread to the United States, and challenge the effectiveness of current vaccines.

As the United States continues its pandemic fight, it is important for policymakers to examine and absorb the lessons learned from COVID-19. An effective pandemic response requires leaders who rely on scientific advice and data, and adapt as the science evolves, communicate clearly and consistently, debunk health misinformation, and avoid using the crisis for political gain. It requires comprehensive planning and preparation, biomedical advances in vaccine and therapeutic development, a national surveillance and testing strategy, robust contact tracing, clear guidance to the public about the early and sustained use of mitigation measures, and coordination and planning between public health leaders and agencies, health care providers, and medical suppliers. Further, because pathogens do not respect borders, international coordination is essential for sharing information and resources aimed at containing infectious disease outbreaks.

Undergirding a resilient response also requires a modern public health system with intergovernmental coordination and federal oversight, a 21st-century public health data infrastructure, and adequate federal public health funding.

Governance of public health has historically been directed by local authorities, with state, local, tribal, and territorial agencies tailoring their efforts to their communities, but taking direction from federal agencies. Under previously published national pandemic plans, the federal government had been slated to play a critical leadership and coordination role with state and local public health departments in the event of a national public health crisis.[7] However, a White House entity that was designed to coordinate and support the interagency pandemic response was dissolved in 2018.[8]

As COVID-19 was spreading through the country in early 2020, agencies within the HHS such as the CDC, the Food and Drug Administration, and the Office of the Assistant Secretary for Preparedness and Response were not coordinated in their actions and clashed over roles and pandemic guidance.[9] The Trump administration created a White House Coronavirus Task Force to improve collaboration, and deserves credit for recognizing the importance of rapidly producing vaccines to counter SARS-CoV-2 and for its prompt and robust investment toward development and large-scale production. However, beyond vaccine development, the task force did not succeed in unifying the federal response.[10]

In the absence of timely federal guidance, states had to determine how to share data, pay for COVID-19 testing and contact tracing, procure personal protective equipment (PPE), and implement mask mandates and social distancing measures. The consequence was a patchwork of measures, which, in many cases, failed to combat the spreading infection.

In January 2021, a more robust and coordinated federal response was launched that provided additional guidance and support to state and local public health departments. The Biden administration reinstated the White House position that is part of coordinating pandemic response. A White House team is spearheading the nationwide COVID-19 vaccination campaign, managing medical supplies, and improving coordination of the federal response. Questions remain, however, about roles of federal agencies during a pandemic and how the nation should invest public health dollars to prepare for the next public health emergency.

Policymakers will need to strengthen our nation's public health system to respond during a pandemic, as well as consider a broader public health modernization effort to determine the vision, strategy, and implementation of a public health system for the 21st- century. This includes aiming to more clearly define roles, responsibilities, and authorities for all relevant governmental entities during a national crisis and hold them accountable for preparing for the next public health emergency.

In addition, public health departments need a stronger and more integrated data infrastructure to collect information, detect the next potential emergency and guide policy response to outbreaks. Years of underfunding has left public health departments with aging computer systems that do not talk with one another or with health care provider systems.

Over the past few months, centralized federal reporting of hospitalization and vaccination data has improved, but requirements of what needs to be collected and reported, as well as privacy regulations, still vary between states and impact the quality of that data collection. Many state and local public health departments rely on paper documents, phone calls, and faxes to communicate. Many also require manual input of data into systems with limited functionality. Consistency of demographic data collection has been particularly poor. Race and ethnicity data for infections, hospitalizations, and deaths have been missing, or slow to be published, in many states.

In a country that is recognized as one of the global leaders in information technology, the United States should have the ability to build a 21st-century data infrastructure for the public health system to identify which populations and communities may be facing more infections, hospitalizations, and deaths, as well ensure vaccines are getting to communities equitably. The data will enable policymakers to prioritize and allocate resources and address gaps as well as promptly detect novel pathogens and support ongoing disease surveillance.

Further, public health capacity and emergency preparedness need to be adequately and consistently funded for the long term. More than 38,000 jobs disappeared from state and local public health departments between 2008 and 2019.[11] Those losses may become bigger as COVID-19 has led to worker burnout. At least 181 state and local public health leaders in 38 states resigned or retired in 2020.

Without a strong public health workforce, states and localities cannot implement foundational public health programs, like obesity and diabetes reduction, drug addiction prevention, maternal mortality prevention, and discouragement of tobacco and e-cigarette use. These services are critical to fostering a healthy population less at risk for public health emergencies like COVID-19 and more able to live longer, happier lives.

The CDC is the primary funder of state and local public health emergency preparedness activities, but its grant funding has fallen significantly over the last few years.[12] Instead of providing funding for the long term, the nation's response to public health emergencies has been to pour money into the system when there is a crisis and then slash the funding a few years later when the danger has ebbed.

When Ebola emerged in West Africa in 2014 and 2015, Congress appropriated $5.4 billion for the international efforts to fight the outbreak, and in 2016, when the mosquito-borne illness Zika threatened the southern United States, Congress appropriated $1.1 billion.[13,14] But the money was time-limited and could not be used to build up overall preparedness within the nation's public health system.[15]

Over the past year, Congress has begun to address the paucity of funding to public health departments, passing bills that include billions of dollars aimed at bolstering the workforce during the pandemic as well as improving virus surveillance and testing, contact tracing, and developing COVID-19 treatments and vaccines.[16]

In March 2021, Congress passed the American Rescue Act, which allocated close to $100 billion in funding to address current and short-term future public health needs.[17] The Biden administration has committed to spend $7.4 billion of that funding to create a 21st-century public health workforce with the epidemiologists and data analysts that will be needed for prevention and response to the next pandemic.[18] But a portion of the American Rescue Act funding is time-limited and specific to responding to COVID-19, raising concerns that once the pandemic has ended, the nation will repeat the boom-and-bust cycle for pandemic funding.[19]

This report focuses specifically on three critical elements policymakers could address to strengthen the public health system—*intergovernmental roles, responsibilities and accountability, data infrastructure, and public health financing*—so that the United States is better prepared to combat emerging disease threats in the future. By taking critical steps to address these shortfalls, the nation will be in a stronger position to support the long-term health of its citizens and leave it in a better place for inevitable emergencies.

Recommendations: Intergovernmental Roles and Responsibilities

Background

The U.S. public health system is a complex network of governmental agencies and private organizations. Public health agencies are led by federal, state, local, territorial, and tribal governments. At each level of government, health agencies possess a varied degree of legal authority to carry out public health activities including disease surveillance, testing, vaccinations, and policy development. Most public health interventions occur at the state and local level, which allows elected and public health officials to tailor efforts to the unique needs of the community. However, this system of governance can create barriers when planning and executing a unified national response during a public health emergency that must be directed by strong federal leadership.

The COVID-19 pandemic created unprecedented challenges and offered important lessons learned for the U.S. public health system. The number of COVID-19 infections, deaths, and hospitalizations in the U.S. indicates an invaluable lesson—resources alone are not enough to protect the nation's health. The U.S. ranked among the top 10 out of 98 countries with respect to preparedness under the voluntary Joint External Evaluation process.[20] Further, in 2019, the Global Health Security Index ranked the U.S. No. 1 out of 195 countries in terms of preparedness.[21] Despite these stellar preparedness rankings, the U.S. continues to lead the world in number of COVID-19 deaths.[22] Thus, cementing the notion that though the United States was prepared in theory and on paper, the country fell short in practice.

The suboptimal U.S. response to COVID-19 is a result of many factors: delayed surveillance and testing; a lack of inventory in the federal Strategic National Stockpile (SNS) and poor distribution of PPE and critical medical material; unclear and varying federal guidance on community mitigation strategies and personal protective measures (e.g., masks) to combat the spread of the virus; and ambiguity at the federal level as to who was in charge during the pandemic.

However, beginning in spring 2021, the country started to see encouraging improvements in COVID-19-related deaths and hospitalizations.[23] This is largely due to the Trump administration recognizing the benefit of COVID-19 vaccines and making an early robust investment toward vaccine development and large-scale production as well as the Biden administration leading the massive logistical effort to distribute and administer vaccinations alongside

the private sector. While these critical steps will protect the country moving forward, it cannot reverse the harm that has already been done. Overall, despite the nation's resources and a previously developed pandemic plan, a two-dimensional readiness effort at the outset of the pandemic was not enough. Exercising pandemic plans prior to an emergency and having a sufficient and trained frontline workforce to respond are important—and clear and consistent federal leadership is a critical enabler.

The federal government plays an essential role in supporting state and local public health departments by providing technical assistance, funding, and guidance in nonemergency and emergency times. HHS leads federal public health activities primarily through its various agencies such as the CDC, the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). In the time of a public health crisis, the secretary of HHS has authority to declare a public health emergency. In 2013, Congress designated HHS as the lead federal department for pandemic response under the Pandemic and All-Hazards Preparedness Act. Under HHS, the Assistant Secretary for Preparedness and Response (ASPR) is the lead coordinator of the aforementioned HHS agencies' preparedness efforts and ensures close collaboration with other federal departments and agencies, especially the U.S. Department of Defense (DoD) and the Federal Emergency Management Agency (FEMA), along with other agencies in the Department of Homeland Security.

The White House plays a critical leadership and coordination role during a public health emergency to ensure a whole-of-government response.

The president can declare a national emergency through several laws, including:

- **Stafford Act**—Authorizes the federal government to provide technical and logistical response assistance and funds traditionally to states, territories, and tribal localities during emergencies through FEMA. Former President Trump declared a national emergency for the COVID-19 pandemic under the Stafford Act on March 13, 2020. This is the first instance in which the Stafford Act was invoked to declare an emergency that covers the entire nation. The act does not supersede other federal authorities.[24,25]
- **National Emergencies Act**—Allows the president to waive federal regulatory requirements. This act grants the Secretary of HHS the ability to waive certain Centers for Medicare and Medicaid program requirements. Former President Trump declared a national emergency under the National Emergencies Act on March 13, 2020 in response to COVID-19.[26]
- **Defense Production Act**—Provides additional presidential authorities including those that can expand the nation's productive capacity and supply through the DOD.[27] Former President Trump first invoked the Defense Production Act in April 2020 to mitigate supply chain issues related to the production of ventilators and N95 face masks.[28]

The HHS secretary can activate additional resources during an emergency through the following Acts:

- **Public Health Service Act**—Allows the secretary to lead all federal public health and medical response to public health emergencies. These authorities include the ability to establish and maintain a Medical Reserve Corps and to declare a public health emergency.[29] Former Secretary Azar declared a public health emergency through the Public Health Service Act on January 31, 2020.
- **Social Security Act**—Permits the secretary to waive or adjust Medicare, Medicaid, the Children's Health Insurance Program, and Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements. These authorities can be accessed only after a public health emergency has been declared under the Stafford Act or National Emergencies Act and the secretary has declared an emergency under the Public Health Service Act.[30]

When the federal government makes an emergency declaration, a variety of resources may become available to support the response including:

- Mobilizing federal assistance to states through FEMA and other agencies and programs in the form of financial, personal, operational, and technical assistance
- Launching FEMA's National Response Framework, which guides the nation in responding to emergencies
- Distributing stockpiled critical medical supplies from the SNS to jurisdictions as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient
- Temporarily easing federal, state, and local regulatory restrictions
- Activating emergency provisions such as the Social Security Act Section 1135 waivers, which can ease some federal regulatory requirements on healthcare providers

The previous administration was inadequately organized at the outset of the pandemic to coordinate an efficient national pandemic response. Prior to 2018, responsibility for coordinating interagency pandemic response had been assigned to the National Security Council Directorate for Global Health Security and Biodefense at the White House. But in 2018, this position was eliminated under a counterproliferation directorate. This created an erosion of coordinated federal pandemic planning efforts.[31] Despite the clarity provided by the Pandemic and All-Hazards Preparedness Act, HHS and ASPR were not empowered to take on the coordinator roles as intended by Congress, and the U.S. response to the COVID-19 pandemic was often disjointed, without clear delineation of roles at all levels.[32] While the HHS secretary initially served as the point person for the federal government's COVID-19 response, he was soon replaced by the vice president as head of the White House Coronavirus Task Force. In addition, FEMA's initial role was unclear since the president had not

declared a national emergency under the Stafford Act until mid-March 2020. Further, working groups created out of the White House Task Force diluted the role of the ASPR.

The federal disorganization also led to unclear guidance from federal agencies on issues such as data sharing, testing, mask mandates, and the timing and use of community mitigation measures. As a result, states and localities implemented a wide variety of interventions at varying times in the pandemic to mitigate the spread of the virus. The different approaches ultimately created a disparate impact on COVID-19 infection rates, deaths, and hospitalizations across the nation. For example, some jurisdictions, like King County, Washington, acted quickly and implemented key public health measures early, in March 2020, such as recommending that people at high risk for complications for COVID-19 stay home.[33] Early in the pandemic, Vermont launched testing and contact tracing, introduced social distancing measures, such as closing restaurants and dismissing all schools, reduced the size of mass gatherings and implemented a statewide mask mandate.[34] Both Vermont and Washington have had among the lowest number of cases and deaths per capita since the pandemic started. These states were among the first to implement stay-at-home orders when containment was not possible, which helped them avoid large spikes in COVID-10 during the winter months; other states like North Dakota never issued a stay-at-home order.[35] To date, North Dakota has the largest number of cases per capita compared with all other states.[36] Similar states that did not implement community measures early in the pandemic continued to see a high number of COVID-19 cases and death rates.[37] Research indicates that if states had implemented evidence-based nonpharmaceutical measures one to two weeks earlier in their response, a substantial number of cases and deaths could have been prevented.[38]

The overall response has also highlighted, and in some cases exacerbated, existing racial inequities. Compared to non-Hispanic white populations, Native Americans are 3.5 times as likely to be hospitalized with COVID-19; Hispanic populations are 3.0 times as likely, and Black populations are 2.5 times as likely.[39] Variable responses across states, including in the collection and reporting of data stratified by race and ethnicity, may have limited states' ability to identify and respond to these disparities.

States should have the ability to tailor public health interventions to meet their state-specific needs. However, the experience of COVID-19 suggests the need for clear federal government leadership and state incentives to ensure a unified evidence-based response plan during emergency times.

Approach to Recommendations

The federal government's COVID-19 response effort fell short partially because of unclear roles and responsibilities with limited coordination and oversight. This section offers recommendations to improve intergovernmental roles and responsibilities during a pandemic in three key areas:

1. **Operational response**—The White House, ASPR, FEMA, and CDC must take lessons learned from COVID-19 to optimize their role in responding to future pandemic threats.

2. **Coordinated state operational response**—Although states must tailor their ongoing pandemic response to the local outbreak, jurisdictions should implement evidence-based strategies that align with the goals of a unified national response at the onset of a public health emergency, and particularly at the peak of a pandemic, when all jurisdictions are similarly affected.

3. **Federal pandemic preparedness oversight**—The U.S. needs a permanent independent body to ascertain the status of the nation's pandemic response system to ensure the nation is prepared to respond to future threats.

Recommendations

1. Clarify and strengthen federal operational roles and responsibilities during a federal response to a pandemic.

The COVID-19 pandemic created an unprecedented catastrophic emergency that necessitated an all-hands-on-deck approach at the federal, state, and local levels. To improve the nation's federal response to emergency events such as a pandemic, the White House should clearly define roles, responsibilities, and authorities for all relevant governmental entities. In order to execute an effective national pandemic response, federal agencies must have detailed operational plans that describe their respective roles and responsibilities, and conduct agency and interagency exercises to improve readiness. The White House has the authority and is positioned to direct federal agency preparedness and response efforts during a public health emergency.

As a part of strengthening federal leadership during public health emergencies such as pandemics, the president should appoint a White House Deputy National Security Advisor for Pandemic and Biothreats Preparedness, who is supported by the National Security Council staff. Currently the HHS secretary is tasked with implementing the nation's plans for mitigating biothreats including infectious diseases. The secretary delegates significant responsibilities to ASPR including identifying and tracking spending for all federal biodefense programs. However, this structure gives the unrealistic charge to one federal department on an equivalent organizational level to direct other similarly positioned federal departments to act, which has contributed to delays in executing the National Biodefense Strategy. An effective cross-agency

response requires a structure that calls on leadership and authority at the level of the White House. The White House is in the right position to appoint a Deputy National Security Advisor that will coordinate, direct, and hold federal departments and agencies accountable for all biodefense preparedness and operational response efforts, including stockpiling efforts by the SNS.

A key role of the Deputy National Security Advisor would be to convene relevant federal agencies for regular pre-pandemic interagency planning meetings. The Deputy National Security Advisor should task the agencies with collaborative pandemic planning efforts, including recommendations for agencies to develop or update pandemic planning guidance, as necessary, and testing those plans in regularly scheduled exercises. When guidance is updated, it should be clearly communicated to state and local governments so that they can include the most recent information in their pandemic planning. A role similar to the Deputy National Security Advisor for Pandemic and Biothreats Preparedness has received support from the Bipartisan Commission on Biodefense.[40]

To further promote cross-agency collaboration, the Deputy National Security Advisor should reinstate the Emergency Preparedness Grant Coordination effort as established by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. In this effort, five agencies—ASPR, FEMA, CDC, Health Resources and Services Administration (HRSA), and the National Highway Traffic Safety Administration (NHSTA)—signed an Interagency Memorandum of Understanding (MOU) to formalize their commitment to health emergency preparedness grant coordination.[41] The Deputy National Security Advisor should require those five agencies renew their commitment to harmonize and coordinate their federal grant programs and activities with jurisdictions and execute a new MOU.

White House leadership and coordination of agency preparedness should be supplemented by congressional evaluations of roles and responsibilities to ensure federal entities have the necessary resources to execute emergency response efforts. To strengthen FEMA's response efforts during a large-scale nationwide pandemic and promote federal coordination, Congress should direct a review of FEMA's existing role, capacity, and authorities. On March 13, 2020, former President Trump declared an emergency under the Stafford Act, which activated FEMA into a lead role in the COVID-19 response. FEMA's expertise is largely with natural disasters, and for those events, routinely coordinates multi-agency responses to a wide variety of emergencies including those involving medical and health care responses through its system of Emergency Support Functions. However, during an infectious disease threat like COVID-19, FEMA's role was not clearly defined to meet the response needs. FEMA's resources were also exceedingly stretched, as it played a coordinating role in the federal response while preparing for the upcoming hurricane season.[42]

Congress should also perform a detailed evaluation of ASPR's capacities and capabilities during a public health threat. ASPR serves a primary function in

supporting the nation's operational response to public health threats as the primary advisor to the HHS secretary on issues related to federal public health preparedness and response for public health emergencies. In addition, ASPR currently holds operational responsibilities for the development of medical countermeasures and coordinating the federal response to public health threats. One of these responsibilities includes coordinating Emergency Support Function (ESF) #8—Public Health and Medical Services.[43] ESF #8 plays a critical part in supporting the nation's response to pandemic threats. It provides additional assistance to state, local, and tribal governments in functional areas such as public health surveillance, medical equipment and supplies, and public health and medical information. Indeed, the catastrophic nature of the pandemic overwhelmed HHS and ASPR, thus compromising the agencies' ability to effectively manage and disperse ESF #8 resources. To that end, Congress should conduct a review of the applicability and utility of ESF #8 as it relates to pandemic threats and other large-scale public health emergencies. Consistent with current statute, the secretary of HHS and Congress should also assess, modify, and strengthen—where determined necessary—ASPR's roles, responsibilities, and capabilities related to leading HHS responses to public health emergencies, including ASPR's relationships with the relevant HHS agencies and partners outside HHS. The HHS secretary should task ASPR with developing a process for regularly engaging with subject matter experts, Congress, nonfederal, and nongovernmental stakeholders to determine standards and protocols for SNS stockpiling and product release during public health emergencies. The Government Accountability Office (GAO) proposed a similar policy recommendation in a January 2021 report.[44]

The CDC plays a critical role in monitoring an outbreak, developing and disseminating guidance and tools for public health emergency planning and preparedness, detecting and characterizing health threats, and informing and supporting the nation's response to public health emergencies. To strengthen and improve the CDC's response efforts for future pandemic threats, the HHS secretary should direct the CDC to analyze the agency's management and response to COVID-19 and identify areas of improvement. The study should result in clear recommendations for corrective actions based on its findings. In its evaluation, the CDC should specifically examine the use of in-house manufacturing practices related to COVID-19 testing kit development, which ultimately lead to contaminated kits and nationwide testing delays, as well as the process for determining public guidance on the use of masks to reduce the spread of an infectious disease. The CDC should also reassess the decision-making process for issuing timely mitigation guidance and protocols for data sharing, and develop disease surveillance indicators, such as case definitions, during a national emergency. At the outset of any pandemic, scientific knowledge and evidence about the behavior of biothreats is consistently evolving. As such, the CDC should allow for flexibility that errs on the side of caution in defining surveillance indicators to improve disease detection and clinical care and mitigate potential spread of novel infectious diseases.

With the guidance from the White House Deputy National Security Advisor for Pandemic and Biothreats Preparedness, ASPR and CDC should clearly define their respective operational roles and responsibilities during public health emergencies and conduct joint pandemic planning efforts including annual exercises to refine these roles and responsibilities.

2. Incentivize states to participate in a coordinated response to national public health threats.

The patchwork response to COVID-19 raises salient concerns about barriers to a coordinated national response during public health emergencies. Although federal guidance was issued in March 2020 that advised strict stay-at-home orders to all states and jurisdictions, numerous jurisdictions in the United States granted exceptions and/or were in close proximity to locations with entirely different regulations in place. One study found that some people avoided adhering to public health recommendations in their jurisdiction by traveling to a neighboring jurisdiction.[45] These researchers determined, using county-level COVID-19 data, that increased mobility from high-incidence to low-incidence locations was consistently associated with increased cases in the low-incidence counties.

States and localities have the flexibility to appropriately tailor public health activities to meet their community needs. In the face of public health threats, particularly those related to the spread of infectious diseases, state mitigation efforts must be supplemented by strong federal leadership through consistent and evidence-based guidance and tools. Pandemic planning experts have found that deploying nonpharmaceutical measures early in the outbreak creates the best chance of limiting the spread of a pandemic.[46,47] At the outset of COVID-19, states were left to make decisions around deploying mitigation efforts without clear federal guidance. The COVID-19 pandemic offered valuable lessons that highlight the consequences of unclear and delayed federal guidance that promoted inconsistent state efforts.

To strengthen future responses to national public health threats, Congress and the executive branch should consider creating incentives to encourage states and localities to follow evidence-based guidelines for disease mitigation. Incentives could involve additional financial resources beyond core funding, such as providing supplemental public health funds, to enhance a state's pandemic response. Guidelines should be science-based and free from political interference.

3. Establish a National Board on Pandemic Preparedness to provide oversight and ensure the United States is equipped to respond to future public health threats.

The ability to respond effectively to public health threats, including novel infectious diseases, largely rests on the capability and resiliency of the nation's public health emergency response system. The United States must constantly

invest in and improve its public health preparedness system to better prepare for and effectively respond to the next pandemic.

In 2007, Congress charted the National Biodefense Science Board, formerly known as the National Preparedness and Response Science Board. This federal advisory committee periodically provides guidance to ASPR and to the HHS secretary on preparing response efforts for emergencies with health impacts.[48] However, there is no congressionally chartered oversight mechanism for evaluating the state of America's pandemic preparedness system, which is reliant on the capabilities and coordination of federal, state, and local agencies. This lack of oversight leaves the nation vulnerable to a suboptimal response to future pandemics.

To ensure the United States is equipped to respond to future pandemics, Congress should create a National Board on Pandemic Preparedness. Indeed, the U.S. public health preparedness system must respond to public health threats beyond pandemics; however, as demonstrated during COVID-19, pandemic threats can uniquely impact every sector of the economy, interrupt social connections, have profound health impacts, and create long-lasting social and economic effects. It is therefore the task force's belief that an adequate measure of the nation's ability to respond to public health threats must be anchored in pandemic preparedness.

The board's primary purpose is to bolster oversight of the nation's pandemic preparedness infrastructure. To achieve this goal, the board will carry out three main objectives: 1) establish a set of metrics that sets benchmarks for evaluation of federal, state, and local pandemic preparedness capacity and capability; 2) gauge, on an annual basis, how the nation fares against these established metrics; 3) develop an annual report to Congress on the state of pandemic preparedness with specific recommendations to strengthen the nation's pandemic preparedness and response.

The board should consider the following thematic areas while developing the measures:

- Infectious disease preparedness and response planning including nonpharmaceutical and pharmaceutical mitigation measures
- Public health, emergency management, and health care system coordination
- Equity in emergency response planning
- Exercising response plans
- Data infrastructure; standardized data collection and reporting; data sharing processes and protocols; data privacy and security standards
- Real-time surveillance and systems
- Laboratory systems

- Vaccination infrastructure, distribution and uptake
- Biosecurity and biosafety
- Stockpiling and supply chain resiliency

Throughout the metric development process, Congress should require that the board consult with stakeholders including relevant federal agencies, private sector organizations, and subject matter experts. The board should also consider alignment with the World Health Organization's Joint External Evaluation. Metrics may change over time based on the specific threat levels of new infectious diseases. In presenting its annual findings, the board should incorporate a color-coding scale. The three-color scale—green, yellow, red—would represent the nation's overall rating in pandemic preparedness and reflect the sum of the nation's score across each metric. The scale can also be useful in informing policymakers and the public of the state of pandemic preparedness.

An effective national response is partially dependent on state-level preparedness. As such, in addition to developing metrics geared toward evaluating the nation's preparedness levels, Congress should require the board to create state-level measures and core requirements for the purposes of assessing state pandemic plans. States must submit their respective plans to the board annually, and the board will use its established measures and core requirements to determine states' levels of pandemic preparedness. A composite index for comparison of states should be included. Congress should mandate that state pandemic plans meet the measures set by the board and consider financial consequences for noncompliance.

The board will consist of eight members, four of whom serve in the federal government: the secretary of HHS, the secretary of DHS, the secretary of DOD, and the secretary of State. The secretary of HHS will serve as the chair of the board. These secretaries oversee agencies and programs that are critical during pandemic emergencies. The secretaries will also be critical in helping to obtain data from within their respective departments for the board's yearly evaluation. The other four members will be public representatives. These members will be appointed by the president and confirmed by the Senate; they should be nominated by an independent scientific body such as the National Academy of Medicine.

The board will be supported by career staff in a new Office of Pandemic Preparedness located at the GAO. The sole purpose of this office and its staff is to support the board in carrying out its functions, particularly producing the annual report to Congress. The board and the Office of Pandemic Preparedness would have an independent budget and would be financed through a mandatory spending stream. Additionally, the board would receive a small portion of earmarked funding from each of the represented departments—HHS, DHS, DOD, and the Department of State.

Recommendations: Data Infrastructure

Background

The COVID-19 pandemic has highlighted the need to strengthen the U.S. public health systems' data infrastructure. High quality data systems are necessary for detecting and monitoring pathogens and guiding the policy response to outbreaks. The response to COVID-19 has been hindered by major gaps in data collection and reporting.

Because states have the greatest authority to mandate and regulate data collection, the quality of federal data is dependent on consistent data submitted by each state. Particular attention has been given to the inconsistent collection of race, ethnicity, and other demographic data. Journalists and academic researchers filled in some of the gaps with their own databases, but collection of pandemic trend data should be the role of the federal government. Over the course of the COVID-19 pandemic, centralized federal reporting of demographics, hospitalizations, and testing data has improved, but there are continued issues with the availability and format of essential data. A recent report from the GAO found that, as of February 2021, information on race and ethnicity is missing for about half of vaccine recipients.[49] Such data is critical to identifying and responding to disparities in disease prevalence, health care access, and policy actions across different populations during a pandemic. This missing data prevents health officials from having a clear understanding of equity issues related to vaccine distribution and vaccine confidence.

There has been a federal funding effort over the past two decades to improve the use of EHRs in health care through the Health Information Technology for Economic and Clinical Health (HITECH) Act,[50] but there has not been the same investment in public health data systems. Many state and local health departments are still using low tech data systems with limited functionality and must resort to using paper documents, phone calls, and fax machines to request and exchange data.[51] Even when EHRs are available, different EHR systems are often not interoperable with each other, creating additional challenges for data reporting between clinicians and public health departments.

Finally, the current public health data infrastructure is highly fragmented. Public health officials draw from a wide range of data types to detect and monitor diseases (Table 1). Data systems across disease categories and levels (local, state, and national) have different requirements, technologies, policies, and privacy laws. Data does not flow freely between public health organizations, and it does not flow between public health systems and private health care

providers. This patchwork data infrastructure leads to both gaps and duplicative work, hindering health officials' ability to collect and share important health data. Additionally, confusing, duplicative, and inefficient processes around data collection and data sharing contribute to increased burden for public health officials and health care providers who are already carrying a heavy workload during the pandemic.[52]

The CDC has been working to fix these gaps through its Data Modernization Initiative (DMI), launched in 2019. The effort takes a comprehensive approach to improving public health data, technology, and workforce capacities.[53] Under this initiative, the CDC strengthened core surveillance systems, released an open data site to foster sharing of data and informatics resources, and provided funding to states to improve interoperability. A full roadmap of activities and expected outcomes can be found on the CDC website.[54]

With the advent of the COVID-19 pandemic, the CDC has led a push under the DMI to increase use of electronic laboratory reporting and electronic case reporting (eCR) in health departments, integrate COVID-19 data from across multiple systems, and expand training programs for data science and informatics.[55] As of May 2021, more than 7,600 health care facilities across the country are sending COVID-19 electronic case reports to public health agencies using eCR, according to the CDC.[56]

The CDC has received an influx of funding to support data modernization efforts over the past year. In both FY2020 and FY2021, Congress appropriated $50 million to the CDC for data modernization.[57] Additionally, the Coronavirus Aid, Relief, and Economic Security (CARES) Act of March 2020 included $500 million for data modernization, and the American Rescue Plan of March 2021 provided an additional $500 million.[58] In FY2020, the CDC used $130 million of CARES Act funding to support "Enhancing CDC Services and Systems for Ongoing Data Modernization," including contracts for cloud migration, enterprise data analysis, and rapid person-based data collection.[59] However, this funding may not be enough for long-term data infrastructure support (see Financing section). To ensure a more interoperable data infrastructure with timely data sharing, current and future funding will have to tie accountability metrics to standards for data reporting, collection, and interoperability.

Table 1

Data Types for Early Detection and Situational Awareness
Emergency room data/Syndromic surveillance
Electronic health records/Electronic case reporting
Electronic lab reporting
Border surveillance
Genomic surveillance
Vital records
Demographic data
Notifiable diseases
Outbreak forecasting modeling
Wastewater surveillance
Pharmaceutical data
Animal health/zoonotic data
Blood bank data
Vaccination registries
Vaccination production, distribution and supply chain
Treatment production, distribution and supply chain
Quarantine/isolation data
Contract tracing data
Hospital capacity and supplies
Search and location data from private companies

Approach to Recommendations

Given the wide scope of data types used for public health, there is a need for a coordinated effort to ensure that data reporting and collection is not burdensome to clinicians, health care facilities, states, and localities, and that data sharing across levels of government and surveillance systems is accomplished with minimal effort. To this end, the first two recommendations in this section call for a set of cross-cutting policy changes to strengthen public health data collection and exchange, both during public health emergencies and nonemergency times. The first set of changes would ensure more alignment and standardization for data collection and reporting; the second would improve data sharing and interoperability. In addition, a final recommendation builds upon vaccine-related data systems developed during COVID-19, which can be standardized and strengthened to better inform future pandemic responses.

Recommendations

1. Establish federal data collection and reporting standards to improve consistent collection of core public health data across data systems, with a prioritized focus on race and ethnicity data.

Establishing cross-cutting data collection and reporting standards

Currently, the quality and type of data collected varies widely across federal programs and states. Standardizing data collection across public health departments, federal agencies, and clinical health care facilities will improve data quality and facilitate data sharing across agencies. By simplifying and clarifying complex data collection processes, data standards can also help reduce the burden on clinicians and public health professionals.

Public health departments may receive data from clinical health care facilities, laboratories, pharmacies, prescription drug monitoring programs, schools, and other sources. Local health department data is usually funneled to state health departments. State health departments and federal health agencies share data bilaterally. Importantly, data collection needs are different at the federal, state, and local level. Any standards must allow for some flexibilities across different levels of government and take into consideration the ability across jurisdictions to meet proposed standards.

Recent efforts through the CDC's DMI have improved electronic standards for data collection related to COVID-19. However, further progress is needed to define core data and standardize data collection across federal programs and diseases. ONC recently established a Public Health Data Systems Task Force to examine policy and technical gaps in data collection and surveillance.[60] This new task force should consider defining a "core public health dataset," developing additional standards for data collection, and developing a plan for implementing those standards, including linking them to funding mechanisms. In these efforts, the task force should engage with the CDC, CMS, state and

local stakeholders, as well as the private and academic sector. A similar recommendation has been made by the GAO and is included in the proposed Health STATISTICS Act of 2021.[61]

"Core public health data" should include essential data that state and local agencies collect and report to the federal level. Any data that is necessary for public health surveillance and response—such as demographic information, electronic laboratory data, travel health data, genomic sequencing data, and electronic vital records data—should be included as core public health data. It will be critical to engage state and local stakeholders in this process to create buy-in, assess limitations, and ensure data needs are appropriately captured. Once core data is clearly defined, standards are needed to inform consistent data collection efforts in state and local public health. There is also a need to ensure clear protocols and processes for data reporting (i.e., who is reporting what data, where, and to whom). Clearer protocols can help reduce duplicative reporting between different public health and clinical organizations. Because legal requirements and infrastructure limitations vary across jurisdictions, such protocols and standards will have to be flexible enough to account for these differences.

Additionally, because efforts around data standardization are spread across multiple different program streams, it can be difficult to track what progress has been made. HHS should submit a report to Congress and the new Office of Pandemic Preparedness on current streams of funding, activities, and program requirements related to data collection and standardization. Congress should provide funding to support these activities.

Prioritizing race, ethnicity, and other demographic data

The health disparities in the COVID-19 pandemic have revealed the urgent need to set standards around race, ethnicity, and other demographic data. Although such standards would be included in the broader process described above, demographic data should be treated as a first priority. Standardization of collection and reporting of demographic data is critical to tracking disparities across different populations during a pandemic and deploying targeted interventions. Additionally, pathogen samples and other collected data must represent individuals from diverse races, geographies, and other demographics. While some progress has been made in demographic data collection throughout the course of the pandemic, many demographic data is still incomplete.[62] The CDC should set national standards to improve the collection and reporting of race, ethnicity, gender, primary language, disability status, occupation, and other demographic data. These demographic data standards should be tied to data collection and reporting standards developed by the Public Health Data Systems Task Force as outlined above. They should also be tied to future funding streams to states and localities to incentivize their use. The CDC should also work with the private sector to ensure that test results and vaccination data, among other data, include complete demographic information.

As recommended in a previous report from the Bipartisan Policy Center, Congress should give the CDC the authority to require race and ethnicity reporting from jurisdictions during public health emergencies.[63] Authority currently falls to states and territories to mandate demographic data collection, which contributes to variable quality of the data. Additionally, the CDC should take steps to ensure that categories used to capture race, ethnicity, and other demographic data are appropriate. The agency should engage with stakeholders to ensure that options included for demographic questions accurately reflect various identities and are sufficiently specific as to capture disparities within certain communities. Finally, some individuals may feel uncomfortable disclosing their demographic information for fear of discrimination. The CDC should acknowledge these concerns and prioritize privacy and transparency in demographic data collection.

2. Improve data sharing and interoperability by establishing integrated platforms for detection and surveillance of public health threats, clarifying privacy standards during public health emergencies, and encouraging data exchange between clinical and public health organizations.

Establishing an integrated infectious disease surveillance system to detect emerging disease threats

The United States currently uses multiple early warning systems across different federal agencies to detect and monitor novel pathogens. For example, the CDC manages the National Notifiable Disease Surveillance System, the National Syndromic Surveillance Program, the U.S. Outpatient Influenza-like Illness Surveillance Network, and the Global Disease Detection Operations Center, among others. Outside the CDC, the Department of Homeland Security's National Biosurveillance Integration Center and the Department of Defense's National Center for Medical Intelligence play a role in detecting and assessing biological threats. Having multiple systems leads to duplicative data entry and creates additional burden for providers. Currently, data from a single case of salmonella must be reported to seven different CDC data systems, including the Laboratory-based Enteric Disease Surveillance System, the National Notifiable Disease System, and others.[64,65] Given that several different federal agencies and data systems are currently involved in disease surveillance, the United States could benefit from a more comprehensive and streamlined approach.

The CDC should establish an integrated infectious disease surveillance system, which would expand and strengthen surveillance efforts. This system could draw from components of its Influenza Surveillance System, which is uniquely multifaceted and comprehensive. The Influenza Surveillance System includes five different categories of data: virologic data, outpatient illness surveillance, mortality surveillance, hospitalization data, and summaries of geographic spread.[66] This data comes from public health, hospital, and clinical laboratories;

outpatient providers; state vital statistics offices; hospital admissions databases and infection control logs; and state health departments. This system plays an important role in identifying early outbreaks and novel types of influenza viruses. However, the United States does not currently have the same capacity for monitoring other novel viruses. Thus, an integrated surveillance system could strengthen surveillance efforts for other novel pathogens before they begin to spread widely. This system could be used to inform modeling and analytics within the National Center for Epidemic Forecasting and Outbreak Analytics, which the Biden administration is currently designing.[67] The CDC should expand data collection for an integrated surveillance system to capture data from all methods of patient care, including telemedicine visits, home health care, travel health, and blood banks. The system should also capture genomic sequencing data from specimens obtained as part of routine surveillance. It could also potentially integrate search and location data from private companies, like search engines and social media. Table 1 lists data types that are important for early detection and could be included in such a system. It will also be critical for an integrated surveillance system to expand data from global sources; thus, global diplomacy and partnership will play an important role in a successful early warning system.

Establishing a national consolidated data platform for use during a public health emergency

Once a disease threat has been identified through early detection systems, public health officials, clinicians, and policymakers need up-to-date data to provide situational awareness and to inform the public health response. This data must be easily accessed and shared across state, federal, and private entities in a timely manner. However, current barriers to interoperability can lead to a slow uncoordinated response during public health emergencies.

To establish federal leadership for data modernization efforts across HHS, Congress should direct the HHS secretary to ensure alignment of data modernization efforts across federal agencies and offer high-level strategic direction. The secretary should delegate operational leadership to ONC, working with CMS and CDC. These agencies should partner with state and local public health departments and the private sector to integrate and modernize public health data infrastructure. Along with designating clear operational leadership roles within HHS, the secretary should ensure that the position of chief technical officer at the CDC be filled immediately to assist with data modernization efforts.

To improve interoperability during a public health emergency between levels of government and different data types, the HHS secretary should ask the NAM to convene stakeholders across the private, public, and academic sectors to study how to design a national interoperable data platform to improve access to health data and other relevant data needs during ongoing public health emergencies.

The NAM study should:

- Propose a national platform that would integrate data from emergency rooms, EHRs, laboratories, as well as genomic data, travel health data, and additional data types outlined in Table 1.
- Consider under what circumstances data should be linked, such that genomic, clinical, and epidemiological data are connected to inform the public health response during a public health emergency.
- Consider the specific data needs of state, localities, tribes, and territories, and ensure the proposed data platform is flexible to meet those needs.
- Ensure that the platform supports the use of application programming interfaces (APIs), which is a method that allows for rapid, cost-effective data sharing, and the Fast Healthcare Interoperability Resources (FHIR) standard for formatting data elements. Both APIs and FHIR standards have been required for IT developers in ONC's 21st Century Cures Act Final Rule.[68]
- Include the core public health dataset defined in recommendation 1, and specify how data should be accessible and to whom during a public health emergency, as well as examine issues on governance, security, and privacy.
- Ensure the data platform minimizes repeated data entry and has clear processes defining how and when changes are made.

The study should conclude in one year and propose an actionable model that could be implemented by the HHS secretary through ONC, CDC, and CMS. Interoperability and participation in the proposed platform should be a condition of future funding mechanisms outlined in the Financing section of this report. As part of the implementation, federal leadership should develop a formal implementation plan with stakeholders to provide clarity and to ensure long-term sustainability of the newly developed model.

Lessons could be learned from the Chicago Department of Public Health's successful partnership with Rush Medical Center to create a comprehensive COVID-19 data platform that collects electronic lab reporting and clinical data from the Epic EHR, which includes hospital capacity. This data is displayed through dashboards and can inform both hospitals and COVID-19 response efforts by identifying when hospitals are getting overwhelmed, and whether specific populations are being disproportionately impacted.[69]

Issuing clarifying guidance defining privacy and security standards during public health emergencies

Health information should be shared with public health authorities in a manner that protects patient data but allows public health officials to have the information necessary to respond to emerging and ongoing emergencies or outbreaks. HIPAA regulates how covered entities (e.g., health plans, health care providers, and health care clearinghouses) and their subcontractors use

protected health information (PHI). However, HIPAA does not cover all entities, most notably, digital wellness applications, such as contact tracing, exercise, and mental health apps, and certain patient portals, such as FollowMyHealth®.[70,71] This is especially concerning given that a recent national survey found that over 50% of adults 50–80 years old have set up patient portals. Unprotected data is often used for marketing purposes, and patients may not be aware that their data is no longer protected under HIPAA. This contributes to an overall lack of transparency for consumers around what data is being collected, for what purpose, and for what duration. Moreover, there is a need for consultation and collaboration with communities that will be impacted by data collection.

In December 2020, the HHS Office for Civil Rights (OCR) issued guidance to clarify HIPAA regulations regarding covered entities and whether subcontractors can use health information exchanges (HIEs) to share patient information with public health authorities.[72] The guidance clarified issues around a subcontractor's ability to share patient data, and the minimum necessary data required to fulfill a public health authority's request. This will permit subcontractors to share PHI data with public health authorities during a public health emergency, without explicit permission from the covered entity, as long as the covered entity is notified within 10 days.

HHS should also issue further guidance on how PHI should be shared during a public health emergency and during an emerging threat, prior to a public health emergency declaration; cybersecurity best practices; de-identification of data; and data expiration processes. Given there is health data that is not protected by HIPAA, Congress should consider extending HIPAA protections to other entities collecting health data including, but not limited to, digital health apps and patient portals.

Updating ONC's United States Core Data for Interoperability Standards and CMS' Promoting Interoperability Program

Electronic Case Reporting (eCR) is the automated real-time transmission of EHR case reports from health care systems and providers to public health agencies.[73] This allows state and local public health agencies to automatically receive relevant clinical data, such as data on transmissible diseases, to inform case investigations and follow-up. The United States Core Data for Interoperability (USCDI) outlines a set of standardized data components that health IT developers (e.g., EHR vendors) have to support. These standards set a baseline for data elements that must be shared across systems, including lab results, vital signs, and demographic information. ONC has an established process to continuously update USCDI, and public health stakeholders have continued to engage with ONC to improve interoperability between health systems and public health departments. While Version 1, which was issued in 2020, and the proposed Version 2 both include elements related to electronic laboratory reporting, the standards do not address all of the data needed to track

population-level trends. ONC should continue to work with the CDC—along with the eCR collaborative, states, localities, tribes, and territories—to ensure that USCDI Version 3 prioritizes data elements that would connect EHR data with public health data.[74] The CDC and ONC should co-chair the development of Version 3, with support from the HHS secretary. To ensure the timely inclusion of public health data into USCDI, the HHS secretary should establish a deadline for Version 3.

To encourage eCR among hospitals, CMS should require that eCR be included as one of the standards that providers have to reach in the Promoting Interoperability Program. This program, formerly known as the EHR Incentive Program, is the latest iteration of the effort to spur EHR uptake and interoperability across the health system.[75] Currently, the program includes eCR as one of six measures that eligible hospitals or critical access hospitals can choose to demonstrate active engagement with public health agencies. Requiring eCR could help increase data exchange of clinical data with public health departments.[76] This policy change has recently been advocated for by Pew Charitable Trusts, The Council of State and Territorial Epidemiologists, and the American Medical Informatics Association.[77]

3. Build upon data collection and sharing efforts during COVID-19 to strengthen vaccination data systems for use during future infectious disease pandemics.

Strengthening federal leadership for developing systems to digitize vaccination information

Widespread vaccination will reduce the number of people who become ill with COVID-19, decrease community disease transmission, and facilitate a safe return to activities during COVID-19 and future pandemics. The CDC has recently issued guidance that advises that those who are fully vaccinated can resume certain activities.[78] Yet there is not currently a reliable system in place to identify who has been fully vaccinated. The federal government should ensure that there is a system that allows for digital verification of vaccination and testing information.

Several private companies are working on platforms that an individual could use to digitally access their vaccination information or COVID-19 test results. Such digital systems may eventually be used by private businesses, such as airlines or restaurants, to check the health status of customers. Currently, New York state is requiring major venues, like theaters and sports arenas, to verify COVID-19 vaccination or health status. Customers may choose to show paper documentation of a test or vaccine, but they can also use Excelsior Pass, a mobile platform developed by IBM for the state.[79] The Excelsior Pass has built-in security measures and does not store any PHI on users' mobile devices. Users can delete passes once they no longer need them.

The Biden administration has stated that the federal government will not issue vaccine passports or collect personally identifiable vaccination information.[80] Yet, particularly in light of the recent change in CDC guidelines, there is demand from private business, cities, and states for systems that allow for digital verification of vaccination and testing information. Individuals, too, may want easy access to their vaccination information so they can resume international travel. The European Union recently announced that Americans with proof of vaccination could now travel to the area.[81] The federal government has a key role to play in promoting the development of a vaccination credential system by ensuring that credentials protect privacy and are synchronized, secure, and high quality. A federally led system would be the best way to promote interoperability and ensure quality and authenticity; such a system would not mandate or track vaccinations but would enable employers and businesses that want to verify vaccination status to easily do so. If not currently feasible, the federal government should, at minimum, develop standards for private sector efforts in this area to prevent fraud and protect privacy.

There are several benefits to promoting strong federal leadership around vaccination credentials. National leadership in this area will be particularly helpful to small businesses that want to reopen cautiously but may have limited resources to spend on vaccination verification processes. Without government support, the onus may fall on business owners and their employees to figure out how to verify health status safely and accurately—and how to pay for verification processes. Federal standards can also help protect against fraud and abuse, similar to the way that Real ID standards improve authenticity.[a] Additionally, federal government involvement in this area will help protect patient privacy. The government can ensure that these digital systems collect only the minimum amount of data necessary and delete the data after it is no longer needed. Finally, government standards can ensure more equitable access so that vaccination verification is not solely available to those with smartphones. If such a framework works well for COVID-19, the federal government could consider applying lessons learned to address future public health crises.

Institutionalizing the current COVID-19 vaccination tracking system

Timely, accurate, and complete pandemic vaccination uptake data is critical to inform vaccine manufacturers and distributors, public health officials, and clinicians. Currently, states manage their own Immunization Information Systems (IIS), which have varying functionalities. Different IISs may collect different types of data, and they are often not interoperable with each other. There was no national real-time system to track administration of pandemic vaccinations before the COVID-19 pandemic started. To manage

a Passed by Congress in 2005, the REAL ID Act set minimum standards related to the issuance of identification, such as driver's licenses. (Department of Homeland Security, "Real ID Frequently Asked Questions." Available at: https://www.dhs.gov/real-id/real-id-faqs)

vaccine distribution and track doses administered during COVID-19, HHS has established a new network of databases that expands and builds upon preexisting immunization data systems.[82] This system integrates data from state IISs with other sources, including patient data from pharmacies and shipment data from the federal distributor and private companies. The central platform newly developed by HHS consolidates all of this data to track vaccine manufacturing, allocation, distribution, and administration. The expanded system allows for the collection of far more detailed data and greater transparency around vaccine supply and demand.

While it is an improvement, the current immunization tracking system is not perfect. Due to interoperability issues and state data infrastructure limitations, some states are still relying on paper data or manual data sharing. Some of the new platforms have suffered from technical bugs, and many health care providers have found them hard to use.[83] Additionally, collection of demographic data, such as race and ethnicity, has been variable across states.[84] HHS should evaluate the utility of the newly developed system, including the success of its implementation. In addition, HHS should formalize and strengthen the system for use during future pandemics. Any needed adjustments should be made to ensure that the systems involved are functional, easy to use, and can capture all needed data in as close to real time as possible.

Recommendations: Public Health Financing

Background

The country's response to COVID-19 reflects underinvestment in health security specifically, but also more broadly in public health infrastructure and programs. State and local public health departments struggled to deal with public health challenges long before COVID-19. Limited and inconsistent funding of public health has allowed COVID-19 to have a disproportionate impact, in particular in rural areas[85] and on communities of color.[86]

Public health spending makes up a small amount of the total money the U.S. government spends annually on health. CMS reported that for Calendar Year 2019, governmental spending on public health was $97.8 billion, or 2.6% of total national health expenditures of $3.8 trillion.[87] As a percentage of total health expenditures, funding for governmental public health activities has fallen for more than a decade from 3.0% in 2008.[88] Yet from 2008 to 2018, the economy saw annual average growth of 3.3%, and national health care expenditures for disease care saw annual average growth of 4.3%. The decade also saw drops in life expectancy, pervasive health disparities, and increasing mortality rates from major communicable disease emergencies and an opioid crisis.[89] Scholars have criticized the official level of governmental public health spending as an overestimate, and argue that actual government spending is between one-third and two-thirds of that number, or between $35 billion and $64 billion when spending on individual health care services—such as behavioral health—is taken out.[90] Measuring government public health spending has been challenging, and produced different estimates because of "the lack of a universally accepted definition of public health activity, the uncertain boundaries between government public health activity and other governmentally provided personal health care and social services, and the difficulty of matching revenue streams with public health activity expenditures."[91]

The money that goes to state and local public health departments is not only a fraction of the above amount but is inconsistent and limited in how it can be used. Though many of the agencies within HHS and a few others focus on public health, most funds go through the CDC. This is provided on an annual basis through congressional appropriations committees as "discretionary" spending. The appropriators can choose what level they want to provide each year, largely to the CDC, and the CDC then gives grants to states and localities largely tied to specific diseases and categories.[92] Public health departments thus

receive very little money they can use to make the long-term investments to develop much-needed cross-cutting capabilities and are thus caught unprepared during emergencies. That has not fundamentally changed with the response to COVID-19. Unfortunately, the CDC's budget has stayed virtually flat over the last decade after adjusting for inflation, and funding for prevention and public health activities and emergency preparedness and response has dropped sharply, despite the worrying trends stated earlier.

The Affordable Care Act established the Prevention and Public Health Fund as the country's first permanent annual appropriation dedicated to improving the public health system and administered through the CDC. Funding was supposed to increase from $500 million in 2010 to $2 billion annually by 2015. However, Congress hasn't fully funded it since 2012. The money has been used instead to offset other spending.[b] Congress allocated only about $900 million to the fund in FY2020 and has directed the funding through the annual appropriations process since FY2014.[93] From FY2013 to FY2027, the fund is set to have $11.85 billion of its funding cut due to congressional action.[94] Declining state budgets have also diminished public health department capabilities following the 2009 recession. Since 2010, spending for state public health departments has fallen 16% per capita, and spending for local health departments has fallen by 18%.[95] States also differ in making public health funding a priority. Adjusting for population, in 2019, Missouri spent the least, at $7 per person, while the District of Columbia spent the most, at $363 per person, followed by New Mexico, at $140 per person.[96] Authors of a study looking at state-level public health concluded that funding "is not being calibrated to need."[97]

Though the country created numerous federal public health preparedness and response program authorities after 9/11, Hurricane Katrina, and the threat of H5N1 avian influenza, the government was still unable to generate a sufficient coordinated response for COVID-19. In 1983, Congress created the Public Health Emergency Fund for the HHS secretary to use in the event the president declares a public health emergency,[98] but that account had zero dollars in it when the pandemic came to U.S. shores. At the start of COVID-19's spread in the United States, the HHS secretary was able to draw $108 million from the Infectious Disease Rapid Response Reserve Fund, which had been created by Congress in 2018 to "prevent, prepare for, or respond to a declared infectious disease emergency,"[99] and then asked Congress for an additional $1.25 billion in supplemental funding. Until that money was approved, the government had to divert $136 million from other accounts to combat the pandemic.[100,101,102]

b The fund "has been raided to support the training of primary care clinicians, avoid cuts to physician reimbursement, finance a small portion of the 21st Century Cures Act, and briefly extend the Children's Health Insurance Program." John Auerbach, "The Promise of and Lessons From the Prevention and Public Health Fund," *American Journal of Public Health* 109, no. 4 (April 1, 2019): pp. 533-534.

In response to the COVID-19 pandemic, Congress did pass five supplemental appropriations measures and the American Rescue Plan outside of regular appropriations, providing almost $400 billion for public health related activities. However, most of the money has gone toward time-limited, COVID-specific purposes, including $178 billion for the Provider Relief Fund; $47.8 billion for COVID-19 testing, contact tracing and mitigation activities; and about $15 billion for COVID-19 vaccines, therapeutics, medical supplies, and products. As of late May, the CDC has awarded only $52 billion of supplemental funding to state, tribal, local, and territorial public health organizations, with $30.2 billion awarded through the Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement for departments to "facilitate capacity for infectious disease control and prevention" and $755 million distributed for emergency response to COVID-19.[103] Though $7.66 billion was provided to HHS to maintain and expand the U.S. public health workforce, the country will have to go further in providing sustained funding that looks beyond the current pandemic to better prepare the country for the future.

History has shown us that sustained investments in health security have been hard to come by. Instead, investments follow a boom-and-bust cycle of "a massive funding response to a crisis, followed by a quick retreat."[104] In FY2020, the country allocated $547 million in the budget for global health security threats, compared to $750 billion for the U.S. military.[105] The Strategic National Stockpile (SNS), too, has suffered from underinvestment, with supplies never being fully replenished following the 2009 H1N1 pandemic.[106] In 2019, although health officials requested $1.5 billion for the SNS, the White House asked Congress to appropriate only $705 million.[107] Insufficient funding has also diminished U.S. capacity to monitor overseas health developments, and only a small proportion of total global development assistance for health has gone toward investments in pandemic preparedness and health systems strengthening, despite the global nature of pandemic threats.[108] The United States has clearly failed to learn lessons of earlier pandemic and simulation exercises, which highlighted critical funding gaps that were expected to hamper a future pandemic response.[109]

As the federal government was caught on its back foot by COVID-19, so too were the states, which had seen their share of funding slashed over the past decade. In FY2018, states spent $860.1 million on all-hazards preparedness and response activities; of that, $741.6 million or 86% came from the federal government. Local health departments reported that a similar percentage of 71% came from the federal government. Federal emergency preparedness support had been falling for years as the following examples demonstrate:

- After adjusting for inflation, funding for the CDC's Public Health Emergency Preparedness Cooperative Program, the "primary source of federal support for state and local public health emergency preparedness and response," decreased by 20% from $847 million in FY2010 to $675 million in FY2020.

- The Hospital Preparedness Program (HPP), a program created after 9/11 and designed to improve medical surge capacity of community and health systems to deal with various public health threats, has experienced a 50% reduction in funding since 2003.[110]

The insufficient funds the federal government provides to states and localities for public health emergency preparedness and response is part of a larger problem in public health more broadly. Public health experts have repeatedly warned policymakers about the dangers of underfunding the public health system and the need for more governance flexibility. In 2012, the Institute of Medicine (IOM) released a report on population and public health, focused on public health financing. The report identified insufficient funding in public health and "dysfunction in how the public health infrastructure is funded, organized, and equipped to use its funding" as the two main issues responsible for the country's poor health outcomes and high health care expenditures.[111] The report advocated giving state and local public health departments greater latitude in how they used federal funds to meet population health goals and incentivizing public health system stakeholders to better coordinate. The Institute also developed a minimum package of public health services, including Foundational Capabilities and basic programs every health department requires, like emergency preparedness and response, as well as management of chronic diseases such as cardiovascular disease and diabetes.

The minimum package, called the Foundational Public Health Services, was defined in such a way that individual elements could have their costs estimated and could help inform public health funding decisions, with the goal that Congress would authorize "a dedicated, stable, and long-term financing structure" to appropriate the necessary money for every community to deliver the minimum package.[112] Lack of investment in these Foundational Capabilities and basic programs (Foundational Areas) are directly associated with health departments' inability to address key challenges of COVID-19 in many cases and poor population health that put the population at higher risk of mortality and morbidity.[113] A seminal study done in 2018 estimated that an additional investment of about $11 billion, or $34.3 per capita, was necessary to close the resource gap and achieve full implementation. Of that $11 billion, $4.5 billion was attributable to Foundational Capabilities and $6.5 billion was attributable to Foundational Areas.[114]

The IOM recognized that building a public health system that would possess Foundational Capabilities and deliver programs in all Foundational Areas required agreed-upon definitions of public health activity across all levels of governments, coupled with a standardized financing accounting system for public health, something sorely missing. Health departments across the country still use highly idiosyncratic financial accounting systems that are not designed for financial and program management, making it difficult to see how particular inputs lead to outcomes or allow for comparisons and accountability.

The 2012 report recommended building a uniform chart of accounts that would complement existing financial account systems. Adoption of such a system would prepare health departments to not only start developing the minimum package of public health services with federal support, but become more efficient and informed in decision-making.[115] In collaboration with state and local health officials, the Public Health National Center for Innovations, and with funding from HHS and the Robert Wood Johnson Foundation, the Public Health Activities & Services Tracking at the University of Washington has piloted and continues to test a Uniform Chart of Accounts with the goal of widespread adoption to increase transparency and accountability for public health investments.[116]

The public has understood the dangers of underinvestment in public health funding as well. A May 2021 survey from the Harvard Opinion Research Program and Robert Wood Johnson Foundation[c] found that over 70% of adults "favor substantially increasing federal spending on improving the nation's public health programs" and the same proportion believes public health agency activities are very or extremely important to the nation's health. Though COVID-19 was unsurprisingly most often chosen as one of the top two health problems currently, public health issues of obesity, heart disease, diabetes, and drug addiction/abuse together were perceived by many as serious challenges.[117]

Approach to Recommendations

The following recommendations fit into a strategy of enhancing the country's ability to combat pandemics and other public health emergencies and also enabling state, local, territorial, and tribal public health departments to engage in the day-to-day activities to promote health and address disparities through the Foundational Public Health Services framework. They build on promising existing activities, models, and opportunities while introducing necessary funding and structural alignment.

For the federal government to **plan** and **prepare** for similar emergencies in the future:

1) Assess federal funding of pandemic preparedness and response, and exempt essential federal public health functions from all budget restrictions

For the federal government to **provide** immediate, necessary resources to impacted jurisdictions in a transparent, accountable, and flexible manner:

2) Replenish and encourage the use of the Public Health Emergency Fund immediately following the declaration of a public health emergency and as the vehicle for supplemental appropriations addressing the emergency

For state, local, territorial, and tribal public health departments to **perform** the

c Robert Wood Johnson Foundation is one of the funders of this project.

necessary functions that support basic public health protections and other key programs and activities:

3) Create a new mandatory fund of $4.5 billion to support foundational state and local public health capabilities, to be administered by appropriators annually to HHS for these purposes

For state, local, territorial, and tribal public health departments to deliver topic-specific programs and activities that **prevent** morbidity and mortality from public health emergencies, reduce disparities across multiple dimensions, and improve quality of life:

4) Reform and increase the funding of the Prevention and Public Health Fund from $900 million to $4 billion to finance Foundational Areas and local needs, including communicable disease control, to improve health and reduce downstream costs of medical care

A public health excise tax would raise at least $7.6 billion to finance the last two recommendations.

Recommendations

1. **Assess existing federal funding of pandemic preparedness and response activities for opportunities to increase coordination and efficiency and improve equity. For programs deemed highest priority to prevent, detect, and address infectious disease threats, create a permanent budget designation named Biodefense Interagency Operations outside annual 302(a) allocations, and should they be established by future legislation, outside overall budget limitations.**

Though the pandemic has not ended, policymakers and researchers have already identified some of the gaps and shortcomings in the federal response.[118,119] For example, underfunding of the SNS led to severe shortages in PPE early on in the pandemic.[120] Many of the recommendations in the first section build on that work with the goal of supporting the mission-critical functions that only the federal government can take on, but there is still a lack of clarity on how and whether federal funding of emergency preparedness and response across different agencies effectively address biological threats.[121] Federal funding to health departments through Public Health Emergency Preparedness cooperative agreements and the HPP have also dropped sharply.[122]

To this end, Congress should form a Joint Select Committee including members representing the relevant authorizing and appropriating committees to evaluate existing federal funding, identify mission-critical investments, and produce legislative recommendations with stakeholder feedback on how interagency funding can be better coordinated and optimized. The large inflow of short-term, limited funding in COVID-19 supplemental appropriations legislation and the focus of testing, treatment, and vaccination of the most vulnerable

populations further warrants an evaluation of the activities that should be funded in the future in anticipation of future pandemics. Those programs deemed mission-critical would receive the Biodefense Interagency Operations (BIO) exemption, allowing them to be exempt from budget caps, including any possible new discretionary spending limits enacted after their expiration at the end of FY2021. Federal departments and agencies should also be allowed to independently request the BIO exemption for their programs to ensure the country remains vigilant and primed for pandemic threats.

Appropriations Committees in Congress would still provide oversight and accountability in approving exemptions, and subsequently as part of their regular reports. The Congressional Budget Office would be tasked with detailing total federal funding, exempt and nonexempt, directed toward pandemic emergency preparedness and response. The National Board for Pandemic Preparedness recommended in the previous section would report on how funding has advanced federal pandemic preparedness capacity and capability.

In addition to the Public Health Emergency Preparedness cooperative agreements and the HPP, examples of programs, projects, and activities that could potentially be tagged with the BIO exemption include:

- National Center for Epidemic Forecasting and Outbreak Analytics: President Joe Biden issued an executive order the day after his inauguration for his senior staff to develop a plan to create an interagency organization "to modernize global early warning and trigger systems to prevent, detect, and respond to biological threats."[123] Envisioned as the disease forecasting version of the National Weather Service, which itself required decades of investment to develop into its current form, the organization would be able to centralize outbreak modeling and analytics expertise to inform public health policy on a permanent basis.[124] Investments up to now have largely been in the form of conditional, academically oriented grants, and researchers have been challenged by data issues, while the center would enable government and academics to work closely and continually improve science and technology.
- HHS Regional Disaster Health Response System: The Bipartisan Commission on Biodefense recommended in a March 2021 report that Congress authorize and fund, on a multiyear basis, a stratified biodefense hospital system, where hospitals would be categorized based on their capability to treat patients affected by infectious diseases due to bioterrorism and other events. CMS would associate hospital funding with hospitals' ability to meet accreditation standards set for each stratum. Such a system would place patients where they could be treated most efficiently and enable resources to be better allocated to where they are needed.[125]
- SNS: The Stockpile was meant to serve as a backstop to states and health care organizations that had exhausted their medicines and medical supplies during a public health emergency. However, the rigorous federal decision-

making process for determining what to stockpile had diminished over time. The SNS's supply of face masks and N95 respirators had not been replenished since 2009 and was woefully inadequate in providing the PPE and ventilators needed, especially during the early part of the pandemic.[126]

Additional funding in future years could support the attainment of pandemic preparedness metrics set by the national board.

Former CDC Director Tom Frieden and other public health officials have proposed a similar idea, including the requirement that designated programs submit a bypass professional judgment budget annually to Congress explaining the resources needed for public health defense.[127]

2. Allocate funding to the Public Health Emergency Fund for use immediately following a Public Health Emergency declaration and use it as the primary vehicle for supplemental appropriations funding.

To enable the federal government to rapidly deploy funding as a stopgap measure in a public health emergency until Congress is able to pass emergency supplemental appropriations, Congress should add significant funding to the Public Health Emergency Fund and consider passing future supplemental appropriations through the fund in future emergencies.

There is currently no money in the existing Public Health Emergency Fund to support a designation of a public health emergency by an HHS secretary. This lack of permanent funding necessitates either the transfer of funds from other programs within the executive branch, to the extent that is possible, or delays in waiting for supplemental funding from Congress. Both of these options have drawbacks and can hamper an emergency response when speed is of the essence.

Though Congress has recently established and maintained the funding of the Infectious Diseases Rapid Response Reserve Fund, that fund is primarily operated by the director of the CDC, not HHS, and has limited authority. The Public Health Emergency Fund is managed by the secretary of HHS and is designed to be used across HHS for a larger range of purposes related to public health emergencies, and contains oversight mechanisms, including a mandated review by GAO.[128] The Infectious Diseases Rapid Response Reserve Fund will be critical in launching the response to future infectious disease pandemic, but would be unable to fund the response to disasters like nuclear accidents, chemical spills, natural disasters, or nonbiologic terrorist attacks.[129] If the Public Health Emergency Fund was not empty at the start of the pandemic, the secretary arguably could have used its funding to better coordinate activities in the agency, spent the money according to criteria much more detailed than the Reserve Fund, and automatically triggered reports from HHS to Congress, as well as a GAO review.[130]

Congresswoman Rosa DeLauro, chair of the House Appropriations Committee, has introduced legislation to allocate a one-time payment of $5 billion to the Public Health Emergency Fund to better prepare the government for future emergencies.[131]

3. Allocate $4.5 billion in permanent annual mandatory funding to a new Public Health Infrastructure Account to support state, local, tribal, and territorial foundational public health capabilities.

The funding would enable state and local health departments to develop the minimal cross-cutting skills that are needed to support their delivery of public health programs and leverage the investment made through the American Rescue Plan to hire and train public health workers and encourage innovation. The $4.5 billion would be fully paid for through the public health excise tax explained in detail below, and though it would be transferred into an account through mandatory appropriations, the money must still be appropriated through the annual appropriations process. Funding would start at a lower annual level and then build up to $4.5 billion to enable jurisdictions to absorb increased funding and strengthen accountability. The HHS secretary would award 90% of the appropriated money in grants to jurisdictions based on factors including population size, level of health disparities, and level of health risk and chronic disease burden in the community, and public health governance structure. The remaining 10% would go toward federal technical assistance, research and development projects related to Foundational Capabilities, and oversight.

The grants would expressly go toward developing the following Foundational Capabilities, listed with the roles they could potentially play in addressing key COVID-19 challenges identified by the NAM and BPC:

1. Assessment/Surveillance
    - Organization and execution of COVID-19 tests and contact tracing
2. Emergency Preparedness and Response
    - Development of public reporting mechanisms, emergency protocols responsive to changing conditions, and advancements in testing technology and capacity
3. Policy Development and Support
    - Understanding of scope of legal mandate and authority, and development of infection control policies, including enforcement
4. Communications
    - Combat misinformation and execution of public information campaigns conveying best practices and responding to concerns

5. Community Partnership Development

    - Coordinate across sectors to frequently perform out-of-scope functions, like procuring necessary materials and working with clinical providers

6. Organizational Competencies

    - Proficiently lead and coordinate with other governmental entities, and provide IT, HR, financial, and legal services underlying all functions

7. Accountability/Performance Management

    - Assessment of progress and setbacks on new processes, programs, and interventions while following state and national mandates and guidelines

8. Equity

    - Understanding disparities in the impact of COVID-19 and policies dealing with COVID-19, and reduce them through the use of data, targeted outreach and education, prioritization of resources, and recognition of the intersection of social determinants of health and unique challenges faced by marginalized populations

All jurisdictions (states, territories, and localities) would be able to apply for the grants and must include a preliminary assessment of their existing Foundational Capabilities in their application. As a condition of receiving the grants, jurisdictions have to specify how the funds will advance specific Foundational Capabilities and agree to the following conditions:

- Adopt and use a uniform "chart of accounts" whereby jurisdictions will crosswalk their accounting systems onto a standardized public health financial data tracking system, where expenditures and revenues can be categorized into Foundational Capabilities, Foundational Areas, and local needs.
- Meet interoperability requirements, data collection, and reporting standards to align with the CDC's DMI, pursuant to the recommendations included in the Data Modernization Initiative.
- Receive accreditation aligned with the Foundational Public Health Service framework within five years to demonstrate progress toward attaining these capabilities.

    - The Public Health Accreditation Board has aligned the standards and domains (groups of standards) in its current version of its accreditation standards and measures with the Foundational Capabilities and will work to further align them to the measures level that is used to evaluate whether standards have been met when they update their process — set to take effect in 2022.[132]

- Meet pandemic preparedness benchmarks set by the National Board on Pandemic Preparedness once released, as described in the second recommendation under Intergovernmental Roles and Responsibilities.
- Funds received will supplement—not supplant—existing state and local dollars funding public health infrastructure.

Beyond these, states and territories must also agree to:

- Develop or modify an existing state health improvement plan to explain how the funds will go toward developing Foundational Capabilities with the participation of all local health departments, including localities that have not applied for these grants.
- Develop a dashboard with community and partner engagement to track progress on equity measures.
- Use a portion of the money to test the ability of entities under their jurisdiction to deal with a public health emergency through simulated exercises and drills.

The increase in mandatory funded programs in the last few decades beyond the traditional entitlement programs of Social Security, Medicare and Medicaid have generated pushback from budget and appropriations committees in Congress and external actors concerned about the federal deficit. However, the longstanding underfunding and lack of attention paid to public health, particularly in states and localities, have deepened gaps in the country's ability to address public health challenges and emergencies. A two-step process of mandatory appropriations into a dedicated fund and discretionary appropriations from that fund presents the possibility of stable funding subject to congressional control. The account would follow the model used by Congress for the 21st Century Cures Act[133]:

1) The NIH Innovation Account in the 21st Century Cures Act is set up with specified amount of funding transferred to the account every year that Congress has authorized to be used for NIH Innovation Projects, defined elsewhere in the statute. In the case of the Public Health Infrastructure Account, $4.5 billion would be transferred annually and authorized to be used as CDC grants to jurisdictions for Foundational Capabilities and supporting activities.

2) While the transferred money for the NIH Innovation Account comes from "direct spending savings" through budget offsets including Medicare and Medicaid reductions, funds transferred from the Prevention and Public Health Fund, and stock sales from the Strategic Petroleum Reserve, among other offsets, the money transferred to the Public Health Infrastructure Account comes from revenue generated by the Public Health Excise Tax. In both cases, the transfer is budget neutral and would not raise the federal deficit.

3) In addition to fully offsetting the transferred money, the legislation contains language ensuring that "appropriations from the "Innovation Account" are made at "no cost" to the Appropriations Committee as measured against its [§302(b)] allocation," so that funding for these Innovation Projects do not supplant funding for other programs and are not supplanted themselves. The same instruction applied to the Public Health Infrastructure Account ensures a commitment to critical funding to states and localities to develop these cross-cutting public health capabilities, as appropriators would not have any incentive to reduce funding since doing so would not have an effect on the allocation of money for other programs and agencies.

This model satisfies advocates and authorizing committees on one side who support stable funding, and budget and appropriation committees that wish to retain their authority over appropriations and not relinquish more control over the budget.

Members in both chambers of Congress have introduced legislation calling for the same amount of money but without a dedicated financing source and containing other differences.[134] Almost 260 organizations, including BPC Action, have supported increasing annual funding for CDC, state, local, tribal, and territorial core public health infrastructure by $4.5 billion.[135]

4. Reform and increase annual funding to the existing Prevention and Public Health Fund from its current level of about $900 million to $4 billion to bolster inadequately supported public health programs and meet local needs

Congress should reauthorize funds from the Prevention and Public Health Fund to go toward grants to local and state health departments to support Foundational Areas of public health, and toward Preventive Health and Health Services Block Grants, which give health departments "the flexibility to solve problems unique to their residents, while still being held accountable for demonstrating the local, state and national impact of the investments."[136] Health departments that are accredited would have increased flexibility to spend these funds and would be encouraged to provide shared services and collaborate on regional initiatives. The Task Force recommends reforming and increasing the funding for the Prevention and Public Health Fund so it solely supports public health programs delivered by states and localities, is protected from cuts and disruptions from both parties, and is tied to broader-based public health reform.

The Prevention and Public Health Fund was unfortunately used to "support federal priorities that were, at best, loosely tied to public health or prevention" and saw billions in dollars of cuts, largely to offset other legislation items.[137] The ACA gave Congress authority to transfer money from the fund to use for broad, authorized purposes, which Congress has used for the past several years to largely supplant instead of supplement existing programs administered by

the CDC, contrary to its initial purpose of expanding prevention and public health programs without subjecting them to the annual appropriations process. For political and fiscal reasons, Congress has also used money from the fund to offset the cost of other items.[138] This has created a "robbing Peter to pay Paul" dynamic.[139] Statutory language would be added to law to prevent Congress from using the Prevention Fund for purposes not specifically articulated as Congress has been doing since 2014, specifically prohibiting the use of the Prevention and Public Health Fund by Congress or the Administration to offset other costs.[140]

Given existing funding of about $900 million, an increase of $3.1 billion annually, phased in over several years, would be a major investment toward the approximately $6.5 billion gap in resources needed for health departments to deliver the programs in Foundational Areas, and a sound investment in light of a McKinsey report that estimates that poor health costs the country about $3.2 trillion annually from premature deaths and lost productivity.[141] Not only has the poor health of the U.S. population left it more vulnerable to COVID-19, but the resource gaps will worsen due to severe effects of the pandemic on population health in areas like mental health and opioid addiction, and the "damage it has made to progress on other public health priorities."[142] Working together with public and private health care partners, public health departments can also use lessons learned from the fight against COVID-19 in redesigning programs so they address "monumental health care disparities."[143]

The Foundational Areas are:

1. Communicable Disease Control
2. Chronic Disease and Injury Prevention
3. Environmental Public Health
4. Maternal, Child, and Family Health
5. Access to and Linkage with Clinical Care

Most of the money in the Prevention and Public Health Fund has been used to combat public health challenges such as diabetes and smoking.[144] But the money has not been enough to fully address America's chronic health issues. COVID-19 told the tale of why this gap was deadly. A study of COVID-19 hospitalizations attributed 30% to obesity, 25% to hypertension, 20.5% to diabetes, and 11.7% to heart failure. Jointly, 63.5% of hospitalizations could be attributed to these four conditions.[145] These results underscore how the poor health in the U.S. population has exacerbated the effects of the pandemic and suggest how effective public health interventions would have limited deaths and serious illnesses from COVID-19. Public health challenges will only continue to grow. Almost half of Americans by 2030 are expected to be obese, and obesity is "associated with increased rates of chronic disease and medical spending… [with] negative consequences for life expectancy.[146] Other challenges include the

increased prevalence of sexually transmitted diseases, the increase in nicotine addiction with the rise of vaping, and the widening health gap between the rich and the poor.[147]

Research has shown that public health investments can both improve health outcomes and reduce health care spending. A 2017 systemic review found a $14 return for every $1 spent on public health interventions in high-income countries.[148] Life expectancy in America increased by 30 years in the 20th century, and public health has been credited as responsible for 25 of those added years.[149] Groups such as Trust for America's Health have recommended restoring and growing the Prevention and Public Health Fund so it would be used to promote public health and prevention.[150]

Financing mechanism—Public Health Excise Tax

The task force believes that a financing mechanism should be identified to fund the $7.6 billion in new annual funding called for in Recommendation Nos. 3 and 4. Taxes on products that have an adverse effect on health not only have the potential to generate substantial amounts of funding but can lead to direct and indirect savings through discouraging behavior that may cause disease. Any revenues raised in addition to what is needed for the Public Health Infrastructure Account and the increase in funding to the Prevention and Public Health Fund could be used to cover losses in state revenue from the implementation of any of the options.

The country has had a long record of levying excise taxes, largely to help finance public goods like highways and airports. According to the Tax Policy Center, "Federal excise tax revenues—collected mostly from sales of motor fuel, airline tickets, tobacco, alcohol, and health-related goods and services—totaled nearly $100 billion in 2019, or 2.9 percent of total federal tax receipts."[151] The following are possible excise tax options to fund new public health appropriations.

The Congressional Budget Office has considered several excise taxes among options for reducing the deficit from 2021 to 2030, and produced the following estimates:[152]

- **Increasing the federal tax on tobacco:** An increase in the federal excise tax on all tobacco products (not including e-cigarettes which are not taxed federally), including cigarettes, cigars, pipe tobacco, and roll-your-own tobacco, by 50%, would generate $3.6 billion annually, and also reduce government expenditures by $80 million annually. Cigarettes are currently taxed on the federal level at $1.01 and from 17 cents to $4.50 on the state level for each pack.
- **Increasing the federal tax on alcohol**: Standardization and increasing the tax on alcoholic beverages to $16 per proof gallon would raise $8.34 billion annually, and $9.56 billion annually if indexed for inflation.

Other options include:

- **New federal tax on nicotine in vaping and other similar purposes:** A tax of $50.33 per 1,810 milligrams of nicotine, as proposed in the Protecting American Lungs Act of 2019, would apply to all nicotine in this category except for approved nicotine replacement therapy and nicotine covered in the federal tobacco tax. This would generate about $1.5 billion annually.[153]
- **New federal tax on sugar-sweetened beverages**: A few localities in the United States have levied soda taxes on sugary drink taxes. The rise in obesity has been linked to excess sugar consumption.[154] A study in 2015 found that a national excise tax of 1 cent per ounce would have positive health effects, save $23.6 billion over 10 years, and generate $12.5 billion in annual revenue.[155] A study in 2020 found that a tax at the same level would raise $80 billion in tax revenues and save $55 billion in national health care costs over 30 years, but a tiered tax (no tax for low sugar levels, 1 cent per ounce for medium sugar levels, and 2 cents per ounce for high sugar levels) would produce approximately double the health gains and savings.[156]

Conclusion

As the United States continues its recovery from COVID-19, the nation needs to turn its focus to revitalizing the public health system and prepare the country for the next wide-scale public health emergency. BPC's Future of Health Care leaders' recommendations represent a common-sense, bipartisan path toward the goal of preventing a repeat of the economic, social, and health disruptions over the past year and a half. Congress and the White House need to create clarity on federal roles during a pandemic; a stronger mechanism for inter-agency cooperation during an emergency; and should ensure the nation is adequately investing in public health emergency preparedness at the federal, state, and local level. The public health system cannot fulfill emergency responsibilities without high quality data; therefore, policymakers should support the development of 21st-century, interoperable data and technology systems to sufficiently respond to health disasters. COVID-19 has shone a bright light on long-standing disparities in the health outcomes across racial, ethnic, and income groups. Providing long-term investments in the public health system of at least $7.6 billion annually will ensure the system develops Foundational Capabilities to address public health emergencies and can carry out foundational public health functions—such as obesity and diabetes reduction, drug addiction prevention, and discouragement of tobacco and e-cigarette use—to foster a healthier population that is less susceptible to infectious diseases like SARS-CoV-2, the virus that causes COVID-19. BPC's leaders appreciate the significant resources Congress has already provided for these efforts and the executive branch's implementation efforts. These recommendations are the next step to build on the lessons learned from COVID-19, and to position the country to support the long-term health of its citizens.

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