A Report by a Working Group of the
NATIONAL ACADEMY OF PUBLIC ADMINISTRATION

Intergovernmental Dimensions of the COVID-19 Responses and Consequences

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March 2022

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Intergovernmental Dimensions of the COVID-19 Responses and Consequences

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About the Academy

The National Academy of Public Administration is a non-profit, non-partisan, and independent organization of top public management and organizational leaders who tackle the nation's most critical and complex public management challenges. With a network of more than 950 distinguished Fellows and an experienced professional staff, the Academy is uniquely qualified and trusted across government to provide objective advice and practical solutions based on systematic research and expert analysis.

Established in 1967 and chartered by Congress in 1984, the Academy continues to make a positive impact by helping federal, state and local governments respond effectively to current circumstances and changing conditions. Learn more about the Academy and its work at www.napawash.org.

Foreword

As we finalize this initial report of the National Academy of Public Administration's (the Academy) Working Group on the Intergovernmental Dimensions of the Coronavirus Disease 2019 (COVID-19) Pandemic (WG or the Working Group), we find that the fourth wave of infections from the omicron variant is waning, although reported cases and hospitalizations remain high in some parts of the country. Known fatalities due to COVID-19 are approaching one million nationally. And government policies to combat the pandemic continue to vary across and within jurisdictions.

The response to the COVID-19 pandemic has highlighted both strengths and weaknesses in the nation's ability to respond to a novel global infectious disease threat with one of the defining characteristics of the response being the disparate alignment of public health and other interventions across the federal, state, and local levels of government. Individual states and local jurisdictions have very differently balanced risks associated with COVID-19 infection against the impact of infection risk reduction interventions on other dimensions of health, society, and family life (e.g., business, religious practices, and school attendance).

Myriad examples illustrate the varied and sometimes conflicting governmental responses to this once-in-a-century pandemic. For example, as we write this, lawmakers in some state legislatures are meeting remotely out of concern about contracting or spreading the infection and are vigorously promoting increased vaccination, frequent testing, and other infection control precautions. Lawmakers in other states are meeting in person and seeking to outlaw vaccine mandates and forbid basic public health pandemic precautions such as masking and social distancing in schools and workplaces. Lawmakers who have historically supported free-market approaches to business now appear intent on preventing businesses from conducting their businesses as they see fit when it comes to infection control precautions.

Disturbingly, public health officials, school board members, and other officials who have sought to effect policies and practices to control the pandemic have been harassed and forced to endure an unprecedented barrage of verbal and physical assaults, threats, and other abuses. More than 300 state and local public health officials and many additional lower-level staff have been fired or forced to retire for promoting or implementing well-established public health interventions to combat the spread of infection. The hostility and growing number of threats and acts of violence against government workers in their professional capacities have prompted the National Association of County and City Health Officials to request protective help for these workers from the U.S. Department of Justice. The harassment and threats directed at public health personnel have driven many out of the field since the onset of the pandemic, and the system is now being further challenged in some jurisdictions by the enactment of public policies that remove authority from the professionals who work to protect public health. Without question, the Nation's long-neglected and underfunded public health system has been pushed to the brink by the COVID-19 pandemic.

About This Report

To increase the understanding of the strengths and vulnerabilities in the intergovernmental response to the pandemic, and to promote dialogue in this regard, the Academy convened the Working Group in the spring of 2021. The Working Group was composed of 14 Academy Fellows and three other experts and comprised broad practitioner, programmatic, managerial, and academic experience at the city, county, state, and federal levels of government. The WG was unfunded and had no specific charge or statement of work. Each WG member volunteered their time and expertise.

The WG focused on the four topical areas that constitute the sections of this report: (1) COVID-19 Testing, (2) Non-Pharmaceutical Interventions, (3) COVID-19 Vaccine Distribution, and (4) Cross-Cutting and Over-Arching Issues, including but not limited to data tracking and supply chain management. Research on each topic proceeded independently to develop findings and recommendations based on each subgroup's selected method(s) of assessing the issue.

Each of the four sections of this report takes different approaches. The COVID-19 testing chapter proceeds from the perspective of county and state government interaction with the federal government, outlining the timeline of events. The Non-Pharmaceutical Interventions (NPIs) chapter draws on the public administration perspective on the structure and interactions of the intergovernmental system across the administrative and political dimensions. The Vaccine Distribution chapter draws on strong public health experience and a range of real-time federal, state, and county reports to assess the adequacy of the vaccination infrastructure across the different levels of government. The chapter on over-arching issues draws on first-hand experience in developing the descriptions of emergency response efforts at the federal level, as well as researching the data collection challenges.

The four sections draw on recent and current research, including specific cases or practices that describe the problem that needed to be addressed in the domain being examined; the facts of what happened; demonstrable vulnerabilities and the strengths and weaknesses in the response; actions that could be taken to improve the response; and changes in law, authority, policy, program design or implementation, or some combination of these things needed to achieve improvement. Each section offers recommendations developed independently and often intended to be a starting point for further discussion or analysis of the intergovernmental context of the pandemic response.

Because of the different areas of expertise of the WG members and variable methods of approaching the four topics, no attempt was made to achieve consensus on the findings and recommendations expressed in the individual sections of this report. While the four chapters are compiled together as a single report, this should not be taken to mean that there was aggregate agreement about the recommendations or that each member of the WG agreed with each recommendation. Instead, the chapters and associated recommendations reflect each subgroup's independent review and interpretation of published materials and, to a significant extent, their first-hand professional experience and subject matter expertise in the topical area.

We have been pleased to serve as co-chairs of the Working Group and are deeply grateful to all the Working Group members who have selflessly contributed to this report. We believe the response to the COVID-19 pandemic offers an unprecedented opportunity to examine federalism in action, and we hope this is the first of many attempts to understand better how government jurisdictions across the spectrum of federal, state, and local government can facilitate the nation's response to the next pandemic, which is not a matter of *if,* but instead only a matter of *when* or *how soon*.

Kenneth W. Kizer, MD, MPH, Co-Chair

Richard F. Callahan, DPA, Co-Chair

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Acronyms and Abbreviations

Acronym or Abbreviation	Definition
2019-nCoV	2019 Novel Coronavirus
ASPR	Office of the Assistant Secretary for Preparedness and Response within the US. Department of Health and Human Services
CDC	U.S. Centers for Disease Control and Prevention
CMS	U.S. Centers for Medicare and Medicaid Services
COVID-19	Coronavirus Disease 2019
DoD	U.S. Department of Defense
DOT	U.S. Department of Transportation
ESF-8	Emergency Support Function #8 Council
FDA	U.S. Food and Drug Administration
FEMA	U.S. Federal Emergency Management Agency
GAO	U.S. Government Accountability Office
GSA	U.S. General Services Administration
HHS	U.S. Department of Health and Human Services
HRO	High-reliability organization

IIS	Immunization Information Systems
IRF	ASPR Incident Response Framework
IZ Gateway	Immunization Gateway
LRN	Laboratory Response Network
MERS-CoV	Middle East Respiratory Syndrome coronavirus
NAM	National Academy of Medicine
NASA	U.S. National Aeronautics and Space Administration
NIH	U.S. National Institutes of Health
NPI	Non-pharmaceutical intervention
OSHA	U.S. Occupational Safety and Health Administration
PHE	Public Health Emergency
PHS	U.S. Public Health Service
PPE	Personal Protective Equipment
SARS-CoV	Severe Acute Respiratory Syndrome coronavirus
SLTT	State, Local, Tribal, and Territorial
SNS	Strategic National Stockpile

The Academy	The National Academy of Public Administration
The Council	The Medical Capability Allocation and Reallocation Council
TSA	U.S. Transportation Safety Administration
VA	U.S. Department of Veterans Affairs
VAMS	Vaccine Administration Management System
WCF	Working Capital Fund
WG or Working Group	The Academy's Working Group on the Intergovernmental Dimensions of the COVID-19 Pandemic
WHO	World Health Organization

Summary and Selected Recommendations

With the goal of better understanding the strengths and vulnerabilities of the intergovernmental responses to the COVID-19 pandemic, the National Academy of Public Administration convened the COVID-19 Working Group on the Intergovernmental Dimensions of the COVID-19 Pandemic in the Spring of 2021.

The Working Group assessed the intergovernmental responses to identify key issues and develop actionable recommendations in four areas that may facilitate the nation's response to the next pandemic.

Methods and Limits

The Working Group was not convened to address a specific topic and did not have a defined statement of work. Initially meeting and deliberating as a single group, it agreed to address the four topical problem areas that constitute the four sections of this report. After identifying these problem areas, the WG split into four self-selected subgroups and independently addressed their chosen problem area using different approaches and methods to assess the issue and develop findings and recommendations. Because of the different areas of expertise of the WG members and variable methods of approaching the four topics, no attempt was made to achieve later consensus or agreement on the findings and recommendations of the subgroups. Instead, the chapters and associated recommendations reflect each subgroup's independent review and interpretation of published materials and, to a significant extent, their first-hand professional experience and subject matter expertise in the topical area.

In reading this report, it should be remembered that it is not a consensus report. Each chapter draws on the collective professional experience of the three to seven members of the subgroup addressing the given problem area, as well as their review of published reports and other materials. The National Academy of Public Administration received no funding to support the Working Group; each member volunteered their time and expertise.

The four problem areas considered by the subgroups are listed here, and their assessments of the intergovernmental response issues and recommendations for improvement are recorded in the four sections of this report.

1. Testing for COVID-19
2. Non-Pharmaceutical Interventions for Infection Risk Reduction
3. Vaccine Distribution
4. Cross-Cutting and Over-arching Issues

Background

The response to the COVID-19 pandemic has highlighted both strengths and weaknesses in the United States' collective capacity to respond to novel global infectious disease threats. Some of the nation's greatest challenges in responding to the COVID-19 crisis have resulted from the disparate alignment of public health priorities and other interventions across the federal, state, and local levels of government. Different states and local jurisdictions came to different

conclusions when balancing the risks associated with COVID-19 infection with the impact of infection risk reduction interventions on other dimensions of health, society, and family life. The variety of responses by government jurisdictions provide an opportunity to examine intergovernmental systems in response to a national crisis, as well as the impacts of specific public health interventions.

The variety of political and policy decisions have raised questions of law, authority, policy, program implementation and coordination, and resource allocation, among other things. These questions have been clearly and repeatedly observed throughout the pandemic in the demonstrable tensions and conflicts between elected officials at different levels of government and between appointed and elected officials at all levels of government. Understanding where the crisis response appeared to go well and where uncertainties about law, authority and other matters impaired an effective crisis response is important because - as recent history has made clear - additional and potentially more serious global infectious disease threats will again confront us in the years ahead.

Working Group Participants
The Working Group was co-chaired by Academy Fellows Dr. Kenneth W. Kizer and Professor Richard Callahan, with 12 additional Academy Fellows and three other experts. Four of the WG members have experience as state health directors (including the District of Columbia) and three have experience with local city or county health departments; several members have experience with multiple different federal agencies, including the U.S. Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA), as well as oversight of the National Disaster Medical System; and others have strong research and academic expertise, including five current or former deans of university graduate programs in public health and public administration.

The Working Group report focuses on issues that have emerged in response to the pandemic through the lens of how problems of policy and intergovernmental functioning affected health and delivery of healthcare services, the acquisition and allocation of supplies and personal protective equipment, and local business activities and economies, among other areas. Each of the four sections has been written by independent teams. They describe the problem that needed to be addressed, the demonstrable response vulnerabilities and the strengths and weaknesses in the response; what actions could be taken to improve the response; and whether the desired improvement requires changes in law, authorities, policy, program design or implementation, or some combination of these things.

Intergovernmental Challenges Issue Areas
Each issue team independently addressed key intergovernmental challenges, as follows:

1. The Testing Issue Team reviewed limitations in public health agencies and intergovernmental relations that prevented rapid scale-up of testing, including lab capacity and contact tracing. It examined the consequences of unclear and/or delayed guidance from the federal government. This issue team developed a timeline of key events considering the federal and state actions.

2. The Non-Pharmaceutical Interventions (NPIs) Issue Team analyzed the intergovernmental responses to this public health crisis for recommendations on the deployment of infection risk reduction NPIs such as social distancing, use of facial masks, restrictions on in-person contacts, and reduction or limits in indoor or outdoor meetings.
3. The Vaccine Issues Team focused on key vaccine distribution vulnerabilities, health equity, variations in rates and designations of eligibility, and technological issues regarding scheduling appointments. The team considered recommendations regarding the roles of federal, state, and local governments in creating guidance on vaccine delivery and implementation of vaccination administration methods for hard-to-reach populations, vaccination priorities during periods of limited supply, and funding for vaccine distribution.
4. The Cross-Cutting and Over-Arching Issues Team considered the merits of centralized versus decentralized response systems, how to balance the relative values of health and economic impacts, the challenges presented by a lack of consistent standards across levels of government, and how to mobilize and use disbursed public authority effectively. This Issue Team includes the lessons learned from decisions made throughout the response process (e.g., Medicare and Medicaid waivers for telehealth payments and use of authorities triggered by the declaration of a National Public Health Emergency).

Overall, this report offers some independent perspectives on how well the intergovernmental public health and human service systems and our decentralized and distributed governance structure protected and provided for the general welfare of the populace. The COVID-19 pandemic offers an unprecedented opportunity to examine federalism in action. From this examination, the members of the Working Group provide over three dozen recommendations that provide a starting point for further evaluating the intergovernmental response to a major public health crisis.

Selected Recommendations

Below are selected recommendations from the 37 recommendations provided by the four subgroups. Complete lists of the sub-group's recommendations are provided in each section. The recommendations are intended to offer insights to enhance and operationalize improved future performance. In some instances, the recommendations are put forward for the purpose of opening a more comprehensive dialogue on the issue.

Section 1: Testing Response
Recommendation 1.1: The Department of Health and Human Services (HHS) should re-affirm the expectation that CDC and FDA will lead efforts to deploy the full contingent of national and academic labs for test development, testing for results, distribution of tests, and immediate data reporting.

Recommendation 1.3: HHS should establish an 'early warning testing system' for airborne transmitted pathogens in settings that would likely be first impacted by such pathogens. These settings should include, among others, airports of departure and arrival of international travelers, cruise ships, military installations, and health facilities serving populations at high risk of carrying such pathogens.

Recommendation 1.4: The Occupational Safety and Health Administration (OSHA) should develop testing strategies to detect airborne pathogens in sectors where workers are in closed or confined environments and/or in critical infrastructure such as transportation, food processing and meatpacking, and K-12 schools.

Recommendation 1.5: In collaboration with state and local public health departments, the CDC should develop criteria for circumstances when infectious disease containment strategies should be shifted to broad population health protection strategies employing non-pharmacologic and/or other interventions for infection risk reduction.

Recommendation 1.7: In collaboration with state and local public health departments, the CDC should develop strategies and capabilities for rapid deployment of large sample size seroprevalence testing for respiratory pathogens.

Section 2: Non-Pharmaceutical Interventions for Infection Risk Reduction

Recommendation 2.3: HHS should request that the National Academy of Public Administration convene an expert panel to develop recommendations on effectively promoting transparency and accountability in intergovernmental public health responses.

Recommendation 2.4: HHS should fund research on promoting public trust in the government's response to infectious disease emergencies, including the use of NPIs for infection risk reduction and vaccine use.

Section 3: Vaccine Distribution

Recommendation 3.2: HHS should sustain a major public health program on vaccine acceptance, including tracking of vaccination uptake, tracking of anti-vaccine activities, research into strategies to counter vaccine hesitancy, and funding for state and local outreach and communication activities.

Recommendation 3.3: HHS should assess the personnel needs of the U.S. Public Health Service (PHS) Commissioned Corps to support responses to infectious disease outbreaks and pandemics and how those needs can be best addressed on an ongoing basis.

Recommendation 3.4: HHS should establish clear standards for vaccination prioritization that include some flexibility for state and local circumstances. These standards should

correspond to the risk of serious illness and death in specific communities. The HHS should encourage the adoption of these standards by providing additional funding to states and local jurisdictions that adopt them.

Recommendation 3.5: HHS should establish a publicly accessible dashboard to track vaccine distribution efforts. This dashboard should have standardized reporting criteria for states and localities, ensuring accurate and reliable data collection and comparable reporting across the country. Data from this dashboard should be used to assist state and local jurisdictions to respond to demonstrated needs.

Recommendation 3.8: From the start of vaccination campaigns, local jurisdictions should lead efforts to reach communities at greatest risk of infection. Strategies to reach unvaccinated populations may include mobile vaccination vans, walk-in community centers, door-to-door outreach, or phone bank efforts. These efforts should be rapidly expanded in the context of the COVID-19 pandemic and should occur throughout all phases of vaccine distribution.

Recommendation 3.10: The CDC should require that all states participate in a common data sharing platform (e.g., IZ Gateway) to facilitate vaccine reporting and should provide funds to states without immunization information systems (IIS) systems compatible with a shared platform to support the transition to a common reporting platform.

Recommendation 3.11: HHS should provide adequate and sustained funding for active engagement of underserved and vulnerable communities in vaccination and other public health efforts. These efforts should work with community members and leaders to solicit their input on gaps in access to services and outreach strategies to build trust.

Section 4: Cross-Cutting and Over-Arching Issues

Recommendation 4.1: Maintain congressional authorization for the Centers for Medicaid and Medicare Services (CMS) 1135 waiver authority to facilitate immediate deployment by CMS to respond to emergent conditions.

Recommendation 4.2: HHS should consider maintaining Medicare's expanded telehealth authority in perpetuity.

Recommendation 4.3: HHS should work with relevant health sector stakeholder organizations, among others, on ways to ensure that the medical supply chain can provide hospitals that participate in the Medicare program with a 90-day supply of their average usage rate of essential personal protective equipment (PPE) items to enhance the health system's readiness and resiliency to manage pandemics and other public health emergencies.

Recommendation 4.4: HHS should work with other agencies (e.g., General Services Administration (GSA), Department of Defense (DoD)), supply chain industry leaders, and

standards-setting bodies (e.g., National Quality Forum, National Institute of Standards and Technology) to develop and broadly adopt a foundational set of technical blockchain standards.

Recommendation 4.5: HHS should work with industry partners and government procurement organizations to promote and adopt blockchain standards for PPE manufacturers, distributors, and intermediaries.

Recommendation 4.6: HHS should seek ways for the Strategic National Stockpile (SNS) to have a working capital fund (WCF) that reduces reliance on new federal appropriations to sustain it so that it is better prepared to respond to public health emergencies readily.

Recommendation 4.10: HHS should work with states and industry stakeholders to move to a fully online, integrated data reporting and database management system. The data collected and updated regularly on a "COVID-19 Dashboard" by Santa Clara County provides a plausible example of what is needed.

Recommendation 4.12: HHS should capture the structure, technologies, and processes of the data systems developed to guide federal responses to COVID-19 in 2020, including roles of the U.S. Federal Emergency Management Agency, Office of the Assistant Secretary for Preparedness and Response, CDC, and DoD.

Section 1: Intergovernmental Dimensions of U.S. COVID-19 Testing Response

By Jonathan Freedman, Richard F. Callahan, and Maria Aristigueta

1.1 Background

The COVID-19 pandemic has been extraordinary in terms of the scope and magnitude of health and economic burden across the globe. The Scientific Academies of the G20 countries found that the pandemic highlighted the need to promote the creation of a global network of surveillance with the need to "...detect emerging unusual clusters of morbidity and mortality that may be the harbingers of a potential new pandemic."[1]

Testing for the COVID-19 infection has been a pivotal weakness of the international approach to global health threats and how the U.S. public health system detects, prevents, and mitigates such threats. As COVID-19 infections began in the United States and the need for expanded testing was seen as central to any possibility of containment, state and local government "...wait(ed) for a test being created by the CDC. The CDC itself was testing only sparingly."[2,3] The U.S. Government Accountability Office (GAO) found that the COVID-19 testing recommended by the U.S. Health and Human Services' national strategy documents did not comprehensively address the characteristics that GAO recommended for an effective national strategy.[4] In Pulitzer Prize-winning reporting, Ed Yong noted that "diagnostic tests are easy to make, so the U.S. failing to create one seemed inconceivable," finding that "it's hard to overstate how thoroughly the testing debacle incapacitated the U.S."[5]

Understanding the U.S. public health infrastructure starts with a recognition that the system is composed of complex intergovernmental dimensions, with legal authority residing in city, county, state, and federal public departments and agencies. Fundamentally, public health systems in the U.S. rely on cooperation to make the system work because, in an intergovernmental model, the federal government manages some functions while states and their localities manage others and customize them to the wants and needs of their respective populations. The intergovernmental dynamics are characterized by persuasion, discussion, and sometimes unfunded mandates, not by hierarchy with command and control.

This Section examines and develops recommendations for improving the intergovernmental relationships in the U.S. public health system, focusing on the early steps to detect COVID-19 in

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[1] Scientific Academies of G20. 2021. S20 Statement on Pandemic preparedness and the role of science. August. Available at https://www.interacademies.org/publication/s20-statement-pandemic-preparedness-and-role-science. Accessed August 30, 2021.
[2] Ibid. page 181.
[3] Lewis, M. 2021. The Premonition: A Pandemic Story. W.W. Norton & Company. Pages 172-177.
[4] U.S. GAO. 2021. Covid-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Action. January. Available at: https://files.gao.gov/reports/GAO-21-265/index.html. Accessed August 30, 2021.
[5] Yong, E. 2020. How The Virus Won: Anatomy of an American Failure". *Atlantic*. September. Page 37.

the United States. At the core of this effort are the long-standing research findings on high-reliability organizations (HROs) where lives are at stake, placing a premium on: "The important values in HROs (that) center around sense-making, not decision making."[6] This analysis and the subsequent recommendations are intended to deepen the understanding of the recent experience in testing for COVID-19 so that the analysis drives the recommendations for improved testing responses in this pandemic and future pandemics.

For sense-making in the COVID-19 pandemic, detection in the U.S. has focused on testing individuals to determine illness. However, for effective public health response, "testing" covers five concurrent public health activities:

1. Determining individual diagnostics for medical intervention;
2. Assessing the community infection rate, tracking of positivity rate changes over time;
3. Providing data to inform public health and elected officials for decision making;
4. Providing clearance of individuals and groups for close contact activities, such as public transit or sports; and
5. Comparison across jurisdictions with states, as well as across states.

Crisis Response within the U.S. Intergovernmental System

The U.S. public health system, which carries out functions ranging from environmental health and communicable disease control to chronic disease and injury prevention, is not uniform in its structure across the United States. In fact, it is "…highly decentralized and fragmented at every level, making coordination challenging."[7] Unlike other countries which have more vertically organized public health systems with a ministry of health and regional/local capabilities, the public health functions in the U.S. are split, with the states, counties, and cities carrying the bulk of the operational responsibilities.

With 59 state and territorial jurisdictions and over 2,459 local agencies, the potential for varied responses is quite high.[8] There also can be great variety in governance structures and varied innovations within each level of government. For example, each of the 119 counties in the United States with populations over 500,000 has its own local adaptation to specific needs, even though they all receive funds from the same federal sources.[9]

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[6] Weick, K. 2006. The Role of Values in High-Risk Organizations. In Leading with Values: Positivity, Virtue, and High Performance. Edited by Hess, E. and Cameron, K. Cambridge University Press. Page 58.

[7] Cigler, B. 2021. Fighting COVID-19 in the United States with Federalism and Other Constitutional and Statutory Authority. *Publius: The Journal of Federalism*, p. 6.
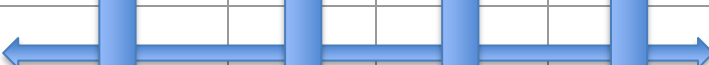
[8] NACCHO. 2019. National Profile of Local Health Departments. P. 21. Available at: : https://www.naccho.org/uploads/downloadable-resources/Programs/Public-Health-Infrastructure/NACCHO_2019_Profile_final.pdf Accessed August 30, 2021.

[9] National Academy of Public Administration. 2021. Coronavirus Relief Fund: Review of Federal Fiscal Assistance and of Innovative County Response Strategies. Available at: https://s3.us-west-2.amazonaws.com/napa-2021/NAPA-NACo-Final-Report-3.11.2021.pdf Accessed on August 30, 2021

The response to an emerging national crisis within the intergovernmental context requires multiple individuals, at varied levels of governments, to effectively engage in the four steps of crisis response, adapted from a model offered by J.M. Sharfstein:[10]

- Identify the crisis;
- Manage the crisis work with elected officials;
- Address communications and political authority; and
- Pivot to long-lasting change.

Table 1 below shows the complexity of crisis response in the U.S. intergovernmental system and the opportunities for cooperation and coordination failures in responding to the COVID-19 pandemic.

Crisis Responses	Federal Agencies	States	Counties	Cities
Identify the crisis				
Manage the crisis				
Address communications and political authority				
Pivot to long-lasting change				

Table 1: Complexity of Crisis Response in U.S. Intergovernmental System
(Table created by the National Academy of Public Administration)

This model calls for a comprehensive and diversified communications strategy for residents on the federal, state, and local efforts intended to counter COVID-19 or future pandemics. A comprehensive strategy might include written and visual messaging, repeatedly delivered through a wide array of means that public health officials, scientists, doctors, and other public servants may not typically utilize. Such means may include social media platforms, video clips, graphic data visualizations, dramatic storytelling, cultural icons, artists, athletes, and influencers.

Importantly, this complex model relies primarily on close coordination and decision making between the CDC and states and political authorities to act in concert. The Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) experience in 2002–2004 amplified awareness that just one plane landing can trigger the need for immediate public health action and intergovernmental coordination. Our history in responding to the potential for a flu-like pandemic in the "Swine Flu" in the mid-1970s also illustrates the challenges in anticipating and crafting a response to a potential national public health crisis. [11]

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[10] Sharfstein, J.M. 2018. The Public Health Crisis Survival Guide: Leadership and Management in Trying Times. Oxford University Press. p. 7

[11] Ibid., p. 6; Neustadt, R. and May, E. 1986. Thinking in Time: The Use of History by Decision-Makers. Free Press.; Lewis, M. 2021. p. 281-294.

Respiratory Disease

Respiratory diseases often have common signs and symptoms but can be caused by a wide range of pathogens, including bacteria, viruses, toxins and irritants, and other factors. For a communicable respiratory disease, determining the pathogen and modes of transmission and risk factors are critical to successful control. The emergence of COVID-19 as a new respiratory pathogen presented significant challenges in distinguishing it from existing pathogens.

When new respiratory pathogens emerge, distinguishing them from existing pathogens is among the most significant and complex public health challenges. It requires careful clinical and non-clinical data and information gathering on cases potentially occurring concurrently in different regions and states, and differential diagnosis, often with laboratory confirmation. The swift deployment of public health capabilities to test and diagnose an emerging and new respiratory pathogen is critical to identify and contain focal cases rapidly, as well as to intervene and mitigate widespread community transmission. Developing and deploying laboratory capability for new pathogens is one of the central roles of CDC and the national Laboratory Response Network (LRN). The LRN is a network of more than 50 national, state, local, and academic laboratories that can respond to public health emergencies and threats, including emerging infectious diseases, chemical terrorism, and bioterrorism.

Table 2 below shows that the responsibility for development and implementation of testing for COVID-19 exists in each of the intersections of intergovernmental cooperation activities across each of the four dimensions of crisis response needed for rapidly developing, deploying, tracking, analyzing, and acting on COVID-19 or other infectious diseases at each level of government.

Crisis Responses	Federal Agencies	States	Counties and Cities
Identify the crisis	Develop tests Perform surveillance and detection Issue guidance to states and localities	Perform surveillance and detection Guidance to localities, health care Mobilize response structures Report findings to CDC	Monitor local conditions Mobilize response structures Report findings to state and CDC

Manage the crisis	CDC, National Institutes of Health (NIH), HHS Issue guidance to states and localities public health and medical sectors Support state and local response Control at ports of entry; domestic interstate travel	Mobilize interventions Coordinate across localities and sectors	Mobilize interventions and respond to public health threats, including testing, contact investigation, case isolation, community control, risk communication
Align communications	HHS, CDC communication to public and sectors White House and Congress	Public health official communications to public and sectors Governor and Legislature	Public health official communications to public and sectors Elected executive, mayor, legislators, and council with appointed administrators
Pivot to long-lasting change	Establish national ongoing control program;[12] assure national funding and response capabilities	Implement control measures; ongoing monitoring; and assure funding and response capability for surveillance, testing, and threat mitigation	Implement control measures; ongoing monitoring; and assure funding and response capability for surveillance, testing, and threat mitigation

Table 2: Development and Testing for COVID-19
(Table created by the National Academy of Public Administration)

Framework for Intergovernmental Action in the U.S. Public Health System

The U.S. public health system is based on a cooperative model in which state and local governments are partners with the national government, developing through consensus practices to protect and improve the health and welfare of their citizens. A 2019 National Academy of Medicine (NAM) report notes succinctly that in responding to COVID-19, "... local execution of

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[12] U.S. Centers for Disease Control and Prevention. 2020. Fiscal Year 2020 Annual Report. Pages 3, 8. https://www.cdc.gov/funding/documents/fy2020/fy-2020-ofr-annual-report-508.pdf.

these programs and functions is often limited by constraints imposed by both federal agencies and state and local jurisdictions."[13]

The intergovernmental system is challenged operationally when confronted with an emerging pathogen. Some public health agencies may wait for state and/or federal guidance and direction, while others may "lean-in" to the threat and take actions before state and/or federal agencies act. Typically, large state and local public health departments do not wait when confronted with an outbreak cluster or detection of an unusual case. The posture of public health agencies when confronting a threat – wait or lean-in – can have significant consequences in the speed and efficacy for a national or regional disease threat. The choice of action or waiting can be further complicated by the politicization of the response when national, state, and local public health agencies, with critical yet fragmented roles, must come together in a coordinated response.

Table 3 below provides a framework for examining the role of federal, state, and local public health agencies when confronting an emerging health threat. Table 3 identifies the specific agency responsible for testing actions and links to intergovernmental mechanisms for implementation.

Public Health Issue	Roles of Agencies		Did Coordinated and Rapid Action Occur? Were Bottlenecks identified?	What are the Intergovernmental Fail-Safe and Resiliency Mechanisms?
	CDC	**State and Local Public Health**		
Emerging Infectious Disease	Epidemiologic and laboratory capability	Epidemiologic and laboratory capability	1. Ports of entry control and coordination between local public health, airlines, Department of Transportation (DOT), and Transportation Security Administration (TSA)	1. Potential for more effective use of state and academic labs
	Public Health and clinical guidance – case identification, reporting, treatment	Public Health and clinical guidance – case identification, reporting, treatment	2. Testing bottleneck at CDC	2. More effective shift from contact tracing for containment of individuals identified by testing to broader community control measures and business lock downs
	Public and risk communication	Public and risk communication	3. Testing of individuals roll-out slow and uneven	3. Regional models of response for state or local action based on geographic proximate jurisdiction and threats
	Threat response at Ports of Entry	Threat response – prevention, intervention, mitigation	4. Compiling of data on testing to inform decision making	

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[13] DeSalvo, K. 2021. Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs. National Academy of Medicine. p. 4. Accessed at https://nam.edu/wp-content/uploads/2021/04/Public-Health-COVID19-Impact-Assessment-Lessons-Learned-and-Compelling-Needs.pdf. August 30, 2021.

			5. Testing distribution is impacted by supply chain issues	

Table 3: Intergovernmental Responses: COVID-19 Public Health Matrix
(Table created by the National Academy of Public Administration)

1.2 Case Identification and Containment – Timeline of Early U.S. Response to COVID-19

An analysis of the timeline for developing and distributing a COVD-19 test in the United States provides a framework for understanding key decision points to contain future pandemics. On December 31, 2019, China reported to the World Health Organization (WHO) a cluster of pneumonia cases in Wuhan, Hubei Province. Soon thereafter, on January 5, 2020, WHO issued a notice indicating an outbreak of "pneumonia of unknown cause – China" and later, on January 12, 2020, reported that "Other respiratory pathogens such as influenza, avian influenza, adenovirus, SARS-CoV, Middle East Respiratory Syndrome coronavirus (MERS-CoV) were ruled out as the cause."

Table 4 below outlines the timeline of significant events during the early U.S. response to COVID-19, noting actions that facilitated case identification and containment. It shows rapid action by the U.S. public health sector to go "on alert" for the existence of COVID-19 in the U.S. Quick efforts were made to notify and inform state and local public health agencies of how best to identify COVID-19. However, the delayed roll-out of testing, exacerbated by contaminated test kits, hampered the ability of public health to pinpoint and contain persons with COVID-19 rapidly. The U.S. public sector did not have COVID-19 testing capability broadly deployed for case containment purposes until roughly 60 days after COVID-19 testing was created. Given the efficient transmission of COVID-19, days of delays in ramping-up testing, along with the insufficient action to slow international and domestic travel likely contributed to many missed opportunities for containment.

As after-action reports and future planning are conducted, the following questions need to be addressed by national, state, and local public health agencies:

- Did the federal government and the states take rapid action to be able to look for and confirm the existence of COVID-19 in the U.S.?

- Was the U.S. public health infrastructure sufficiently activated to identify and contain COVID-19?
- When barriers to ramp-up occurred, what were the actions to rapidly resolve them?

Situation/Event/Prompt		Impact/ Consequence
Day 0 to 30 Days (December 31, 2019 to January 31, 2020)[14]		
December 31	China reports to WHO cluster of cases of pneumonia in Wuhan, Hubei Province	Warning signal
January 5	WHO: Pneumonia of unknown cause – China	Warning signal
January 7	CDC: COVID-19 Incident Management System established	CDC emergency mgt structure engaged
January 8	CDC: Advisory and case definition -- questionnaire re: China travel + symptoms = isolate. No testing available.	U.S. public health agencies informed of what to look for; no testing available
January 12	China shares the genetic sequence of COVID-19	New pathogen
January 12	WHO: China update. Other respiratory pathogens such as influenza, avian influenza, adenovirus, SARS-CoV, MERS-CoV were ruled out as the cause.	New pathogen likely cause of illness
January 17	CDC: Advisory and case definition -- questionnaire re: China travel + symptoms = isolate. Urge detailed travel history. Testing only available via CDC	Testing established; only via CDC
January 21	First case identified in Washington State	COVID-19 in the U.S.
January 29	CDC publishes Assay Information for the 2019 Novel Coronavirus (2019-nCoV) "At this time, diagnostic testing for 2019-nCoV can only be conducted at CDC."[15]	Labs cleared to develop tests
Day 31-60 (February 1, 2020 to February 29, 2020)[16]		
February 1	CDC: Advisory and case definition -- Provide decision algorithms.	Testing only available via CDC
February 12	CDC tests contaminated[17]	Testing ramp-up impacted

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[14] World Health Organization. 2020. Archived: WHO Timeline – COVID-19. https://www.who.int/news/item/27-04-2020-who-timeline---covid-19.; U.S. Centers for Disease Control and Prevention. 2020. Lab Advisory: Published Assay Information for the 2019 Novel Coronavirus. https://www.cdc.gov/mmwr/volumes/69/wr/mm6905e1.htm.
[15] Ibid.
[16] U.S Centers for Disease Control and Prevention. 2020. Health Alert Network Messages. https://emergency.cdc.gov/han/2020.asp.
[17] New York Times. 2020. Coronavirus Test Kits Sent to States are Flawed, CDC Says. https://www.nytimes.com/2020/02/12/health/coronavirus-test-kits-cdc.html.

Situation/Event/Prompt		Impact/ Consequence
February 14	CDC reports: "...begun working with five public health labs to conduct community-based Influenza based surveillance so we can test those with Flu-like symptoms for Novel Coronavirus. Those public health labs are in Los Angeles, San Francisco, Seattle, Chicago and New York City..."[18]	Expansion of testing beyond CDC announced
February 18	CDC notes only select U.S. state and local public health laboratories and Department of Defense laboratories can perform approved COVID tests.[19]	Expansion of testing
February 29	CDC guidance on test performance problems[20]	Testing expansion impacted
Day 61 and forward (March 1, 2020)		
March 5	FDA preventing the use of other available test kits[21]	Limitations on testing expansion
March 23	CDC -- "As of March 23, more than 90 state and local public health labs in 50 states, the District of Columbia, Guam, and Puerto Rico verified they are successfully using [the] diagnostic kits."[22]	Testing for Case Identification and Containment Deployed

Table 4: Timeline of Early U.S. Response to COVID-19
(Table created by the National Academy of Public Administration)

1.3 Community Transmission-Timeline of Early U.S. Response to COVID-19

Communicable disease pathogens can have variable rates of transmission. Early in the pandemic, state and local public health officials began reporting COVID-19 cases that could not be linked to a known case or other contacts. This meant that containment of COVID-19 through traditional disease investigation and isolation efforts was losing effectiveness and community transmission

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[18] U.S. Centers for Disease Control and Prevention. 2020. Transcript for CDC Media Telebriefing. https://www.cdc.gov/media/releases/2020/t0214-covid-19-update.html.html.

[19] U.S. Centers for Disease Control and Prevention. 2020. Lab Advisory: Reminder: COVID-19 Diagnostic Testing. https://www.cdc.gov/csels/dls/locs/2020/reminder_covid-19_diagnostic_testing.html.

[20] U.S. Centers for Disease Control and Prevention. 2020. Coronavirus Disease 2019 Situation Summary. https://web.archive.org/web/20200301012205/https://www.cdc.gov/coronavirus/2019-nCoV/summary.html.

[21] Patel, N. 2020. Why the CDC botched its coronavirus testing. https://www.technologyreview.com/2020/03/05/905484/why-the-cdc-botched-its-coronavirus-testing/.; Boburg, S., et al. 2020. Inside the coronavirus testing failure: Alarm and dismay among the scientists who sought to help. https://www.washingtonpost.com/investigations/2020/04/03/coronavirus-cdc-test-kits-public-health-labs.; Yong, E. 2020. How the Pandemic Will End. https://www.theatlantic.com/health/archive/2020/03/how-will-coronavirus-end/608719/.

[22] Willman, D. 2020. Contamination at CDC lab delayed rollout of coronavirus tests. https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html.

of the virus emerged. The advent of laboratory testing for COVID-19 made it possible to use the expanded capabilities to determine disease prevalence, clinical care, and control of community transmission.

Table 5 below shows a timeline of significant events related to the rollout of COVID-19 testing capabilities. As the timeline shows, there were significant challenges in the deployment ranging from supply chain constraints to targeting, efficacy, and availability. This aspect of the COVID-19 response presents a critical period in which multiple public health assessment and control activities must be orchestrated against time and the potential of the pathogen to spread rapidly. Intersecting the constraints of time and disease risk were the challenges of:

1. Allocating limited testing capacity toward personal and individual care versus testing for contact investigation and community control;
2. Mixed public messages and communication downplayed the severity of the threat and weakened the credibility of public health.

The timeline outlines the amount of time to develop a test and shows how the development and deployment of testing impacted the community responses.

The inability to establish a robust testing capability early on significantly limited mitigation of community transmission. Additionally, alternative efforts to understand risk and transmission in controlled settings such as cruise ships, military naval vessels, airline flight staff, and transit workers limited the information base for public health response. Thus, public health officials were left with no choice but to implement stricter non-pharmacologic solutions like closures of schools, businesses, and public gatherings to reduce potential transmission. Broad public announcements that everyone could be tested whenever requested hampered response. The limited public health testing capability needed to be triaged to ensure it was targeted where mitigation efforts could best be deployed. This was especially challenging when certain types of COVID-19 tests were found to be ineffective and/or unreliable. (The timeline does not address other weaknesses that occurred in the testing supply chain with certain nasal swabs, for example.)

The timeline highlights three issues that respond to the question asked earlier:
- The urgency of rolling out an effective test for a new pathogen;
- The nested connection of testing to other public health recommendations; and
- The dependence of credibility of public health decision making on the effectiveness of testing.

January 29	CDC publishes Assay Information for the 2019 Novel Coronavirus (2019-nCoV) "At this time, diagnostic testing for 2019-nCoV can only be conducted at CDC."[23]	Labs cleared to develop tests
March 8	CDC – Testing should be prioritized based on clinical symptoms, risk factors, health care personnel, and travel[24]	Prioritizes the use of testing capacity
March 25	Los Angeles County – Guidance to prioritize testing due to limited capacity[25]	Insufficient supply
April 15	FDA – More than 30 molecular and serologic COVID-19 test types approved under Emergency Use Authority[26]	Government, university, and commercial labs developing capability
April 16	Los Angeles County – warns against using certain tests as basis of confirmed COVID-19 case reports[27]	Variation in test efficacy
July 6	NY Times -- Months Into Virus Crisis, U.S. Cities Still Lack Testing Capacity[28]	Variation in testing across the U.S.

Table 5: Testing Capabilities: Timeline of Rollout of Significant Events
(Table created by the National Academy of Public Administration)

1. Did the federal government and the states take rapid action to be able to look for and confirm the existence of COVID-19 in the U.S.? As noted in Table 5 above, the testing roll-out involved an extended time frame.
2. Was the U.S. public health infrastructure sufficiently activated to identify and contain COVID-19? The nested connection of testing to other public health recommendations and issues noted of past underinvestment complicated activating the public health system, with COVID not being contained.
3. When barriers to ramp-up occurred, what were the actions to rapidly resolve them? The recommendations below are intended to address barriers that emerged in the COVID-19 testing roll-out.

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[23] U.S. Centers for Disease Control and Prevention. 2020. Lab Advisory: Published Assay Information for the 2019 Novel Coronavirus. https://www.cdc.gov/mmwr/volumes/69/wr/mm6905e1.htm.
[24] U.S. Centers for Disease Control and Prevention. 2020. Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019. https://emergency.cdc.gov/han/2020/HAN00429.asp.
[25] Los Angeles County Department of Public Health. 2020. LAC DPH Health Alert. http://publichealth.lacounty.gov/eprp/lahan/alerts/LAHANCOVID032520.pdf.
[26] U.S. Food and Drug Administration. 2020. Coronavirus Daily Roundup: April 15, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-15-2020.
[27] Los Angeles County Department of Public Health. 2020. LAC DPH Health Advisory. http://publichealth.lacounty.gov/eprp/lahan/alerts/LAHANCOVID041620.pdf.
[28] Mervosh, S. & Fernandez, M. Months Into Virus Crisis, U.S. Cities Still Lack Testing Capacity https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html.

1.4 Findings and Recommendations

Finding: The contemporary approach to intergovernmental relations or federalism emphasizes collaboration among and across governments, allowing for distinct priorities and needs of populations in different states and local municipalities. This comes at a cost to efficiency in a public health crisis where mandates from the national government may make implementation more uniform and efficient.

The difficulty that was encountered by the politicizing of the disease adds to this challenge. Where the intergovernmental system creates the opportunity for population-specific uniqueness in applying requirements for prevention (i.e., lax vs. aggressive response), the same system provides practices that may be emulated. For example, the CDC was able to provide guidance and fill-in where the states were less able. The latter was necessary in February 2020 when some states were unable able to process testing in their labs. However, the tension that emerged was that testing had to spread beyond CDC to become more widely available.

Finding: The U.S. intergovernmental system presents a set of predictable challenges to crafting efficient, effective, and equitable responses to a rapidly emerging health crisis.

This institutional design places a premium on a careful and in-depth analysis of lessons learned in the COVID-19 response, with the development of recommendations that address responsibilities not only at each level of government but in the intergovernmental spaces where those interactions connect. The analysis presented here demonstrates the need for a consistent policy at the national level, with significant pre-crisis planning sessions to create clear expectations for testing development, deployment, data collection, and reporting requirements. The recommendations below use the lessons learned from the COVID pandemic to improve the intergovernmental role in testing for a future public health emergency:

Recommendation 1.1: HHS should re-affirm the expectation that CDC and FDA will lead efforts to deploy the full contingent of national and academic labs for test development, testing for results, distribution of tests, and immediate data reporting.

Recommendation 1.2: CDC and FDA should coordinate testing implementation with varied federal agencies, including the Occupational Health and Safety Administration, Transportation Security Agency, U.S. Department of Transportation, and state and local public health and emergency response agencies.

Recommendation 1.3: HHS should establish an 'early warning testing system' for airborne transmitted pathogens in settings that would likely be first impacted by such pathogens. These settings should include, among others, airports of departure and arrival of international travelers, cruise ships, military installations, and health facilities serving populations at high risk of carrying such pathogens.

Recommendation 1.4: OSHA should develop testing strategies to detect airborne pathogens in sectors where workers are in closed or confined environments and/or in critical infrastructure such as transportation, food processing and meatpacking, and K-12 schools.

Recommendation 1.5: In collaboration with state and local public health departments, the CDC should develop criteria for circumstances when infectious disease containment strategies should be shifted to broad population health protection strategies employing non-pharmacologic and/or other interventions for infection risk reduction.

Recommendation 1.6: Incorporate in the federal funding for preparedness programs of state and local governments a requirement for pre-event planning for rapid deployment of tests in the community as well as at critical transit points, including but not limited to airports.

Recommendation 1.7: In collaboration with state and local public health departments, the CDC should develop strategies and capabilities for rapid deployment of large sample size seroprevalence testing for respiratory pathogens.

Recommendation 1.8: Have FEMA and CDC jointly convene a national task force to consider whether inter-state compacts should be expanded to develop greater capabilities for testing and sharing results across populated regions of states in advance of a public health emergency.

The COVID-19 pandemic has been extraordinary in its scope and the magnitude of health and economic burden across the globe. The response in the United States highlighted the challenges of coordinating testing across 59 states and territories, 2,459 local health departments, and various federal agencies in an intergovernmental system built on the expectations for coordination and cooperation. Added to the politicization of COVID-19 and supply chain issues, the intergovernmental dynamics caused inconsistencies, inefficiencies, inequities, and ineffectiveness which negatively affected the containment of COVID-19.

The lessons learned and recommendations in this section are intended to improve intergovernmental responses to future infectious diseases disasters, including but not limited to new pathogens causing a worldwide pandemic. The recommended intergovernmental design calls for a consistent policy at the national level, with significant pre-crisis planning sessions for clear expectations of testing development, deployment, data collection, and reporting requirements within the U.S. federal system.

Section 2:   Non-Pharmaceutical Interventions (NPIs)

By Stephanie Newbold, Marc Holzer, Lauren Larson, and Gene Migliaccio

2.1 Background

Public sector leadership matters in intergovernmental challenges. As Alexander Hamilton noted in *Federalist* 27, the people's confidence in their government is proportional to the quality of that government's administration. Addressing a global pandemic involved all aspects of the intergovernmental system: the President; Governors of the 50 states; local government officials across the country; elected representatives at the federal, state, and local levels; and public health agencies – from the federal CDC to state and local public health programs.

The COVID-19 responses highlighted the need for clarity and complementary directives from each level of government. An ineffective or uncoordinated intergovernmental response during a global pandemic affects outcomes on death rates; allows virus transmission to spread more rapidly and infect vulnerable populations; undermines economic stability for individuals, families, and communities across the country; and ultimately impacts public confidence in our democratic institutions.

An analysis of the intergovernmental responses within the United States to this public health crisis suggests recommendations for the deployment of a multitude of options to minimize the effects of public health crises. Key in response to COVID-19 has been the significance of non-pharmaceutical interventions for infection transmission risk reduction. NPIs such as social distancing, use of facial masks, restrictions on in-person contacts, and reduction or limits in indoor or outdoor meetings offered the potential to significantly reduce transmission rates.[29] However, NPIs faced complex challenges in development and implementation. The adoption of NPIs also provided visible indications of the success of governmental responses to address the public health crises. A positive correlation emerged between citizens' confidence in their governments and their willingness to comply with governmental requests and recommendations when called upon.[30]

Governments can implement many types of NPIs to contain the public spread of viruses and diseases. Some are much easier to enforce than others. NPIs that were more straightforward and less demanding for citizens to accept included washing hands regularly, staying home when one feels ill or is running a fever, and maintaining physical distancing in public spaces. Other NPIs such as the closing of in-person dining, workplaces, public facilities, restaurants, and schools

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[29] An, B.Y., Porcher, S., Tang, S.-Y. and Kim, E.E. (2021), Policy Design for COVID-19: Worldwide Evidence on the Efficacies of Early Mask Mandates and Other Policy Interventions. *Public Administration Review*, 81: 1157-1182. https://onlinelibrary.wiley.com/doi/full/10.1111/puar.13426

[30] Hamilton, A. 1787. The Federalist Papers: No. 27. https://avalon.law.yale.edu/18th_century/fed27.asp.; Deslatte, A. (2020). "The Erosion of Trust in During a Global Pandemic and How Public Administrators Should Counter It." *American Review of Public Administration,* 50: 6-7, pp. 489-96. https://journals.sagepub.com/doi/full/10.1177/0275074020941676.

proved more problematic. Still, other NPIs, such as requiring everyone to wear facemasks when in public, became flashpoints for contention.

A lack of consensus on problem identification resulted in confusing, ambiguous messages to state and local governments, the public, and media outlets. States like New York, New Jersey, Washington, and California that faced the first onslaught of infections took immediate non-pharmaceutical actions that included closing schools and universities, restaurants and bars, retail outlets, public transit, tourist sites, and public performances.[31] For example, Governor Andrew Cuomo of New York and Governor Phil Murphy of New Jersey mandated that every person over the age of two years old wear masks when out in public. Other states, including Texas, Louisiana, and Florida, were more aligned with the White House's position that COVID-19 was nothing more than a flu-like virus and kept their states open for business without mandating the wearing of masks in public. Developing consensus across each level of government – federal, state, and local – that the problem is perilous with the need for immediate action would facilitate effective NPIs.[32]

The purpose of this section is to provide contextual analysis, resources, and recommendations that:

1. Explain the need for establishing best practices for state and local governments;
2. Address intergovernmental tensions that emerge when intervening in a non-pharmaceutical manner;
3. Incorporate transparency and accountability practices when making decisions regarding the implementation of NPIs; and
4. Emphasize the possible consequences that can arise when government – at any level – fails to meet the needs and expectations of the public during times of extraordinary crisis.

2.2 Findings and Recommendations

Finding: One of the most significant challenges facing the United States at the onset of this crisis was the lack of agreement among levels of government regarding the seriousness of the coronavirus.[33] For airborne pathogens, the reality is that in a public health crisis, transmission readily crosses state borders.

Recommendation 2.1: Develop consensus on NPI guidelines and agreements in advance of epidemics.

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[31] Bowman, A. & McKenzie J.H. 2020. Managing a Pandemic at a Less Than Global Scale: Governors Take the Lead. *American Review of Public Administration,* 50: 6-7, pp. 551-59.
https://journals.sagepub.com/doi/full/10.1177/0275074020941700.
[32] Kettl, D. 2021. Lessons From the Pandemic for Government Leaders at Every Level.
https://www.govexec.com/management/2021/05/lessons-pandemic-government-leaders-every-level/173987/.
[33] Rozell, M. & Wilcox, C. 2020. Confronting Federalism in the Age of COVID-19. *American Review of Public Administration,* 50: 6-7, pp. 519-25.

Improving intergovernmental relationships and responses will require that the federal government lead the development of comprehensive NPI operating procedures in collaboration with state and local public health organizations. Those guidelines can be drawn from best practices across units of government in the United States, as well as from cities and countries around the world that developed consensus to apply effective mitigation strategies. In developing NPI guidelines, states and local governments need to develop pre-deployment agreements across their jurisdictions. These guidelines need to emphasize key principles of organizational behavior, including the relationships between people, structure, technology, and the external environment.

Every level of government must emphasize the importance of relationships between formal and informal authorities and how the chain of command should work from the federal government to the states and localities. The U.S. faced a significant challenge during the COVID-19 pandemic in coordinating response mechanisms between the federal government, the 50 states, and the 80,000 units of local government across the country.

To improve intergovernmental relations, varied levels of government could address similar key questions:

1. How do states or local governments develop NPI guidelines to respond to a public health crisis in the absence of federal government action?
2. What occurs when the federal governments and various state governments disagree on the magnitude and scope of the problem?
3. What happens within states when there is disagreement regarding the implementation of various non-pharmaceutical interventions?
4. Can states function adequately in a public health crisis without a coordinated, national response to develop interstate collaboration?

Finding: Throughout the COVID-19 pandemic, tensions and disagreements between state and local leaders arose over how best to implement non-pharmaceutical interventions.

Recommendation 2.2: Create an Intergovernmental Task Force to develop recommendations on mechanisms to address tensions between elected officials at different levels of government.

A uniquely American theme emerging from this crisis is that political partisanship prevented a unified response to the disaster. Politics intersected adversely with science and epidemiological expertise. Visible disagreement occurred between:

- New York State Governor Andrew Cuomo and New York City Mayor Bill DeBlasio;
- Kentucky Governor Andrew Beshear and the Kentucky Republican-led legislature; and
- North Carolina Governor Roy Cooper and North Carolina Republican-led legislature.

In other states, opposition to NPIs was manifested in other ways:
- In California, varied legal challenges arose to Governor Gavin Newsom's NPI restrictions;

- In Michigan, Governor Gretchen Whitmer's implementation of COVID-19 restrictions was heavily and violently opposed, with the U.S. Federal Bureau of Investigation thwarting a plan of radical extremists to kidnap the governor and her family;
- Tensions on international travel and airport security notifying county or state officials for potential case tracking.

Internationally, other countries, notably Taiwan, South Korea, and New Zealand, were far more successful than the United States in implementing NPIs to mitigate the transmission of COVID-19. This was largely due to the lack of politicization associated with implementing NPIs that included closing their borders; mandating the wearing of facial masks by all children and adults; and restricting businesses, public schools and universities, and public spaces to control the spread of the virus.

Finding: Maintaining transparency and accountability during crisis management is critical to preserving the citizenry's confidence in their respective levels of government.

Recommendation 2.3: HHS should request that the National Academy of Public Administration convene an expert panel to develop recommendations on effectively promoting transparency and accountability in intergovernmental public health responses.

Mechanisms need to be developed that address the following:

1. Who has the responsibility in an intergovernmental system to measure governmental transparency and accountability?
2. How can state and local public health organizations manage to advance transparency, accountability, and public confidence in government without federal guidelines?
3. How can public health agencies design increased institutional protections to minimize political partisanship and maximize public confidence?
4. Can transparency and accountability be incorporated with the principles of emergency management: mitigation, preparedness, response, and recovery?

Finding: The clear interconnections between public health interventions and public trust call for more research across different regions and levels of government to develop an increased understanding of messaging, implementation, and measuring impacts in real-time.

Recommendation 2.4: HHS should fund research on promoting public trust in the government's response to infectious disease emergencies, including the use of NPIs for infection risk reduction and vaccine use.

The development and implementation of NPIs as responses to the COVID-19 pandemic illustrated the connection between complex intergovernmental directives, public health, and public trust.

Steps to restrict economic and social activity and guide individual action through NPIs caused significant disruptions in people's routines, livelihoods, job security, and emotional well-being. Adding complexity, the implementation of NPIs occurred against the backdrop of declining confidence in American government.

A 2020 Gallup Poll surveyed the confidence and trust Americans maintained in their government. Thirty-five percent of Americans only had "a fair amount" of trust and confidence in government, another 35 percent had "not very much" confidence and trust, and 17 percent of citizens had "none at all."[34] When only 13 percent of the country holds that they have a "great deal" of trust and confidence in government, it increases the likelihood that the citizenry will pose serious objections to government-mandated restrictions.[35]

When governmental institutions fail to protect the safety of the public, citizen confidence in the public sector decreases. Public health crises disproportionately affect specific populations. Increasingly, individuals and groups become vulnerable, driven by:

1. Mental health challenges due to lack of engagement and socialization, aggravated by the closing of schools and businesses;
2. Family care challenges including maintenance of housing, utilities, health insurance, transportation, food insecurity, and childcare; increases in domestic violence; and increased debt at high interest rates; and
3. Unbalanced impacts between the financially affluent and the poor.

To improve intergovernmental relationships, future NPI responses must consider the many uncertainties that ensue when values conflict. What happens when efficiency and responsibility, or economy and representativeness, conflict? The tools of intergovernmental management in a pandemic must be expanded to resolve disagreements transparently between agency experts when the external political environment shapes the public's response to the pandemic. The recommendations presented in this section attempt to provide a framework for anticipating and responding to the conflicts between values to make the most responsive decisions that best serve the public.

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[34] Gallup. 2022. In Depth: Trust in Government. https://news.gallup.com/poll/5392/trust-government.aspx.
[35] Ibid.

Section 3: Vaccine Distribution

*By Jia Ahmad, Georges Benjamin, Josh Sharfstein,
Deborah Parham Hopson, and Susan Gooden*

3.1 Background

The task of distributing COVID-19 vaccines rapidly to the U.S. population was unprecedented, but it was not unanticipated. Prior to the pandemic, however, the U.S. did not adequately build a robust vaccination infrastructure across local, state, and federal levels of government.

Gaps in the federal vaccine infrastructure. The federal government plays a strong role in childhood vaccination, setting policy and providing vaccines for millions of children on Medicaid and for the uninsured through the Vaccines for Children Program. Corresponding efforts for adult vaccination, however, are much more modest. Gaps include confusing recommendations, poor reimbursement by public payers, including Medicare, and inadequate safety net funding for the uninsured.[36] In 2019, the national rate of influenza vaccination was 43%, far below the population goal of 70%.[37]

Another major shortcoming at the federal level is historical underinvestment in promoting vaccine acceptance. Despite increasing activity by anti-vaccine groups, and even efforts by state actors to undermine vaccine confidence, the federal government provides only minimal resources to bolster the foundation of public confidence. [38] There is no systematic surveillance, for example, of vaccine refusal and little federally funded research to understand and address concerns about vaccine safety and effectiveness.

Gaps in state and local vaccine infrastructure. Since the 1970s, the federal government has cut its share of total public health expenditures in half, shifting spending to address rising health care costs.[39] These cuts -- and corresponding drops in state and local support-- eroded the capacity of public health departments to prevent disease, promote health, monitor population health, and promote vaccination. A 2017 survey found that even though 88% of local health departments provide vaccinations, 25% reported a decrease in staff for immunization programs, with two out of five reporting that they had less than two employees conducting immunization

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[36] Tan L. Adult vaccination: Now is the time to realize an unfulfilled potential. *Human Vaccines and Immunotherapeutics.* 2015;11(9):2158-2166. doi:10.4161/21645515.2014.982998. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4635860/.

[37] Baumgartner JC, Radley DC, Shah A, Schneider EC. How Prepared Are States to Vaccinate the Public Against COVID-19? Learning from Influenza and H1N1 Vaccination Programs. The Commonwealth Fund. 2020 Dec. Available at: https://www.commonwealthfund.org/publications/issue-briefs/2020/dec/how-prepared-are-states-vaccinate-public-covid-19. Accessed May 15, 2021.

[38] Commissioners of the Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA. Announcing the Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA. Lancet. 2021 Mar 27;397(10280):1165-1167. doi: 10.1016/S0140-6736(21)00372-X. https://pubmed.ncbi.nlm.nih.gov/33639088/.

[39] Manni N & Galea S. COVID-19 and the Underinvestment in the Health of the U.S. Population. Milbank Q. 2020 Jun. 98(2):239-249. doi: 10.1111/1468-0009.12462. https://pubmed.ncbi.nlm.nih.gov/32333451/.

services.[40] These health departments reported significant challenges with vaccine hesitancy and public confidence in vaccine safety and efficacy.[41] Many health departments also experienced billing challenges that threatened the sustainability of their vaccination efforts.

Another major deficiency at the state and local level relates to the capacity to monitor vaccination uptake. Only about one-quarter of local health departments are supported by an epidemiologist.[42] Health departments have been unable to modernize, relying on sluggish data technologies like paper records, phone calls, faxes, spreadsheets, and manual data entry.[43] These obstacles have hindered the deployment of immunization information systems -- confidential computerized databases that record vaccine administration. Few states and local jurisdictions mandate reporting to an IIS and those that do lack mechanisms to enforce them, leading to incomplete data collection.[44] Varying patient consent requirements, provider education, and challenges with data matching have undermined data quality.[45] Finally, data sharing -- between jurisdiction and with the CDC -- has been a significant legal and technical challenge.[46]

3.2 Early in the COVID-19 Pandemic, State and Local Health Departments Urgently Called for Additional Funds to Support Vaccine Distribution

In summer and fall 2020, anticipating that the vulnerabilities of the public health infrastructure would impede vaccine distribution and other COVID-19 response measures, representatives of federal, state, and local institutions called for Congress to bridge the funding gap for COVID-related public health activities.

The National Association for County and City Health Officials wrote a letter to Congress requesting that they dedicate $8.4 billion to vaccine distribution efforts, including building data systems, supporting mass vaccination clinics, ensuring cold-chain storage and transportation, procuring PPE and supplies, funding communication efforts, and hiring and training additional

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[40] National Association of County and City Health Officials. Local Health Department Immunization Programs: Findings from a 2017 NACCHO Assessment. July 2018. Available at: https://www.naccho.org/blog/articles/local-health-department-immunization-programs-findings-from-a-2017-naccho-assessment. Accessed May 15, 2021.
[41] Ibid.
[42] Weber L, Ungar L, Smith MR, et al. Hollowed out public health system faces more cuts amid virus. *Associated Press*. 2020 Aug. Available at: https://apnews.com/article/e28724a125a127f650a9b6f48f7bb938. Accessed May 15, 2021.
[43] Council of State and Territorial Epidemiologists. Driving Public Health in the Fast Lane: the Urgent Need for a 21st Century Data Superhighway. 2020 Sep. Available at: https://debeaumont.org/news/2019/white-paper-driving-public-health-in-the-fast-lane/. Accessed May 15, 2021.
[44] Scharf LG, Coyle R, et al. Current Challenges and Future Responsibilities for Immunization Information Systems. *Academic Pediatrics*. May-June 2021. https://doi.org/10.1016/j.acap.2020.11.008
[45] Ibid.
[46] Scharf LG, Coyle R, et al. Current Challenges and Future Responsibilities for Immunization Information Systems. *Academic Pediatrics*. May-June 2021. https://doi.org/10.1016/j.acap.2020.11.008

workers.[47] The Association of Immunization Managers underscored the need for additional resources not only to train and equip health departments for distribution but to strengthen vaccine confidence, combat misinformation, equip health providers to advise the public on vaccination, and support concurrent routine vaccination programs.[48] The National Association of Governors echoed the request for additional funding, adding requests for guidance on allocation, logistics of vaccine storage, data, and communication.[49] Federal health leaders also chimed in with their support for increased funding. Testifying before the Senate Appropriations Committee, CDC Director Robert Redfield estimated that the CDC and states would require at least $6 billion to facilitate COVID-19 vaccine distribution.[50]

The federal government responded belatedly to these demands. The second major stimulus bill, approved in December 2020, appropriated $8 billion for vaccine distribution efforts.[51] Funds took additional weeks to reach states and localities. The American Rescue Plan, passed in March 2021, provided additional resources, including $7.5 billion to support vaccination distribution and administration through public health departments and other partners and $1 billion for vaccine confidence and education activities.

3.3 After Vaccines Became Available, the U.S. Struggled with the Initial Rollout of the COVID-19 Vaccination Effort

In May 2020, the Trump Administration announced the launch of Operation Warp Speed, a public-private partnership dedicated to expediting solutions to the COVID-19 crisis. Vaccine development and distribution were an anchor of this effort. Between March and November 2020, the federal government awarded six companies the contracts for vaccine development and manufacturing while purchasing 600 million doses to facilitate low or no-cost distribution to the public.[52] Even before a vaccine was proven to be effective, Operation Warp Speed presented Congress with a plan for a federal vaccine distribution strategy utilizing the McKesson Corporation as a central distributor to send vaccines to state and local immunization programs. The Centers for Disease Control and Prevention provided states with interim guidance on

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[47] National Association of County and City Health Officials. Letter to Congress, October 1 2020. Available at: https://www.naccho.org/blog/articles/naccho-highlights-needed-supports-for-local-health-department-response-to-covid-19. Accessed May 15, 2021.

[48] Association of Immunization Managers. AIMS Statement on the Need for Federal COVID-19 Vaccine Resources. September 2020. Available at:
https://cdn.ymaws.com/www.immunizationmanagers.org/resource/resmgr/aim_statement_on_covid-19_fe.pdf.
Accessed May 15, 2021.

[49] National Governors Association Submits List of Questions to Trump Administration on Effective Implementation of COVID-19 Vaccine. Available at: https://www.governor.ny.gov/news/national-governors-association-submits-list-questions-trump-administration-effective. Accessed May 15, 2021.

[50] C-SPAN. Senate Appropriations SubCommittee on Coronavirus Response, Dr. Robert Redfield, CDC. Available at https://www.c-span.org/video/?475764-1/coronavirus-vaccine-widely-late-2021-cdc-director.

[51] Montague, Z. The Second Stimulus Package: Here's What's Included. The New York Times. 22 December 2020. Available at: https://www.nytimes.com/2020/12/22/us/politics/second-stimulus-whats-included.html. Accessed May 15, 2021.

[52] U.S. Government Accountability Office. COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation. April 2021. Available at: https://www.gao.gov/products/gao-21-443. Accessed May 15, 2021.

planning for vaccine distribution and required states to submit their own plans for feedback. Many of these state plans echoed earlier calls to the federal government, requesting additional funding and highlighting the many challenges for distribution that still lay ahead.[53]

In November 2020, pharmaceutical companies Pfizer, Moderna, and AstraZeneca reported successful Phase 3 trials for their vaccines. By December 18, the FDA had approved emergency use authorizations for both Pfizer and Moderna vaccines. Vaccine distribution efforts started days afterward but were slow to operationalize -- by the end of the year, only 2.8 million people were vaccinated, far short of the goal of 20 million the Trump administration had initially established.

Four major challenges marked the rollout, each related to intergovernmental issues.

1. *States did not set consistent priorities for vaccination groups.*

Given that vaccine supplies would initially be limited while production scaled up, federal agencies asked NAM to develop guidelines for prioritizing sub-populations for vaccination. NAM released these guidelines in October 2020,[54] and the CDC's Advisory Committee on Immunization Practices began adapting and distributing this guidance to states in December 2020.

The federal government did not require state adherence to federal guidelines for vaccine prioritization, and state approaches varied greatly, leading to inconsistent vaccine access across the country. States had flexibility in deciding when to prioritize groups for vaccination and how to define them. What resulted was tremendous variability by state in policies for vaccine access.

Many states expanded vaccine eligibility long before the supply was sufficient to support it, leading to long waits and confusion for residents.[55] One point-in-time analysis in February found that the majority of states did not align with CDC recommendations for vaccine prioritization.[56] For example, in Phase 1b of vaccination, the CDC recommended that people with comorbid conditions placing them at higher risk should receive the COVID-19 vaccine. The CDC provided a list of comorbid conditions to consider, but many states deviated from this list -- neglecting to include some conditions or adding others. Some states required validation of comorbidities, while others did not. In many states, the list of prioritized conditions was difficult to find -- even some

[53] Duke-Margolis Center for Health Policy and the National Governors Association. Supporting an Equitable Distribution of COVID-19 Vaccines: Key Themes, Strategies, and Challenges Across State and Territorial COVID-19 Vaccination Plans. December 2020. Available at: https://healthpolicy.duke.edu/sites/default/files/2020-12/Supporting%20an%20Equitable%20Distribution%20of%20COVID-19%20Vaccines%20FINAL.pdf. Accessed May 15, 2021.
[54] The National Academies of Sciences, Engineering, and Medicine. A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus. October 2020. Available at: https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus#sectionPublications. Accessed May 15, 2021.
[55] Weise E. Somewhere in there, the vaccine got overpromised: How the COVID-19 vaccination process turned chaotic and confusing. February 18, 2021. USA Today. Available at: https://www.usatoday.com/story/news/health/2021/02/17/covid-19-vaccine-rollout-operation-warp-speed-coronavirus/6786555002/. Accessed May 15, 2021.
[56] Kates J, Dawson L, Tolbert J. The Next Phase of Vaccine Distribution: High-Risk Medical Conditions. Kaiser Family Foundation. February 2021. Available at: https://www.kff.org/coronavirus-covid-19/press-release/states-set-different-covid-19-vaccination-priorities-for-people-with-high-risk-conditions/. Accessed May 15 2021.

local health departments were not informed when states were deviating from federal guidelines, leading to great uncertainty about who could be vaccinated.[57]

2. *Unclear communication about forthcoming vaccine shipments complicated state and local distribution efforts.*

Many state, territorial and local health officials have reported that they lacked information on vaccine shipments from the federal government and manufacturers, including the number of doses they would receive and when they would arrive.[58] Shipment sizes fluctuated dramatically early on -- for example, 54 jurisdictions reported that the number of doses for allocation in the second week of Moderna implementation was 65% lower than first.[59] But states and localities were not advised of these changes in advance and were unable to plan for local distribution efforts. In February, the National Governors Association sent a letter to the Biden Administration requesting greater transparency about vaccine shipments.[60] Some officials noted that a lack of transparency had been an intergovernmental challenge in prior vaccination efforts, including a 2004 flu vaccine supply shortage and the H1N1 epidemic in 2009.[61]

3. *Weak data infrastructures for arranging vaccine appointments and tracking vaccinations led to public confusion and distress.*

Prior to the rollout, the CDC paid Deloitte $44 million in a no-bid contract to develop the Vaccine Administration Management System (VAMS), designed to offer states technology to manage scheduling, inventory, and reporting for COVID-19 vaccinations.[62] The system was plagued with several problems, such as unexpectedly canceled appointments, unreliable registration, inconsistent access, and frequent crashes. Only a minority of states used VAMS, and some that did quickly pivoted to commercial systems like PrepMod. In some cases, providers resorted to using paper to track vaccinations or the online scheduler Eventbrite to schedule appointments.[63] The online registration system was also inaccessible to many populations who lacked familiarity with or access to technology tools, requiring local flexibility and innovation in outreach.

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[57] U.S. Government Accountability Office. COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation. April 2021. Available at: https://www.gao.gov/products/gao-21-443. Accessed May 15 2021.
[58] Weise E. Somewhere in there, the vaccine got overpromised: How the COVID-19 vaccination process turned chaotic and confusing. February 18, 2021. USA Today. Available at: https://www.usatoday.com/story/news/health/2021/02/17/covid-19-vaccine-rollout-operation-warp-speed-coronavirus/6786555002/. Accessed May 15, 2021.
[59] U.S. Government Accountability Office. COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation. April 2021. Available at: https://www.gao.gov/products/gao-21-443. Accessed May 15, 2021.
[60] National Governors Association. Executive Committee Letter to President Regarding Vaccine Distribution Process. February 2021. Available at: https://www.nga.org/advocacy-communications/executive-committee-letter-to-president-regarding-vaccine-distribution-process/. Accessed May 15, 2021.
[61] Lupkin S. Moderna Increases COVID-19 Vaccine Shipments While Pfizer Lags Behind. February 1, 2021. NPR. Available at: https://www.npr.org/sections/health-shots/2021/02/01/962954518/moderna-increases-covid-19-vaccine-shipments-while-pfizer-lags-behind. Accessed May 15, 2021.
[62] Ferguson C. What went wrong with America's $44 million vaccine data system? MIT Technology Review. January 2021. Available at: https://www.technologyreview.com/2021/01/30/1017086/cdc-44-million-vaccine-data-vams-problems/. Accessed May 15, 2021.
[63] Ibid.

The CDC also invested in IZ Gateway, a software infrastructure designed to centralize and standardize patchwork regional vaccine registries (or immunization information systems) across the country. The purpose of this platform was to create a shared platform to standardize data collection and facilitate intergovernmental communications – both for interregional use and state reporting to the CDC. However, state participation in the IZ Gateway was optional, and many states lacked the internal data infrastructure to participate.[64]

4. Federal, state, and local governments failed to execute vaccination strategies that prioritized equity.

COVID-19 has had a disproportionate impact on communities of color, but Black and Latinx people received smaller shares of vaccines compared to their share of cases -- and deaths.[65] In March 2021, the Black share of the vaccinated population lagged behind the general population in every state.[66] As late as May, CDC data showed that among people who were fully vaccinated, only 9% were Black (though they represent 12% of the population), and 12% were Latinx (though they represent 17% of the population).[67] The disparities are even starker when considering the disparate impact of COVID-19 on racial minorities, including a nearly twofold increase in age-adjusted mortality for Black and Latinx people.[68] Analyses also demonstrate that socially vulnerable counties identified by the CDC's social vulnerability index have lower rates of vaccination than average.

Immunization programs have long struggled to provide equitable access to vaccines, and prior vaccination efforts -- like the annual influenza vaccination -- have also had lower rates of vaccination among racial and ethnic minorities.[69] Many factors may contribute, including that racial and ethnic minorities are less likely to be insured, and people who have access to health care are more likely to receive the vaccine. Racial and ethnic minorities have also been subjected to racism and other forms of violence by medical institutions and may mistrust the medical system as a result.

When crafting a framework for vaccine distribution, the National Academy of Medicine acknowledged the disparate impact of COVID-19: their guidelines indicate that "in each population group, vaccine access should be prioritized for geographic areas identified through

[64] Foley KE. How the U.S. Plans to track COVID-19 vaccine doses. December 11, 2020. Quartz. Available at: https://qz.com/1941989/how-the-us-plans-to-track-pfizers-covid-19-vaccine-doses/. Accessed May 15, 2021.
[65] Ndugga N, Pham O, et al. Latest Data on COVID-19 Vaccinations Race/Ethnicity. Kaiser Family Foundation. May 2021. Available at: ttps://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-race-ethnicity/. Accessed May 15, 2021.
[66] Walker AS, Singhvi A et al. Pandemic's Racial Disparities Persist in Vaccine Rollout. New York Times. 5 March 2021. Available at: https://www.nytimes.com/interactive/2021/03/05/us/vaccine-racial-disparities.html. Accessed May 15, 2021.
[67] Centers for Disease Control and Prevention. COVID Data Tracker. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic. Updated May 25, 2021. Accessed May 25, 2021.
[68] Centers for Disease Control and Prevention. COVID-19 Racial and Ethnic Health Disparities. 10 December 2020. Accessed June 1, 2021 at https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-deaths.html
[69] Usher-Pines L, Maurer J, Harris KM. Racial and Ethnic Disparities in Uptake and Location of Vaccination for 2009-H1N1 and Seasonal Influenza. *American Journal of Public Health*. 2011 July; 101(7):1252-1255. doi: 10.2105/AJPH.2011.300133.

CDC's Social Vulnerability Index."[70] Some states and localities did use the Social Vulnerability Index or other measures to pursue equity in the distribution process, and several went further to consider race and ethnicity in prioritization. However, these efforts were too few and far between to avoid significant and ongoing gaps.

3.4 The U.S. Vaccination Effort is Making Progress, but Many Challenges Remain

As of the drafting of this report in January 2022, 63% of the U.S. population was vaccinated with the primary series, including 74% of people over 18 and 88% of people above 65 Vaccinating such a significant portion of the population is a remarkable achievement. However, many more people still can benefit from vaccination. Moreover, fewer than half of people with the primary series have received a booster. Growing and maintaining high rates of vaccination will be an important component of the pandemic response for the foreseeable future.[71]

Two key issues remain obstacles to achieving optimal vaccination rates.

1. *Vaccine hesitancy*

Mistrust of government and medical institutions and anti-vaccination disinformation campaigns have dampened demand for vaccines. Further, many Americans who were ambivalent about the vaccine may have been dissuaded by the temporary pause in administrations of the Johnson & Johnson vaccine.

2. *Poor access to vaccination*

Many people live in rural and urban communities without sufficient infrastructure to access vaccines. For example, a recent analysis in Pennsylvania, a state that relies heavily on pharmacies for local COVID-19 vaccine distribution, showed that 67 counties have at least one "pharmacy desert" with few to no pharmacies available.[72] Many Americans living in rural areas struggle to access health care in their local communities and lack transportation options to larger urban centers.

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[70] National Academies of Medicine. A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus. October 2020. Available at: https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus#sectionPublications. Accessed May 15, 2021.
[71] New York Times. See How Vaccinations Are Going in Your County and State. Available at: https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html. Updated February 5, 2022. Accessed January 26, 2022.
[72] AARP Pennsylvania, Drexel University College of Nursing and Health Professions. Disrupting Disparities in Pennsylvania: Retooling for Geographic, Racial, and Ethnic Growth. April 2021. Available at: https://aarp-states.brightspotcdn.com/6f/b6/de161f3a4a63a23e811693d90b68/aarp-drexel-pennsylvania-disrupting-disparities-design-0421-final.pdf.

3.5 Findings and Recommendations

Finding: A decentralized and underfunded public health infrastructure eroded the nation's capacity to mount a rapid mass vaccination effort. Sustained funding is needed to rebuild federal, state, and local vaccination efforts.

Federal financial commitments to reinforce public health infrastructure and bolster vaccine distribution are commendable and should be sustained. Historically, funding for public health has been reactionary and quickly cut after an emerging threat subsides. To ensure that we build a robust system ready to address the next crisis, the "boom or bust" cycle must be broken.

Recommendation 3.1: To support current and future vaccine efforts, the federal government should establish policy best practices and provide regular, consistent funding for adult immunization, as well as significant resources to support the state and local public health workforce.

Recommendation 3.2: HHS should sustain a major public health program on vaccine acceptance, including tracking of vaccination uptake, tracking of anti-vaccine activities, research into strategies to counter vaccine hesitancy, and funding for state and local outreach and communication activities.

Recommendation 3.3: HHS should assess the personnel needs of the U.S. Public Health Service Commissioned Corps to support responses to infectious disease outbreaks and pandemics and how those needs can be best addressed on an ongoing basis.

Finding: Weak federal guidance led to a patchwork of unequal vaccination efforts. In a pandemic, greater federal leadership is necessary.

States and localities had unchecked authority on vaccine distribution priorities, and many did not follow recommendations established by the CDC. Many lacked the capacity to reach some vulnerable populations and did not receive adequate support from the federal government. This has led to an unfair and confusing national distribution system, which undermined the effectiveness of the pandemic response.

The federal government should strengthen the vaccine distribution process by establishing minimum expectations for states and mechanisms to intervene when state actions are insufficient to reach key goals. Federal, state, and local distribution efforts should be clearly reported to the public, and the federal government should establish accessible websites (e.g., dashboards) to facilitate transparency and accountability.

Recommendation 3.4: HHS should establish clear standards for vaccination prioritization that include some flexibility for state and local circumstances. These standards should correspond to the risk of serious illness and death in specific communities. The HHS should encourage the

adoption of these standards by providing additional funding to states and local jurisdictions that adopt them.

Recommendation 3.5: HHS should establish a publicly accessible dashboard to track vaccine distribution efforts. This dashboard should have standardized reporting criteria for states and localities, ensuring accurate and reliable data collection and comparable reporting across the country. Data from this dashboard should be used to assist state and local jurisdictions to respond to demonstrated needs.

Recommendation 3.6: The federal government, manufacturers, and states should maintain standards for transparency regarding vaccine availability in intergovernmental channels and with the public.

Finding: The vaccine appointment registration process relied too heavily on individual initiative and online systems, undermining the access of many eligible populations at high risk for COVID infection. From the onset of vaccine distribution efforts, public health agencies should pair simple, accessible online registration portals with active outreach efforts to underserved communities.

The inability to access online vaccine registration systems has significantly impacted vaccination rates in vulnerable populations. People without technological literacy and in rural and remote areas without broadband access have struggled to access vaccine appointment registration systems. These populations often overlap with those disproportionately impacted by COVID-19 – such as the elderly or those experiencing structural vulnerabilities – underscoring the urgency of bridging the digital divide. While many state and local public health agencies did engage in active outreach (e.g., door-to-door outreach or engagement with community sites), these efforts came at a later point in vaccine distribution.

Recommendation 3.7: The federal government should ensure that each state can provide a simple, accessible national appointments system to register for vaccine appointments with both online and phone options. If a state cannot provide an appropriate level of service, the federal government should step in and provide it directly.

Recommendation 3.8: From the start of vaccination campaigns, local jurisdictions should lead efforts to reach communities at greatest risk of infection. Strategies to reach unvaccinated populations may include mobile vaccination vans, walk-in community centers, door-to-door outreach, or phone bank efforts. These efforts should be rapidly expanded in the context of the COVID-19 pandemic and should occur throughout all phases of vaccine distribution.

Recommendation 3.9: From the start of vaccination campaigns, local, state, and federal authorities should specifically allocate vaccine doses to assure fair access for underserved and disproportionately affected areas.

Finding: The nation's data infrastructure failed to support key elements of vaccine distribution. Significant investment in modernization is urgently needed.

The CDC has appropriately identified the need for a stronger data infrastructure to support state vaccine distribution efforts. But its modest investments are inadequate to address the monumental task of modernizing local data systems across the country, many of which still rely on paper or manual data entry to track information.

Recommendation 3.10: The CDC should require that all states participate in a common data sharing platform (e.g., IZ Gateway) to facilitate vaccine reporting and should provide funds to states without IIS systems compatible with a shared platform to support the transition to a common reporting platform.

Recommendation 3.11: HHS should provide adequate and sustained funding for active engagement of underserved and vulnerable communities in vaccination and other public health efforts. These efforts should work with community members and leaders to solicit their input on gaps in access to services and outreach strategies to build trust.

Finding: Communities of color have been vaccinated at disproportionately low rates, exacerbating health disparities. Public health agencies should establish efforts to enhance the trust of these communities.

There has been some progress on the racial gap in vaccinations in recent months, but significant gaps remain.[73] These disparities are a consequence of long-standing structural barriers to health care access, as well as a failure to plan for vaccine distribution in this pandemic adequately. These efforts should persist after the pandemic to prepare better for future challenges.

Recommendation 3.12: The federal government should provide sustained funding for active engagement of communities of color in vaccination and other public health efforts. These efforts should work with community members and leaders to solicit their input on gaps in access to services and outreach strategies to build trust.

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[73] Walker AS, Sun A, et al. The Racial Gap in U.S. Vaccinations is Shrinking, but Work Remains. *The New York Times*. May 15, 2021. Available at: https://www.nytimes.com/interactive/2021/05/14/us/vaccine-race-gap.html. Accessed May 25, 2021.

Section 4:   Cross-Cutting and Over-Arching Issues

By John Kirlin, John Bartrum, Vikki Wachino, Rich Callahan, Gene Migliaccio, Lauren Larson, and Kenneth W. Kizer

4.1 Introduction

As each section of this report shows, intergovernmental dimensions – the interactions between federal, state, county, and local governments – are evident in almost all the wide range of public policy responses to COVID-19 in the United States. The most challenging of societal problems in this nation are worked out in a distinctive American intergovernmental system. The constitutional allocation of powers between the federal and state governments requires joint action in many areas and invites varied state actions to address different circumstances, contexts, and weighing of competing values. Invigorated intergovernmental response systems must meet the potential for future public health and other emergencies of increasing frequency and intensity.

This section develops recommendations for improved intergovernmental responses to future pandemics. The recommendations focus on operational areas that impact a range of actions. The recommendations are developed from evidence in five case studies:

1. Medical care services, especially for Center for Medicare and Medicaid Services;
2. Supply chains, including the Strategic National Stockpile;
3. Emergency Support Function #8 Council (ESF-8);
4. Data collection for disease surveillance and case management; and
5. Data systems to support responses to pandemics.

Case 1: Intergovernmental Adaptations within Existing Policies in Health Care Services

By Vikki Wachino with contributions from John Bartrum and other members of the Working Group

Nationally, regionally, and locally, the health care delivery system needed to advance specific goals related to the public health emergency (COVID-19 diagnosis, treatment, and vaccinations) and continue to support health care service delivery despite major disruptions. Those disruptions included the need for social distancing, the decline in service use and payment, and the economic dislocation of people and organizations. Our health insurance system operates through a variety of independent payers (employers, Medicare, Medicaid, the Department of Veterans Affairs (VA), DoD, individual market), and health care delivery is generally operationally independent of payers. Levers over health care delivery exist at different levels of government, but intergovernmental responsibilities vary by payer. These healthcare delivery levers operate autonomously from public health functions in most cases.

Key Intergovernmental Roles and Relationships in Health Care Financing and Delivery, and Public Health:

Medicare is run by the federal government, with decisions that affect public and private providers across the country but with few intergovernmental touchpoints.

Medicaid is jointly run by the federal and state governments and operates as a state/federal partnership. Local governments rely on state decision making with no independent direct relationship to the Center for Medicaid and Medicare Services.[74]

Commercial insurance constitutes a broad array of different types of private health insurance. CMS has regulatory responsibility over some aspects of some commercial plans such as eligibility for coverage eligibility and some coverage standards. Most remaining functions are regulated by states. Many commercial payers set payments for medical procedures in relation to Medicare rates.

Skilled nursing facilities and nursing homes have limited medical staffing but greater integration into Medicare and Medicaid payment and regulatory systems than assisted living facilities (below). They are also more integrated into supply chains for medical supplies, equipment, and PPE, but still at lesser levels than hospitals.

Assisted living facilities are state-licensed. Most revenues are private payments, with some payments from Medicaid. States enforce quality through surveys and responses to

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[74] U.S. Centers for Medicare and Medicaid Services. About Us. https://www.medicaid.gov/about-us/index.html.

complaints. Assisted living facilities have very limited medical staffs and commonly very limited relationships with the supply chain for medical supplies, including PPE.

Key Aspects of the Intergovernmental Response:

Telehealth – The federal government responded quickly through administrative and congressional action to expand the Medicaid 1135 waiver authority for national emergencies to expand telehealth use in Medicare substantially. States have always had more Medicaid flexibility, and they broadened that use. [75]

Quantity of Providers (licensing, conditions of participation, site of service/alternate care sites) – There was extensive, immediate flexibility through CMS and state use of 1135 authority in Medicare and Medicaid. Furthermore, states relaxed licensing requirements to promote the flow of medical providers and volunteers across state boundaries and licensing requirements.

Provider relief funding – The Trump Administration requested more than one round of provider relief funding, and Congress provided. The initial round was released quickly but heavily favored well-established providers with significant Medicare revenues. Small providers struggled, and there was no easy, fast, or reliable mechanism to address the needs of providers whose primary relationship was with Medicaid. (This improved somewhat over time).

CMS guidance – The Centers for Medicaid & Medicare Services regulations were expected to follow CDC guidelines and report COVID-19 transmission rates to CDC, testing requirements, survey, and enforcement. State actions responding to CMS Are unclear to date.

Public health functions – The intergovernmental system has public health functions that were structurally, organizationally, and culturally separated from medical health care delivery. There are organizations, policies, and funding at the federal, state, and local levels, but police power authority to affect public health behaviors of individuals and firms is constitutionally at the state level.

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[75] U.S. Centers for Medicare and Medicaid Services. Page updated on December 1, 2021. 1135 Waivers. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers.

Findings and Recommendations

Finding: 1135 authority, which is designed to increase access to and flexibility of health care providers in emergencies, was quickly and widely deployed by CMS and worked well (though we do not yet know the impacts of having waived so many core requirements).

The 1135 authority has probably never been so widely used in both Medicare and Medicaid by all 50 states and the District of Columbia. The 1135 approvals for Medicaid cover provider enrollment, prior authorization, appeals, long-term services, and supports requirements. Having the 1135 authority along with a few other authorities, automatically driven by the Public Health Emergency (PHE) declaration, sped the responsiveness with significant consequences for the PHE.

Finding: Most of the Medicare-related changes have been issued by the Centers for Medicare & Medicaid Services through regulation and sub-regulatory guidance.

Finding: The Executive Branch and Congress acted quickly to expand coverage across insurance programs for testing and vaccinations.

Finding: Congress provided fiscal relief through an increase in the federal Medicaid matching rate, tied to the maintenance of effort. Congress also made some modifications to 1135 (telehealth for Medicare).

Finding: Coverage was sustained (through Medicaid) by Congress's maintenance of effort/continuous coverage requirement.

Beyond that, gains in access to coverage have been modest. Recent changes in Marketplace open enrollment and investment in navigators are significant, with very recent improvements in access to coverage.

Finding: 1115 demonstrations were used only to a limited extent (relative to other emergencies/public health disasters, for example, Hurricane Katrina).

In 12 states, demonstrations were used for relatively modest purposes such as benefits scope, payment, and some application information requirements.

Finding: 1915(c) home and community-based programs were a major vehicle of the public health response with respect to Medicaid.

Fifty states and the District of Columbia changed their home and community-based services programs for a wide range of purposes, including but not limited to changed eligibility requirements, level of care assessments, virtual evaluations, and scope of services.

Finding: CMS focused its role on sustaining health care delivery. There was limited (public) focus on public health response per se.

To the extent that CDC, other federal agencies, and states led on public health, consistent with their authorities, CMS's lack of specific public health focus is not surprising. It should defer to public health agencies. At the same time, a CMS-specific public health role seems like a missed leadership opportunity.

Finding: From the initial outbreak in Washington State, many deaths occurred in "nursing homes." One challenge is that this category of "long-term" or "congregate" care includes very different providers.

"Skilled nursing facilities" and "nursing homes" are often used synonymously, while "assisted living," also called "residential care" facilities, are ignored or swept into the "nursing home" terminology. The National Center for Health Statistics sorts long-term care providers into five categories, listed here with numbers of facilities in 2016:

- Adult daycare (4,600)
- Home health agency (12,200)
- Hospice (4,300)
- Nursing home (15,600)
- Residential care facility (28,900)

Finding: The average number of beds or licensed maximum capacity of nursing homes was 1,660,000, and of Residential care facilities, 996,100.

Of Nursing homes, 97.5 percent were Medicare-certified, and 95.2 percent were Medicaid-certified, while only 48.3 percent of Residential care facilities were Medicaid-certified. A similar difference emerges in average daily staff hours per patient, with 3.8 in nursing homes and 2.64 in residential care facilities, with the greatest differences in services provided by registered nurses (20 minutes daily more) and in licensed practical/vocational nurses (41 minutes more daily). A special allocation of limited PPE (surgical masks, gloves, goggles, and gowns) was made to certified (Medicare or Medicaid) facilities in May 2020.

Recommendation 4.1: Maintain congressional authorization for the Centers for Medicaid and Medicare Services (CMS) 1135 waiver authority to facilitate immediate deployment by CMS to respond to emergent conditions.

Recommendation 4.2: HHS should consider maintaining Medicare's expanded telehealth authority in perpetuity.

Congress and the administration should now carefully examine the successful experience with 1135 waivers, including the critical question of the continuation of virtual health care. Another important question is extending 1135 authority beyond provider supply/provider issues. Given the variety among long-term care providers, multiple actions are needed to improve data systems. Until the capacity of nursing homes to treat a COVID-19 patient and prevent the spread of infection is documented, COVID-19 patients should be kept out of nursing homes. None should be in Residential care/assisted living facilities. Improving the medical care capacity of nursing homes required to treat pandemic-level respiratory infections seen in COVID-19 would be very expensive. Assisted living/residential care facilities are much less prepared. As their source of financing is mostly private pay, any significant increase in capacity would require a fundamental change in funding.

Case 2: Supply Chains

Adapted from John Bartrum[76]

The COVID-19 pandemic was one of the first mass whole-of-nation mobilizations in modern memory for most Americans, revealing significant gaps in the nation's readiness. The President and Congress can, and must, significantly enhance the resiliency, diversity, readiness, and security of the U.S. supply chain. The focus here is on the medical supply chain, but the principles can be applied to other industries.

- Enhance the "just-in-time" inventory or "stockless production" systems the medical industry uses with a more resilient, diverse, and secure structure.
- Expedite the ability to increase market transparency, integrity, and transaction time in the medical supply chain to build a more resilient, diverse, and secure structure.
- Enhance the resiliency, diversity, and security of the Strategic National Stockpile to respond to future events.

Supply Chain Resilience

Most U.S. hospitals maintain only days or weeks of excess critical supplies required to respond to a hazard event, emergency, or pandemic. These policies increase the supply chain risk to the system. A "just-in-time" inventory system has many positive financial attributes for American organizations, including hospitals. For example, it can reduce expensive space requirements and financial carrying costs that impact the cost of health care. The downside of this method is that it reduces local facility surge capacity of the hospital and suppliers during emergency events.

The federal government can implement policies now that will enhance the ability of hospitals to respond in times of emergency surges without impacting the very valuable"just-in-time" or "self-distributions models" that reduce long-term health care costs. For example, it could consider developing a federal policy requiring hospitals that participate in Medicare (over 6,000 U.S. hospitals in 2019) to maintain a supply bubble of 90 days of its average usage rate of a select number of key PPE items (N-95s, Nitrile gloves, surgical masks, etc.).

A supply bubble is not a stockpile, but a rotational stock of items used routinely. The bubble expands the hospital's readiness to meet emergency demands while maintaining its overall supply policies. The quantity of the limited PPE bubble should be based on each hospital's average usage rate, not on a government-specific quantity. This approach could:

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[76] Bartrum, J. 2021. How to Build More Resilient, Diverse, and Secure Supply Chains to Ensure U.S. Economic Prosperity and National Security. National Academy of Public Administration. https://s3.us-west-2.amazonaws.com/napa-2021/Build-More-Resilient-Diverse-and-Secure-Supply-Chains-Article-4.14.2021-Bartrum-002.pdf

- Reduce some of the early resupply requests from hospitals not in the immediate threat by providing the supply chain more time to respond as the hospital will have on-hand a more robust stock of PPE;
- Provide distributors with more time to re-balance re-supply requests to the highest affected areas in their network;
- Provide manufacturers with more time to expand capacity and thus reduce shortages; and
- Be applied by other countries or the World Health Organization to reduce global immediate resupply demand to further enhance the time for the market to respond.

The U.S. Centers for Medicare and Medicaid Services could be the implementing arm for a federal Emergency Response Limited PPE Supply Bubble policy. CMS sets conditions of participation of hospitals in the Medicare and Medicaid programs and oversees service provision through an independent accreditation process. With its accreditation process, the CMS Medicare program is a viable option to implement, oversee, and offset the initial financial carrying cost of a limited supply bubble policy. The accreditation function promotes improved patient quality and safety concerns for Medicare beneficiaries, which benefits all patients. Ensuring Medicare program hospitals are prepared to support Medicare beneficiaries during a disaster is not so dissimilar. The CMS reimbursement mechanism could provide a structure to support this policy for participating hospitals.

Quality Control of Supply Chains

As demand on PPE supply chains was overloaded during the COVID-19 pandemic, the gap created between excessive need and supply shortages resulted in intergovernmental friction and the opportunity for "bad actors" to interfere in the market. An example is the expansion of the "Gray Market," where providers offer unofficial, unauthorized, or other supply not intended by the original manufacturer into the supply chain. This pollutes the market with poor-quality supplies and increases mistrust in the process.

In a normal PPE market, the manufacturers, intermediaries, and end users take time to validate each transaction – primarily through paper document reviews, calls, and manual processes. The urgency of demand and the expanded PPE supply from the "gray market" affected not only health care providers, but also procurement officials, importers, financing teams, and legitimate manufacturers. More rigorous certification and validation requirements now add weeks for true holders of PPE to gain financing and contract options to deliver a legitimate product. These steps add time and cost in procuring PPE for front-line staff.

New tools can be used to increase market transparency and integrity and reduce transaction time in the medical supply chain to build a more resilient, diverse, and secure structure. For example, a blockchain is a decentralized, distributed record or "ledger" of transactions in which the transactions are stored in a permanent and near inalterable way using cryptographic techniques, serving as a tool to ensure market integrity. A radio frequency identification chip or similar technology linked to the blockchain can be read from a distance, with characteristics to support long-transport, including a unique identification code, which can prove shipment validity for the

transaction. If such a tool were integrated into a blockchain solution, the validation process could be reduced from weeks to hours. It would lower intermediate transaction costs that are passed along to the end user while supporting faster times to deliver end products since nothing ships until the deal is final. The benefits will not only expedite and simplify the transactional encounters, but also can lower the overall supply chain costs.

Creating a Working Capital Fund for the Strategic National Stockpile

Since the initial funding of the SNS, the budget never exceeded $700 million of support in any one year. Most years were funded at less than $600 million a year.

A stockpile without the ability to rotate items will need to pay to dispose of the expired stock and pay full replacement value at current-day costs. Ironically, several of the items in the SNS are used by its sister federal government organizations, including within HHS. The effect of an expanding mission, flat funding, and no ability to generate revenue through a rotation program further reduced the ability of the SNS to be ready to meet its full range of missions.

A working capital fund will improve the SNS by allowing it to sell its expiring stocks into the medical supply system and use the proceeds to purchase fresh stocks. If the average SNS inventory item has a service life of five years, annual funding of $600 million a year will take 13 years to replace the $8 billion asset level. This basic analysis highlights the mission risk and the likelihood that the SNS funding would not support critical needs increase each underfunded year.

Recommendations

Recommendation 4.3: HHS should work with relevant health sector stakeholder organizations, among others, on ways to ensure that the medical supply chain can provide hospitals that participate in the Medicare program with a 90-day supply of their average usage rate of essential PPE items to enhance the health system's readiness and resiliency to manage pandemics and other public health emergencies.

Recommendation 4.4: The HHS should work with other agencies (e.g., GSA, DoD), supply chain industry leaders, and standards-setting bodies (e.g., National Quality Forum, National Institute of Standards and Technology) to develop and broadly adopt a foundational set of technical blockchain standards.

Recommendation 4.5: The HHS should work with industry partners and government procurement organizations to promote and adopt blockchain standards for PPE manufacturers, distributors, and intermediaries.

Recommendation 4.6: The HHS should seek ways for the SNS to have a WCF that reduces reliance on new federal appropriations to sustain it so that it is better prepared to respond to public health emergencies readily.

Legislation should require other federal agencies to serve as rotational stock partners with the enactment of SNS WCF authority. This requirement can significantly increase funds available to replace the SNS stock prior to expiration, reducing the operational response risk profile without any new SNS funds being provided. The SNS can operate more effectively to increase its resiliency, diversity, and security to address national disasters.

Case 3: Emergency Support Function #8

Adapted from John Bartrum[77]

Under the federal government's ESF-8, public health and medical services provide the mechanism for federal assistance to supplement State, Local, Tribal, and Territorial (SLTT) partners in response to a disaster, emergency, or incident that may lead to a public health, medical, behavioral, or human service emergency, including those that have international implications.

The Medical Capability Allocation and Reallocation Council (the Council) established under ESF-8 evaluates requests for high-demand and limited federal medical resources. The Council coordinates federal medical assistance to supplement SLTT medical resources based on validated requirements in support of major disaster events (e.g., pandemics, natural disasters, domestic terrorist attacks). The Council was under the leadership of the ESF-8 Manager, who is the HHS ASPR.

The mission of the ESF-8 Council is to coordinate among federal partners when prioritizing, allocating, and reallocating medical capabilities to support requests from SLTT using objective criteria to assess immediate and future needs.

Activation of the ESF-8 Council

On March 13, 2020, President Trump declared an emergency under Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act; 42 U.S.C. §5191(b)) in response to Coronavirus Disease 2019. As part of this declaration, all SLTT partners became immediately eligible for FEMA's Public Assistance Program, which provides direct and financial assistance for emergency protective measures. The President's March 13, 2020 emergency declaration letter to the Acting Secretary of the Department of Homeland Security, the Secretary of the Department of Treasury, the Secretary of the Department of Health and Human Services, and the Administrator of FEMA stated that the President "believe[s] that the disaster is of such severity and magnitude nationwide that requests for a declaration of a major disaster … may be appropriate."

After the ESF-8 function was established by the triggering of the Public Health Emergency and a Stafford Act declaration, the mission of ESF-8 expanded with direct FEMA support. In late March, it became clear that a collective and layered force provider approach was required to best leverage limited high demand medical capabilities and forces. The existing ASPR Incident Response Framework (IRF) works ideally for a local or a regional response where all or most of the forces are ASPR-owned national defense medical system teams. The COVID-19 response was beyond the IRF exercised or assumed framework with the need to use all available federal force providers

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[77] "Cheese Lays the Foundation for Supplemental Federal COVID-19 Medical Support to States and Local Communities." May 2021. Under review for publication.

collectively. For example, before the formation of the Council, limited or no ESF-8/FEMA missions were provided to the PHS Commissioned Corps or VA for COVID-19. DoD missions were occasionally sourced without ESF-8 coordination.

By April 22, 2020, the President had approved major disaster declaration requests for all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. By July 2020, FEMA's operational tempo had increased dramatically with the following situational awareness: 114 concurrent Major Disaster Declarations, at least one in every State, five Territories, the Seminole Tribe of Florida, and the District of Columbia.

Analysis

A Swiss Cheese metaphor describes a strategy that, like any slice of cheese has holes, but layers of cheese have no holes that go all the way through the block of cheese.[78] When applied to government policy, it describes the need for coordinated partnerships as no one level or solution set is independently sufficient across the whole nation. When applied to the intergovernmental response to the COVID pandemic, we see that the multiple layers of available medical forces (in-state personnel, cross-leveling within hospitals, contract medical support, volunteers, State National Guard, and supplemental federal forces) helped to reinforce gaps in any single layer. Further, supply layers comprising the commercial supply chain, local healthcare industry, state strategic stocks,national stockpile, or donations helped cover local supply shortfalls. Technology tools crossed layers to support local and state partners as they sought to optimize alternative care sites from local hotels to large facilities such as conference centers, share lessons learned or guidance for rural response teams, or extend response concepts to support front-line response teams.

The layered approach promoted the operating design notion that federal support is supplemental to local and state partners. As applied to ESF-8, federal resources support capabilities are those that fill in where local, state,mutual aid, or contracted support resources are insufficient or unavailable. Further, the federal supplemental support was the last in and first out to allow for rotation to other areas of supplemental need. The ESF-8 team, specifically the medical force partners, evolved with new processes and tactics, which improved operations, promoted a stronger coalition among the force providers, and resulted in more joint force operations as the public health disease data was refined over time.

The Council provided value to the intergovernmental system through its initial development and operation action in March to expand visibility, coordination, and unity of effort. Prior to this partnership, the participants provided or made ready medical personnel available through a less coordinated and synchronized process. The Council allowed federal partners to change the tempo of operations, shift tactics, and adjust policies as the knowledge of the virus and outbreaks evolved over the spring and summer.

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[78] Gehlert, H., Schaff, K. 2022. Top Pandemic-themed Public Health Media Bites of 2021. https://www.phi.org/press/top-pandemic-themed-public-health-media-bites-of-2021-metaphor-edition/.

For example, in late March 2020, the quantity of medical support requests was already high. The Council met almost daily from March through May to resolve requests for supplement support from states who were anticipating or experiencing actual needs to mitigate the initial COVID-19 wave. While they were able to cut back to meeting three to four times a week in June, meetings were more frequent in July and early August as the team responded to COVID-19 spikes that were more local and or regionally focused. ESF-8 Council Planning Lines of Effort included:

Promoting requirements-based force requests in lieu of specific force and specific force capabilities to provide the most flexibility
Promoting multiple force sourcing reviews to multiple partners to build the best team for the requirement. The effort promoted joint federal force agency teams.
Promoting State Self-Sufficiency: • Used data to assist state leadership in cross leveling and in-state transport. • Provided technical assistance for medical support contracting. • Coordinated RFI with FEMA and conducted research to provide states with a list of potential medical support contractors for their consideration. • Provided medical support to state lessons-learned discussions. For example, the VA provided a webinar on a tool for states to validate medical support contractors.
Partnering with the ESF-8 Health Care Resiliency Task Force and other ESF-8 workgroups on a variety of efforts, such as: • Developing concepts of operations and guidance to states aligned to the response doctrine. • Supported requirement reviews to assist with validation of supply chain issues.
Force structure and employment: • Facilitated interagency discussions on size, scope, and content of teams to support capability based on the skills and structure of the providing organization. • Facilitated discussion on opportunities for force providers to consider how to position forces from an enduring vs. discrete event response.
Promoting efforts within HHS to encourage expanded federal employee volunteers to support or augment the PHS team to expand response capacity.
Providing staffing support for Operation Warp Speed, CDC, and other federal initiatives.
Providing support beyond the direct force planning process with improved coordination to state and local communities.

Table 6: Creating the Rural Response Team Concept of Operations
(Table created by the National Academy of Public Administration)

As with the force providers, the ESF-8 planning team was supported by ASPR, Coast Guard, Army, Air Force, Navy, Public Health Service officers, and federal civilians. The ESF-8 Council demonstrated significant value by having a coalition of willing medical force providers work

collectively to create unity of effort to source and partner on mission requests. The Council partners all recognize that each has a special set of skilled federal medical personnel available and can provide a nimble and responsive process to address critical "hot spot" needs. The operational employment of the dedicated resources falls to the federal partner executing the mission under its authorizations and authorities.

Findings and Recommendations

Finding: A layered planning and operational method is not unique to the preparedness and response or military planning approach. The foresight to develop and implement the approach early in the COVID-19 response, including clear communication of a doctrine based on an integrated, scalable approach to reinforcing local healthcare systems, proved beneficial.

Recommendation 4.7: Congressional leaders and the Presidential should build on the ESF-8 Council framework.

A body like the ESF-8 Council can coordinate and validate the allocation of medical response resources based on metrics for need. This approach can be used in all future major disaster events, including pandemics, natural disasters, and domestic terrorist attacks, to allocate resources more effectively. The Council process allowed for the coalition to leverage the diverse federal resources in support of validated requirements, with each federal organization sustaining and controlling its unique authorities. In the end, the Council served as a unifier and forum that promoted an effective cross-agency partnership of great value in a pandemic or any disaster.

The framework should consider:

Response Doctrine: Locally executed, state-managed, and federally supported under the principles of:
- Engaged partnership;
- Tiered response;
- Scalable, flexible, and adaptable operational capabilities; and
- Unity of effort.

Unique Authorities: Sustain the unique authorities of each agency as they all have other missions related to the response. A desire to shift or create overlapping authorities may unintentionally hinder rather than promote cross-agency partnership.

Limited Federal Medical Capabilities: Recognition that the federal government will not have the medical resources to provide full support to all states independently.
- The response is a partnership to build on the knowledge of state-managed and locally-executed actions before being supplemented from federal force providers, allocated by a data-driven process.

Federal Layered Approach: Federal policy for a layered national preparedness plan that effectively funds the structure and systems via a shared state and federal approach.

- Develop a capability matrix in partnership with federal and state agencies that specifies the response capabilities each state and the federal government should maintain to enhance future response. Any federal funding to the state level should be linked to co-funding with the state to build out and maintain capabilities in the matrix.

- Conduct annual exercises at the regional and local levels, with national exercises at least every other year based on events including but not limited to pandemics, natural disasters, or domestic terrorist attacks.

- Create a national planning cell jointly managed and staffed by the ESF-8 force providers and coordinated through these partners to build and execute exercises under the direction of the ESF-8 Manager.

Case 4: Data Collection

Adapted from John Kirlin[79]

Lack of needed data crippled understanding and responding to COVID-19. This was first noticeable in the lack of data from China, but data problems were dramatically compounded when it became important to understand the spread and impact of COVID-19 within the United States.

Observations and Analysis

Early evidence of the weakness in available data is seen in the efforts of news organizations to develop data themselves in late January. Individual states and counties tracked their own cases and presented them to the public with varying speed and accuracy, but those tallies provide only limited snapshots of the nation's outbreak.

In a narrower example of data gaps, the first outbreaks of COVID-19 in the United States in the Seattle Washington area were soon understood to have resulted in the deaths of at least 37 people at a single nursing home facility in Kirkland, WA. The CDC issued additional guidance for nursing homes on March 19. In May, the CDC attempted to obtain data on deaths in nursing homes and similar congregate care facilities, resulting in estimates that over 40 percent of all COVID-19 deaths in the United States occurred in such facilities.

How could the public health data systems prove to be so inadequate to the needs of analysts and policy makers confronting COVID-19? Congress attempted to improve this situation in the "Paycheck Protection Program and Health Care Enhancement Act" (Public Law 116-139-April 24, 2020), requiring that "…not later than 180 days after the date of enactment of this Act, the Secretary shall issue a report on the number of positive diagnoses, hospitalizations, and deaths because of COVID-19, disaggregated nationally by race, ethnicity, age, sex, geographic region, and other relevant factors…"

But the problems in the current data system will not be addressed simply by reports to Congress. The current system reflects the federal system division regarding guidance from the CDC and authoritative action by state and local governments. The CDC succinctly notes that: "Each state has laws requiring certain diseases be reported at the state level, but it is voluntary for states to provide information or notifications to CDC at the federal level."

It is not surprising that data collection, run by state and territorial jurisdictions, reflects their legitimate interests and available resources. As noted by the CDC, states can respond quickly and require personal identification of individuals within disease reports, allowing targeted disease control and prevention. The CDC focuses on "notifiable" diseases, with systems for 57 jurisdictions (50 states, five territorial health departments, New York City, and the District of

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[79] John Kirlin. 2020. "COVID-19 Upends Pandemic Plan." *American Review of Public Administration*. https://journals.sagepub.com/doi/full/10.1177/0275074020941668.

Columbia) sending information on individual cases stripped of personal identifiers to the CDC. The list of notifiable diseases can change annually.

On April 5, 2020, the CDC issued an "interim case definition" for COVID-19, a standard step preceding being added to the list of notifiable diseases. This case definition includes clinical and laboratory criteria, and epidemiologic linkages (e.g., close contact with a confirmed case or travel to an area "of sustained, ongoing community transmission"), resulting in "probable" or "confirmed" cases. The time of this action is notable as 8,501 COVID-19 deaths had occurred in the nation at that point, rising quickly to 60,966 by April 30, 2020. The CDC case definition and inclusion as a notifiable disease came after travel bans, personal hygiene and social distancing guidance, and stay-at-home orders, all significant public policies, but at the toe of the slope of rapidly increasing deaths.

How California, the nation's largest state with a highly developed governmental sector, collects data on reportable diseases and conditions identifies two issues for further examination. First, this bottoms-up labor-intensive system relies on a mix of telephone calls, faxes, mailed documents, and some electronic submissions. Second, some diseases, such as influenza, are systematically analyzed with multiple data sources over time. However, these analyses appear to assemble available data into a "usable" overview, in contrast to an intentional design of the most effective data collection.

Findings and Recommendations

Finding: Addressing COVID-19 demonstrated the need for both surveillance (population-level) and case (individual-level) data. These needs should be addressed separately but will complement each other in policy making and organizational-level responses.

For surveillance/population-level data, two strategies should be pursued:

Recommendation 4.8: Improve the data collected through state public health agencies and the CDC, including:
- Accelerate definitions of a disease. For COVID-19, CDC issued its notifiable disease guidance on April 5 after many deaths and much significant policy making.
- Through agreements among all states or new federal law, establish a real-time web-based national data system to receive standardized reports from the 57 public health jurisdictions. These reporting jurisdictions could collect additional data beyond the standard data required of all, at their discretion.

Recommendation 4.9: Obtain depersonalized information about communicable diseases through new federal legislation and/or contracts with those holding health data on large fractions of the population.

This promise of data analytics is of increasing importance in all industries. This is what Google promises to Ascension, a Missouri-based health system, and others with whom it enters into agreements.[80] This is what Kaiser is building internally. Artificial intelligence promises greater advances in the power of such analyses.

States should take the lead for case/individual-level data, though existing associations of states and public health professionals will provide arenas for joint learning. Two actions should be pursued to improve the current system:

Recommendation 4.10: The HHS should work with states and industry stakeholders to move to a fully online, integrated data reporting and database management system. The data collected and updated regularly on a "COVID-19 Dashboard" by Santa Clara County provides a plausible example of what is needed.

Recommendation 4.11: Review and, where possible, increase the effectiveness and efficiency of data collection. For example, the eight types of data collected by the State of California for reporting on influenza may be reduced to five easily collected electronically, or expanded to 10, also collected electronically, but each set of protocols should be examined and improved when possible.

While the local detail of the current public health data collection is likely to remain valuable, analyses of data held by large health care systems and their contractors will become increasingly critical. For example, it should be able to differentiate individuals in skilled nursing facilities from residents in assisted living facilities. The goal is to make quickly available granular data critical for informed decision making by health professionals, Governors, or the President.

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[80] Ascension. 2019. Ascension and Google working together on healthcare transformation. https://ehrintelligence.com/news/ascension-to-expand-google-ehr-search-tool-integration-across-sites; https://ascension.org/News/News-Articles/2019/11/11/19/51/Ascension-and-Google-working-together-on-healthcare-transformation.

Case 5: Align Data Systems to Support the First Responder Role

By John Bartrum

Observations and Analysis

Compare first responder health providers to public health providers. Certainly, an overlap in skills will exist. However, the mission capability they are asked to bring to bear can impact the organizational cultural mind-and data needs. As a public health policy expert, a doctor or nurse at the CDC will work in an organizational culture of more deliberation based on a higher certainty of the science to develop and deploy guidance. On the other hand, a doctor or nurse health responder to the front lines may operate with less uncertainty as they develop data with each treated patient. This is no different than a house designer who can build a safer house based on data to prevent a fire compared to a firefighter who has to respond to the data available within the heat of fire response.

The framework to link data from intergovernmental response is more complicated than merely having one master data file. Case 4 highlights opportunities to enhance CDC data, recommending a cloud-based reporting structure with enhanced CDC access to data and the ability to analyze the data more quickly. It highlights the more deliberate organizational culture of a public health agency seeking to fully understand the science behind the data as they provide recommendations or guidance.

In the COVID-19 response, the data needed to support the supply chain system differs from the data required for public health responses in a pandemic. The federal government does not control the commercial supply nor its data, as it does not control all the public health data. During the COVID-19 response, the federal government worked with its commercial supply partners to build a control tower of data to coordinate and understand supply gaps. The opportunity exists to keep this structure in place with occasional response exercises and simulations to test the ability to activate the system, which took time to build during the response. However, this system needs to protect proprietary commercial information and prevent unauthorized or malicious use of these data against commercial entities.

For the medical response function, an immediate need existed to enhance the national ESF-8 medical response based on data-driven information so that decision makers could facilitate a more efficient allocation of high-demand, low-density medical capabilities. To support future events, the ESF-8 Council developed a data-driven matrix framework. Further into the COVID-19 response, as data were consolidated, this framework served as more of a dashboard, providing actual hospital data by zip code, population density, and other elements. This allowed more refined decisions related to requests from states as compared to available resources. Tools of this nature to support exercise planning and future operations should be sustained. However, there is less need to sustain all the live data feeds if the capability exists to turn on the data and add those elements needed for future events.

Findings and Recommendations

Finding: Data and personnel are required in any intergovernmental response, as illustrated in the ESF-8 response in Case 3. However, just as there are many different types of mission sets, skills, requirements, and capabilities to bring to bear on a national response, the type of staff and data can be and likely are different.

Recommendation 4.12: HHS should capture the structure, technologies, and processes of the data systems developed to guide federal responses to COVID-19 in 2020, including roles of the U.S. Federal Emergency Management Agency, Office of the Assistant Secretary for Preparedness and Response, CDC, and DoD. As a second step, develop a "sustainment plan" which can keep this knowledge relatively current for future disease disaster response. The goal is to ensure future leaders are familiar with the criteria-based set of data tools used for the COVID-19 response, and thoughtful consideration is given to the identification of enhancements to these decision tools. Annual or biannual exercises under the plan are recommended.

Appendices

Appendix A: COVID-19 Working Group Member Biographies

Kenneth W. Kizer, *MD, MPH,* Co-Chair, Chief Health Care Transformation Officer and Senior Executive Vice President, Atlas Research; He is a highly experienced physician executive who has been elected to both the National Academy of Medicine and the National Academy of Public Administration and whose diverse professional experience includes senior leadership positions in the public and private sectors, academia, and philanthropy. He has previously served as founding president and chief executive officer of the National Quality Forum; Under Secretary for Health, U.S. Department of Veterans Affairs, and chief executive officer of the nation's largest healthcare system, during which time he engineered the internationally acclaimed transformation of the Veterans Healthcare System in the late 1990s; founding Chairman, President and CEO, Medsphere Systems Corporation, a leading commercial provider of subscription-based health information technology; founding Director, Institute for Population Health Improvement and Distinguished Professor, University of California, Davis; inaugural Chief Medical Officer, California Department of Managed Health Care; Director, California Department of Health Services; and Director, California Emergency Medical Services Authority, where he was the architect of the state's EMS and trauma care systems in the early 1980s. During his record tenure as California's top health official, he won high praise for orchestrating the state's response to the then new HIV/AIDS epidemic, implementing California's famed Tobacco Control Program and the '5-a-Day' for Better Nutrition Program that was later adopted for national implementation, pioneering Medicaid managed care, and restructuring many of the state's public health programs. He also has served on the U.S. Preventive Services Task Force and as chairman of The California Wellness Foundation.

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Appendix B: Searching for Best Practices in COVID-19 NPI Responses

The intergovernmental response to COVID-19 invites funding a systematic strategy to identify and understand effective pandemic NPI measures. The following recommendation maps elements for effective collection and analysis of best practices for NPIs from the COVID-19 responses:

- Search for best practice cases over a multi-year period.
- Identify a manageable set of best pandemic mitigation practices evaluated for the potential to serve as adaptable models. Utilize terms such as "best practice" and "model program" to narrow the number of possibilities to those that have been independently vetted in a specific service or type of public health, hospital, or advocacy organization.
- Evaluate with multiple staff and stakeholders to reach a consensus on which programs to pursue as real-time practical applications. Focus on performance improvement through 1) managing for quality; 2) developing human resources; 3) adapting technology; 4) building partnerships; and 5) measuring for effective performance.
- Interview program directors for updates. Award-winning public health innovations may no longer exist due to problems of organizational politics, budget cutbacks, leadership changes at the organizational or political levels, or other factors. Interviewing staff can lead to a deeper understanding of the potential applicability of that case. Suggested questions could include:

  1. How long did it take for the innovation? What is the "back story"?
  2. Is it still operating?
  3. What data is available as to its success? Have there been performance issues?
  4. What are the most important lessons learned? Have there been constraints or dilemmas confronting key decision makers?
  5. Beyond what is posted to the website, can a program share the application that led to its award-winning designation? News articles?
  6. Is there a manual or training video to share?
  7. Are program staff available for further information?

Appendix C: References

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