

Strategic Emergency Response in Nontraditional Crisis Situations: Case Studies on Legal Authorities and Collaborative Dynamics for Effective Resource Management

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Abstract

This document presents two case studies with associated instructional prompts to examine key lessons and insights from the US response to COVID-19 test kit shortages in 2021 and 2022, focusing on decision-making, procurement processes, and distribution strategies. It is an educational tool designed for government officials, researchers, educators, students, and others to learn from the experiences and critical decision processes of leaders during this significant event.

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Overview

Course objectives and outcomes

The objective of this course is to explore how legal authorities and collaborative dynamics can be integrated to enable more effective resource management and procurement during nontraditional crises and achieve challenging policy outcomes. Through an exploration of two case studies based on the government's response to the COVID-19 pandemic, participants can discuss alternative approaches to achieving successful outcomes, consider opportunities for building cohesive team structures, and analyze examples of public-private collaboration and industrial policy.

Using past experiences as a guide, students and participants in this course will learn how to use both innovative approaches and traditional practices to solve complex procurement problems in emergency situations.

Target audiences

This class may be taught in its entirety or modified to accommodate a particular audience's learning needs and time availability. With either approach, the three primary audiences of this course will be as follows:

- US government executive branch personnel, members of Congress and their staff, and others who may be responsible for federal emergency procurement and provision of resources during future events
- Officials of state, local, tribal, and territorial governments who are or may be responsible for emergency procurement and provision of resources during future events
- Students and participants in academic and training programs focused on degrees or topics related to areas such as emergency management, homeland security, national security, and defense

Course organization

This course is organized into five modules. Module 1 provides an introductory lesson designed to set the stage for deeper exploration of the course objectives. Module 2 provides foundational background on existing legal, doctrinal, and procedural frameworks for resource management in disasters in the United States. Modules 3 and 4 both introduce case studies from the COVID-19 pandemic response that illuminate key challenges and highlight nontraditional policy and operational responses to those challenges. Module 5 presents an analysis and integration exercise that affords an opportunity for critical examination and synthesis of the case studies.

The course structure is designed to allow it to be taught as a whole or to have relevant modules excerpted and used on their own in appropriate instructional contexts. Instructor-specific content is presented in blue boxes, allowing it to be easily removed to become a student-only version of the material.

Module 1. Introduction

The introductory lesson provides an opportunity for the instructor to interact with the participants to gauge their general understanding of and perspectives on the government's response to the COVID-19 pandemic. This module should consist of an interactive discussion with the participants to encourage participation, promote an atmosphere of respect, and emphasize critical thinking as an important aspect of the course.

The global COVID-19 pandemic had been raging for just over a year, but in the northern hemisphere, the early summer of 2021 led much of the public into a false sense of security. Although the new infection counts were still significantly high, the rollout of the vaccine and the increased outdoor activity made possible by warmer weather meant almost 100,000 fewer new hospitalizations per week than six months earlier in January and 93 percent fewer weekly fatalities. However, that lull would be short-lived.

Overconfidence led people to lower their guard and resume much of their prepandemic lifestyles. Coupled with emerging COVID-19 variants, new cases skyrocketed, and by August 2021, weekly new cases had risen to more than 85,000, fatalities had grown tenfold, and new precautions and policies were needed to combat the resurgence. By January 2022, weekly average hospitalization numbers reached a peak of over 150,000, and fatalities matched the levels of the previous winter. Tim Manning, White House COVID-19 Response Coordinator, described the situation in December 2023 as follows:

All through the COVID pandemic, supply lines, supply chains, and logistics were extraordinarily challenged. Everyone in the world experienced shortages, from toilet paper to food, and certainly, the medical response side was no different. In fact, many point to the global shortage of rapid diagnostics and the ability to test for COVID-19 as a reason that the pandemic blew up, and governments lost control of the response.

Throughout 2021 we were very closely modeling the progression of the disease. New variants were emerging in other parts of the world; genetic mutations of the COVID virus, growing in unvaccinated populations, and breaking out to circulate through the globe. We were concerned that there would be an escape from both our ability to test for the disease and for the acquired immunity to protect people who had previous infections from being reinfected. The reason for the shortage in testing was fairly complicated, but in its simplest form, there was an extraordinarily high demand for tests, which were newly approved under FDA emergency use authorizations, and production couldn't keep up. This was exacerbated by a high degree of stockpiling on the part of the public. In order to do everything from travel on an airplane, move around your community, reopen schools, or go back to work, one needed to prove a negative test. That drove extraordinarily high demand for PCR testing, molecular testing, and rapid antigen testing.

Question prompts

- What were your experiences with the availability of tests, personal protective equipment (PPE), and other important items during the COVID-19 pandemic?
- 2. What were your roles or responsibilities in response to the pandemic, if any?
- 3. What significant barriers and challenges in the response to the pandemic did you observe?
- 4. How did you assess data and information to make decisions about your work, home life, family care, and other "normal" activities?
- What do you know now about the government's response or supply chain issues that 5. you wish you had known during the pandemic?

Module 2. Legal, Doctrinal, and **Procedural Frameworks for Resource** Management in Disasters—A Short **Primer**

This module provides participants with an initial understanding of how government agencies traditionally approach emergency resource provision and procurement. This allows the instructor to gain a general grasp of the participants' expertise on and experiences with this topic.

In many ways, the contributing factor that turns an event into a crisis or emergency is a lack of capacity or capability to find and apply the right resources in sufficient amounts to stabilize the situation. Low-level incidents, such as a traffic accident or brush fire, are managed with resources on hand by the agencies typically tasked with responding to these events. In normal circumstances, these agencies respond with tools and materials based on preplanning and experience. When an event grows and evolves beyond the capabilities and capacities of the assigned organization, however, an agency can employ unique mechanisms within the emergency response world to call for additional resources. The following section contains a brief explanation of the established doctrine, processes, and legal authorities for emergency resource procurement.

- What is your general understanding of how different levels of government and their 1. agencies respond to disasters and emergencies (federal, state, local, military, etc.)?
- What is your understanding of how governments at different levels procure 2. resources?
- What resource constraints do government agencies face? What advantages can 3. government agencies use for effective resource procurement and provision?
- 4. Describe the process of fulfilling a critical supply need from a local government all the way up to the federal government. What authorities or arrangements are essential to success?

Local jurisdictions

In most towns, cities, parishes, and counties, routine ("blue-sky") purchase and contracting rules and procedures are guided by state and local jurisdictional laws and ordinances. Depending on the jurisdiction, these might be a combination of relatively easy "one-stop" purchases, bid and proposal competitions, and more onerous, multilayered processes.

Mutual aid agreements between agencies and organizations provide resources that are generally common to both the requestor and the provider but can also be used to supplement resources that the requestor does not possess at all or possesses in insufficient quantity. Mutual aid agreements are usually developed in advance and are legal arrangements that can specify terms of resource exchanges, including costs, liability, and limitations. Doctrinal guidance from the Federal Emergency Management Agency (FEMA) provides additional information on the use of mutual aid: National Incident Management System Guideline for Mutual Aid JFEMA.

Local jurisdictions that officially declare conditions of emergency generally also include provisions that allow exceptions to time-consuming, routine processes in order to expedite procurement of needed supplies and resources. The states of North Carolina and California provide good examples of these processes and authorities for their local jurisdictions (see North Carolina's Local State of Emergency Declarations - Some FAQs and California's Governor's Office of Emergency Services "Quick Reference Guide for Local Government").

In addition, traditional emergency management doctrine includes the expectation that the next "higher" level of government will help find and procure resources when requested by a jurisdiction engaged in crisis response. This assistance occurs most often with requests from local (town, city, county, or parish) up to the state government. The requested resource may

be identified as an object (e.g., sandbags) or described as a mission to be accomplished (e.g., evacuating people from a flooded area.) In the latter case, the providing agency determines what types of resources might be necessary to achieve an objective as opposed to merely procuring objects or supplies described by the requesting entity. It is not necessarily the responsibility of the providing agency to pay for the acquired resources found for the requestor. The Association of State and Territorial Health Officials developed an informative description of the declaration process from a public health context: Emergency Authority and Immunity Toolkit.

Question prompts

- What are some challenges that local jurisdictions might face in a traditional response to an emergency in terms of procuring resources?
- 2. How might these challenges be amplified in a larger emergency?
- 3. What conditions or environments might exacerbate these challenges?

States and territories

As with local jurisdictions, states and US territories follow their respective rules and procedures established for day-to-day resource procurement. In many cases, state and local governments may enter into preestablished contracts with multiple vendors for commodities and other materials that may be needed during a crisis response. By creating stockpiles, procuring contracts for vendor-managed inventory, and establishing multiple sourcing, emergency management agencies can reduce the risk of shortage and ensure a more effective and efficient response. The types of resources that can be purchased may be restricted in the guidelines by the state or territory's executive or legislative branches (e.g., a rule to buy only US-made products, if available) or set forth in grant guidance from federal grantors (e.g., a rule to buy only approved items from an established list). For example, FEMA sets guidelines for the use of federal grant funds in emergency and exigent circumstances (see Fact Sheet: Procurement Under Grants: Under Exigent or Emergency Circumstances). Mutual aid agreements between states and territories are generally governed by the congressionally established Emergency Management Assistance Compact (EMAC), which requires states and territories to incorporate preestablished language into their state law in order to participate in the EMAC (see Public Law 104–321 104th Congress Joint Resolution and Emergency Management Assistance Compact).

As with local jurisdictions, states and territories that officially declare conditions of emergency most often also include provisions that allow exceptions to routine processes in order to expedite the procurement of needed supplies and resources. For an example of this, see the State of Oregon's emergency process and procedure: <u>Department of Administrative Services:</u> **Emergency Procurement.**

A state's national guard, when operating under state active duty status and reporting to the governor as its command in chief, is available to carry out emergency response missions within that state as directed by the governor through the Adjutant General (or "TAG"). Examples of these missions include assisting with evacuations, conducting helicopter rescues, and running large sheltering and feeding operations. In addition, when the emergency is more wide-scale or longer in duration, such as the mass vaccination center operations during the COVID-19 response or the extensive rescue operations during Hurricane Katrina, states, localities, and some territories may access federalized National Guard and other federal resources from nearby military installations immediately under a direct life- or property-saving condition or through a more deliberate process called "Defense Support to Civilian Authority" ("DSCA"). The Congressional Research Service produced this primer to explain the general DSCA process: Defense Primer: Defense Support of Civil Authorities.

When states have exhausted their ability to procure necessary resources through these methods, they can turn to the federal government and request assistance through the provisions of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (see Stafford Act, as Amended - FEMA P- 592 vol. 1 May 2021). This law has been applied for thousands of disasters since its establishment in 1988 and is the basis for a multitude of policies, doctrine, and implementation of rules in Title 44 of the Codes of Federal Regulation, or "CFR."

Question prompts

- What are some challenges that state and territorial jurisdictions might face in a traditional response to an emergency in terms of procuring resources?
- 2. How might these challenges be amplified in a larger emergency?
- 3. What conditions or environments might exist that exacerbate these challenges?

Tribal nations

Tribal nations generally follow the same types of resource procurement processes as state entities. Historically, a tribal nation's access to federal assistance has more closely resembled that of a local government in which requests go through the state where the disaster occurred. However, in 2013, the Sandy Recovery Improvement Act of 2013 established that federally recognized tribal nations may request assistance either through the states where they are geographically located or directly from the federal government (for specifics on the 2013 law, see Sandy Recovery Improvement Act of 2013 | FEMA.gov). FEMA also published pilot guidance on this process in 2023 (see <u>Tribal Declarations Interim Guidance</u>).

Federal coordination

For the most part, federal coordination of emergencies and disasters falls under FEMA's jurisdiction. Under the Stafford Act, FEMA exercises authority on behalf of the President to coordinate the various federal agencies to use the resources of the US government to assist governors in their response to disasters, including access to the Disaster Relief Fund, a flexible budget account that has its own set of rules for use and replenishment apart from the normal federal budget. However, FEMA is not always in a coordination role by default; according to the Stafford Act's description of FEMA's authorities, the President must declare an emergency or disaster under the act to put FEMA in the coordination role. Other agencies have their own authority and exercise it without specific presidential direction, such as the US Coast Guard in waterborne oil spills, the Environmental Protection Agency in land-based hazardous material spills, and the Department of Health and Human Services (HHS) in public health emergencies declared by the department's secretary.

In addition to coordinating the response to emergencies and disasters, procurement and contract professionals throughout the government perform day-to-day resource management. Federal procurement is a complex system of regulations, agency rules, and practices, and it is often governed by the specific language included in appropriations laws when the budgets are passed. Furthermore, when various emergencies are declared, additional regulations apply, often accompanied by flexibility and extraordinary power to waive restrictions. Each agency has its own processes and rules for large purchases, often involving long, drawn-out series of committee meetings, risk management planning, and numerous rounds of revisions, all of which can take months—even years. Procurement in times of crisis, however, can vary. US law contains a wide range of emergency authorities, including the National Emergencies Act, the Stafford Act, and the Public Health Emergencies Act. In addition, laws that are not emergency acts per se but contain extraordinary authorities can allow the government to perform actions typically outside of its jurisdiction in certain situations. Although some emergency procurement efforts may focus on "sole source" acquisition to speed up the buying of a certain product that has very limited or no alternate suppliers, many preparedness efforts include risk management strategies of establishing multiple-source contracts for the same or similar products or services to mitigate the risk of shortfalls, maximize scalability, and prevent nonavailability (see, for example, 50 USC Ch. 34: National Emergencies and the Stafford Act, see Stafford Act | FEMA.gov).

Generally speaking, federal acquisitions follow a range of US laws in Title 10 and Title 41, known colloquially as the "procurement code," and a set of rules known as the "Federal Acquisition Regulation" (FAR) (FAR | Acquisition.GOV). Several other procurement authorities, such as Other Transaction Authorities, allow for wide flexibility in procurement in certain circumstances, as well as in structuring crisis acquisition strategies.

Combined, these laws and rules set out the guidelines and boundaries of what is possible and establish how the US government goes about spending money, with the primary goal of providing rules for fair and open competition, as well as the most effective use of tax dollars. However, a wide range of provisions is granted for emergency needs, and they are catalogued in Part 18 of the FAR. One example is the requirements that must be met in order to waive free and open competition described in FAR, Part 6. As with most parts of US law, agencies must adhere to additional internal rules for how these laws and regulations are implemented; the Department of Defense (DOD), for example, has additional rules for what must be included in a justification and approval document for review by the appropriate official (see <u>Justification</u> and Approval ([&A]).

The Defense Production Act allows for a wide range of unusual financial transactions, such as direct funding of an industry to support continued manufacturing of important products that may not have a commercial market, buying heavy equipment and transferring it to an industry, and, most notably, intervening in the open market and reprioritizing a company's delivery schedule to take (or give) priority in delivery, or even direct what a company is making (see 50USC Ch. 55: DEFENSE PRODUCTION). Many other laws also contain useful emergency provisions. The Trade Act of 1974, for example, contains the ability to provide emergency waivers for tariffs imposed under Section 301 of the act. This was used throughout the COVID-19 response to lower the cost and increase availability of some critical response supplies.

Question prompts

- What are some resource-procuring challenges that federal agencies might face in a traditional response to an emergency?
- 2. How might these challenges be amplified in a larger emergency?
- 3. What conditions or environments might exist that exacerbate these challenges?

Challenges

When an emergency event evolves beyond the capabilities and capacities of the assigned organization, an agency can use mechanisms within the emergency response world to call for additional resources. For example, agencies might rely on agreements such as mutual aid to supplement their resources with those from similar agencies, execute prearranged contracts with suppliers of resources, or invoke emergency powers or statutes that set in motion larger governmental relationships to expand the ability to reassign or procure resources well beyond the reach of the affected agency or jurisdiction. The organizations most familiar and experienced with these traditional scaled logistic networks predominantly include firstresponse agencies supported by emergency management agencies.

The majority of incidents that rely on some type of networked or hierarchical resource support are stabilized with processes that are routinely used and are commonplace in jurisdictions that have some level of mature response networks. The doctrinal emergency management approach for governmental logistical response is generally—and colloquially—as follows: 1) use your own stuff, 2) buy it if you can, 3) ask a neighbor, 4) ask the next "higher" level of government for help to find or procure it, and 5) go international. For recurring and routine events, even on the scale of large hurricanes and wildfires, this process is mostly sufficient.

However, events outside the norm in either context or scale—or both—have the potential to break this emergency resourcing methodology. The main constraints and barriers occur when 1) the needed resource is in short supply (globally as well as locally), 2) the event is affecting multiple entities who are all seeking and competing for the same resources, 3) the event itself affects the accessibility or use of a resource, and 4) the resource is nonexistent in terms of viable production capability. Other challenges emerge as entities outside the traditional response ecosystem also compete for the same logistical assets that traditional systems are attempting to access.

The global response—and that of the United States in particular—to the logistical challenges of the COVID-19 pandemic demonstrated the complications of all of the constraints mentioned previously. One can imagine other large-scale or novel scenarios that might produce similar challenges to the "tried and true" approaches to emergency resourcing. For example, consider all the jurisdictions across the West Coast, Canada, and the Pacific Basin searching for rescue and recovery resources following a Cascadia subduction zone earthquake. Imagine another pandemic that involves disease transmission routes, treatments, and personal protection measures that differ from the COVID-19 experience, or consider events from the cyber and space environments that unfold in ways outside the capacity and capability built within the traditional system. Some recent case studies of how the government innovated new procurement and delivery systems on a national scale can provide insights and learning opportunities for future emergencies.

Module 3. Case Study A: Mobilizing **Industry—Navigating Uncharted Procurement Territories**

In this case, instructors and participants engage in a discussion of how the collaborative efforts between government entities and private-sector diagnostic manufacturers can overcome barriers and ensure the timely availability of critical testing resources. The summary exercise brings together the key points and lessons that can be derived from the case in its entirety.

Case abstract: How could the US government expand production and availability of rapid antigen over-the-counter COVID-19 tests on the open retail market?

By early fall of 2021, it had become obvious that market forces were inadequate to drive additional production of rapid antigen COVID-19 tests or, in some cases, to drive private sector manufacturers to reenter the market. Innovative and unprecedented government policy and procurement actions would be needed to provide incentives and allow for expanded production that would reach retail consumers while adhering to federal acquisition rules and protecting taxpayer dollars.

Question prompts

- What is your understanding of how production and procurement of COVID-19 emergency supplies (e.g., protective masks, test kits, PPE) could have been implemented?
- 2. What challenges might we have expected the COVID-19 pandemic to present to the production and provision of these essential supplies?

Introduction

This case study delves into the intricate challenges involved in acquiring rapid antigen tests amidst the global COVID-19 pandemic. The narrative unfolds against a backdrop of supply chain disruptions, logistical complexities, and an unprecedented demand for testing resources. Focused on the late summer and fall of 2021, the case explores the collaborative efforts between government entities and private-sector diagnostic manufacturers to overcome barriers and ensure the timely availability of critical testing resources.

The challenge at hand involved addressing widespread shortages, from essential goods to medical supplies, experienced during the COVID-19 response. A critical bottleneck emerged in the form of a rapid diagnostics shortage, intensifying the pandemic's negative impact. This case study centers on the endeavor to secure an adequate supply of rapid antigen tests to meet soaring demand and curtail the further spread of the disease.

Since the first half of 2020, the rapid global spread of COVID-19 had posed significant challenges to supply chains and component sourcing, particularly affecting the United States. Although the US maintained substantial manufacturing capacity, logistical issues arose because of a heavy reliance on components sourced from China. This dependency on international suppliers—especially from China where much of the manufacturing had shifted in previous years—exacerbated the constraints on supply lines as the pandemic progressed worldwide. These factors collectively affected the US's ability to respond effectively to the escalating situation.

Various national-level response efforts led to intense international competition for both the raw materials needed for these tests and the completed diagnostic tests themselves, as well as a range of COVID-19 response related materials. In addition to rapid antigen testing, the entire world faced shortages of essential components for polymerase chain reaction (PCR) testing, such as pipette tubes and reagents. Similarly, limited supplies of single-use bioreactor bags and tube sets hindered the production of vaccines. In example after example, critical items used in production worldwide were often sourced from a just a few specialized companies. For instance, the glass for vaccine vials was supplied globally by just two companies, presenting a complex challenge for both manufacturers' supplies and for international relations.

This limited-manufacturer scenario was mirrored in other areas, with varying degrees of severity. For example, the pandemic caused an approximate tenfold increase in the demand for syringes and needles compared to pre-outbreak levels, further straining the supply chain and manufacturing capabilities.

The global market competition was further exacerbated by misinterpretations and misunderstandings regarding the actions of the United States. Other countries formed perceptions based largely on media reports, which often proved to be either false or misinterpreted. In an effort to counteract those purported US actions, some countries threatened or implemented reactive measures. This situation underscores the effect of media narratives on international relations and policy-making, particularly in a tense global environment.

Question prompts

- What are the main components of the problem presented in this case?
- 2. Who is, or might be, responsible for these different components that contribute to the larger issue?
- Why did the government have to insert itself into what might normally be a business 3. equity or process?
- 4. Can you think of any other similar or analogous problems that would lead to this
- Given what you know about the challenge so far, how would you go about solving 5. the problem?

Background

As the COVID-19 response unfolded, global supply lines faced disruptions that affected various sectors. Shortages became a ubiquitous challenge, with rapid diagnostics identified as a linchpin for effective pandemic management. With containment of the disease hinging on testing and isolation, the shortage of these tests was recognized as a catalyst for the escalation of the pandemic, prompting a reevaluation of the US government's response strategies to increase production.

New variants were emerging outside of the US; genetic mutations of the COVID-19 virus were increasing in unvaccinated populations and breaking out to circulate through the globe. These mutations caused concern about both the ability to test for the disease and whether acquired immunity would protect previously infected people against reinfection. The underlying reasons for the testing capacity shortage were complicated with many causes, but in its simplest form, there was an extraordinarily high demand for the tests newly approved by the Food and Drug Administration (FDA). In order to complete basic tasks such as traveling on an airplane, moving around your community, attending in-person schools, or going back to work, a negative test was required. This requirement drove up demand for PCR testing, molecular testing, and rapid antigen testing. Although manufacturers were, in many cases, scaling up production, they were still unable to meet that demand. Coupled with a high degree of public stockpiling, the insufficient production led to dramatic shortages and a detrimental feedback loop that was difficult to interrupt.

Test manufacturers faced multiple challenges, including shortages in raw materials. As cases throughout the US dropped dramatically in the early summer of 2021, demand likewise dropped, and some companies intentionally scaled back their production. For other companies, it took longer to receive emergency use authorizations from the FDA, resulting in slower scaleup of production. The scarcity of raw materials such as thermoplastic resins was exacerbated by competition and reduced availability following Tropical Storm Yuri in Texas the previous year.

Question prompts

- Besides rapid antigen tests, what other types and categories of supplies were experiencing shortages?
- 2. What other factors contributed to these shortages?
- 3. Who is responsible for mitigating these types of shortages?
- 4. How would these shortages be addressed in a nonemergency setting?

Key players

Innovating approaches to scale up production of tests for the open market required a wide range of traditional and nontraditional players. Major stakeholders in the acquisition of rapid antigen tests included the DOD and its Defense Logistics Agency (DLA) and the HHS and its Assistant Secretary for Preparedness and Response (ASPR), with policy oversight by the White House's Office of the COVID Response and Office of Management and Budget, all working closely with US-based, private-sector diagnostics manufacturers.

Under normal circumstances, the federal agencies involved might coordinate preparedness activities through the National Security Council's interagency policy process, but that system focuses on the operational arms of the agencies, and historically, no formal channel to coordinate supply chain, industrial policy, or acquisitions exists. Furthermore, the government's relationship with the overall private sector and industry is generally best characterized through the lens of procurement rules in which direct contact is extremely limited and rare—ex parte communications between the government and a potential vendor can be grounds for elimination from the bid process or spur protests by other vendors if the first vendor were to win a procurement competition. As a result, beyond general advertising and discussions of strategic-level capability, the government rarely engages in detailed discussions of a company's production capacity or pricing in relation to potential purchases.

Question prompts

- 1. Given the key players identified, what factors would you anticipate contributing to or hampering an effective solution?
- 2. What other interests or perspectives should have been considered? Are there other potential players who should have been included?
- 3. Who is, or should be, ultimately "in charge"?
- Are there other similar or analogous problems that you can think of that would 4. present this interagency, multisectoral dynamic?
- 5. Given what you know now about the challenge and the players involved, how would you go about solving the problem?

Initial steps

In summer 2021, disease spread modeling from the Centers for Disease Control and ASPR indicated a potentially huge surge in cases in late summer and fall. The US government, equipped with tools including the Defense Production Act and substantial financial resources, sought to expand public availability of tests. Because of concerns about the possibility of low production capacity, the government commenced outreach efforts to CEOs of major diagnostic companies with FDA-approved tests. However, no swift resolution was reached because of constraints such as limited manufacturing capacity and prior experience with missed market windows that had resulted in large volumes of unsold inventory.

In some cases, manufacturers were sympathetic but lacked the basic manufacturing capacity to scale production, and typical construction timelines to expand production were too long. In other cases, traditional appeals to public health concerns proved inadequate; some companies that weighed potential expansion against their view of a fiduciary responsibility to its shareholders opted not to take on the risk of missing the peak demand and finding themselves with excess inventory. This left few options aside from devising innovative and unprecedented contractual and regulatory structures to alleviate that risk. Although some more draconian options for resolution were available in the Defense Production Act, they would likely be resisted and therefore result in both costly delays and failure to acquire additional tests in the necessary time frame. Industry participants needed assurances to undertake the additional risk—to trust that the US government could provide some measure of certainty that they would

not be "left holding the bag." Companies required policy structures designed to backstop the risk to the company, thereby mitigating the decision's associated risks and incentivizing them to rapidly expand production.

Question prompts

- What potential strategies can you think of to begin to solve the problem at this 1.
- Who are the major players and influencers at this point? 2.
- 3. What are the various perspectives, biases, interests, and motivations of those players?
- 4. How would you find paths to effective coordination and collaboration among all these different interests?
- 5. Were the companies right to be risk averse?
- 6. What are some potential ramifications of failing to solve the problem?

Potential ramifications of failure

A failure to address the manufacturing challenge would result in a severe shortage of rapid antigen tests, leading to long lines, increased need for social distancing, decreased travel, work limitations, and ultimately more deaths. The mismatch between public demand and test availability, particularly during the case spikes of the winter and summer of 2021, underscored the gravity of the situation.

Barriers and innovative solutions

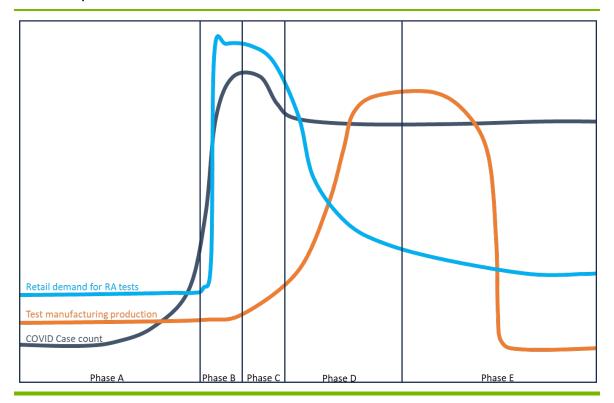
Traditional government procurement processes, with their extensive reviews, risk assessments, and prolonged timelines, proved impractical for the urgent situation. This case study details the unprecedented challenge of orchestrating billion-dollar acquisitions within a timeframe of a few days, necessitating the creation of a unique procurement vehicle similar to an advanced market commitment (AMC) within the federal acquisition framework.

As previously discussed, manufacturers faced the significant issue of a mismatch between their capacity to surge production and the actual timeline of public demand during a pandemic. For example, when a new variant emerged and disease transmission increased, the initial growth of the disease was geometric yet gradual, causing minimal public concern. However, as the rate of infection accelerated and cases began doubling daily, the public's anxiety escalated, leading to panic buying and an exponential surge in demand.

Earlier in the pandemic, manufacturers had responded by ramping up production, but the increase in their output often lagged behind the rapid spread of the disease. Public concern and panic grew as case counts rose, and with them, panic buying and stockpiling increased. Other preventative measures began to take effect in the population in succession—isolation, quarantine, and avoidance of public gatherings all came into play. The exponential growth eventually slowed and began to level off, and with it, demand softened as people sensed (despite the high baseline of disease circulating) that the explosive growth and danger was behind them. It was in this environment that industry participants found their products reaching the market, one with soft demand and relatively low interest but at a volume scaled for the peak. Consequently, as the infection rate began to stabilize and the public's panic subsided, the demand for these products decreased at just the moment a large volume of products hit the shelves, resulting in a missed market window and expiring excess inventory.

In these previous instances, this delayed response resulted in manufacturers being left with large unsold inventories of COVID-19 tests. In one notable case, a major manufacturer opted to destroy a significant volume of rapid antigen tests rather than incur the costs associated with storing them, highlighting the complexities and difficulties of matching manufacturing timelines with the unpredictable dynamics of pandemic-driven demand. See Figure 1 for a visual representation of the demand-production offset. Earlier on, when growth is just starting, public demand and concerns generally stay low yet above production levels, leading to a general sense off scarcity (phase A). As geometric growth accelerates, public concern grows dramatically, demand for testing explodes, and panic buying sets in (phase B). Companies begin to increase production to match demand, but before new production can come to market, positive cases begin to level off, with daily reporting no longer showing geometric increases (phase C). Public concern begins to wane and demand softens drastically just as high-capacity production and distribution comes online, leading to an oversupply in the market and unsold goods (phase D). In response to oversupply, manufacturers begin to contract, including layoffs and liquidation of inventory (phase E).

Figure 1. Relative temporal relationship between changing COVID-19 case count reporting, public demand for testing, and test manufacturers' production in early COVID-19 pandemic waves



Source: Author data.

Limited research and development and medical production in uncertain markets are common, and recently, the development of the AMC—which de-risks production for manufacturers by providing a guaranteed market (purchase) commitment should they proceed with manufacturing and the market prove unsupportive—has functioned as a way to mitigate those limitations. There have been privately funded attempts to use this structure in the past, such as the Gates Foundation's establishment of an AMC for pneumococcal disease in 2007. But no such structure exists within the FAR, and no precedent existed for a federal contract structured to provide that assurance.

Question prompts

- 1. Do any governmental mechanisms or approaches exist to solve this problem?
- 2. What steps or strategies might you suggest at this point?
- 3. Of the strategies you suggest, which one do you think would be the most successful?

What did the US government do?

The solution to the procurement challenge involved crafting an innovative contractual vehicle for the various companies, given that no federal procurement mechanism for an AMC existed that could accelerate the typically lengthy acquisition timelines. The breakthrough came through a government team who navigated the procurement regulation landscape and bureaucratic processes quickly, in collaboration with the Office of Management and Budget (OMB) and the DLA, leveraging unique authorities and emergency powers under various national emergency declarations.

The desired public policy outcome was wider availability of over-the-counter rapid antigen COVID-19 tests at widely accessible retail locations. In order to achieve this, the manufacturing industry needed a way to mitigate the financial risk of bearing the high costs associated with aggressively fast-tracking production scale up and potentially missing the demand peak and being stranded with unsellable goods. A major US government purchase in which the government acquired tests directly would have exacerbated the shortage by buying up available supply and taking that supply out of circulation. This typical response of the government to such a challenge would have worsened the situation. So, the key aspect was structuring the contract to achieve both the traditional procurement goal of acquiring materials and the desired public policy outcome, which was in many ways very different from standard federal awards. Instead of the typical requirement for scheduled delivery of goods, the contract needed to incentivize manufacturers to significantly increase their production capacity for the availability to the general public. The public policy outcome in the short term was not for the US government to immediately acquire tests directly, but rather to ensure their availability to the public without causing market shortages, all the while assuring the manufacturers that there would be a ready buyer when retail demand softened to the point that the tests could be shifted into the strategic national stockpile for future response needs.

This led to the creation of a clever "inverted" indefinite delivery, indefinite quantity (IDIQ)—style contract. A typical IDIQ is used to provide a vehicle for situations in which the government does not necessarily know how much of a thing or service it may need and when it will need it; by contrast, this IDIQ structure required that the total contracted quantity be available for government purchase within a very short timeframe but with a focus on the company prioritizing and fulfilling its retail contracts first and the government withholding its orders until a surplus manufacturing capacity was reached. The US government's orders were deprioritized, allowing companies to sell excess products to the government only after meeting commercial demands. This approach derisked the scaling up of manufacturing and ensured the availability of products for public use without triggering a shortage through government acquisitions.

Process and interactions

The initial step of creating the novel AMC-style procurement action to spur production involved gathering key government players – experts in procurement, contract structure, budging, and public health, identifying major hurdles and leveraging emergency authorities to form a plan of action. The approach involved using FAR Part 6 exemptions for "industrial mobilization" and "urgent and compelling need," coupled with a direct presidential directive, and issuing a wide range of IDIQ contracts to every US supplier who had an FDA-approved rapid antigen test. The language invoking the Defense Production Act was incorporated into a presidential speech, mobilizing the DOD to support industry efforts to manufacture rapid antigen tests. Subsequent interactions involved obtaining approval from the OMB and collaborating with various departments to expedite the process.

The FAR allows for exceptions to normal free and open competition in scenarios that involve an urgent and compelling need related to national security or life and safety. Using these exemptions, especially for urgent industrial mobilization, typically falls outside the standard envisioned use and necessitates a presidential directive to the secretary of defense. This process, as outlined in various DOD procurement manuals, involves a well-established policy procedure that includes obtaining concurrences and preparing memos. However, this method can be time-consuming, potentially taking months to complete all the required paperwork and official routing.

The President invoked the Defense Production Act in a speech on September 9, 2021, mobilizing the industrial sector to produce rapid antigen tests as part of the efforts to combat the pandemic under the public health emergency declaration. This directive necessitated the coordination of several government entities. OMB was pivotal in this process, as it had to approve the transfer of funds from HHS to DLA.

In response to this directive, a collaborative effort ensued involving senior leadership from the OMB, DLA, the Office of the Secretary of Defense, the deputy secretary of defense, and HHS. This collaboration was marked by exceptional speed and efficiency, facilitating the movement of more than a billion dollars. The aim was to issue solicitations promptly and engage directly with procurement officers from the DOD. These officers liaised with test manufacturers to assess their production capacities and establish contracts that would maximize the availability of these crucial tests. The overarching goal was to leverage all available resources to combat the pandemic effectively.

- What were the keys to solving the test procurement challenge? 1.
- 2. Are these keys replicable?
- 3. Was there an overarching goal or outcome that drove decision-making?
- 4. Can you identify a policy philosophy that that shaped the outcome?

Key to solving the problem

The pivotal aspect of success lay in crafting an unconventional procurement deal and leveraging unique exemptions and emergency powers. The collaboration between the government and private sector manufacturers focused on incentivizing rapid production. The awarding of an unusually structured IDIQ contract, coupled with a distinctive ordering mechanism, allowed manufacturers to prioritize commercial contracts, derisking their decisions and encouraging accelerated production for the general public.

Conclusion

This case study illuminates the innovative strategies, collaborative efforts, and regulatory acumen that collectively facilitated the resolution of a critical testing shortage. The successful navigation of these challenges not only underscores the agility required in unprecedented times but also provides valuable insights for future instances in which traditional methods fall short in addressing urgent and complex problems.

Summary exercise: mobilizing industry— navigating uncharted procurement territories

This exercise is designed to facilitate an understanding and awareness of the challenges faced and innovations developed to overcome severe issues in the government's production and procurement of COVID-19 testing kits in 2021. The aim is to guide participants through an exploration of the strengths and limitations present in legal frameworks and doctrinal approaches, as well as to encourage thoughtful discussion on the application of traditional authorities in the case studies. The exercise is also meant to foster an appreciation of how vital coordination across a spectrum of stakeholders—including government entities, the private sector, nongovernmental organizations, and community groups—is for managing emergency resources effectively. A focus is placed on the significance of organizational dynamics and individual collaboration, recognizing their often subtle yet important contributions to the challenges and opportunities in developing innovative and effective strategies. The objective is to equip participants with insights and skills to identify and engage with the critical factors that underpin successful collaboration in future emergency procurement and provision scenarios.

This exercise is designed to facilitate an understanding of the challenges faced and the innovations developed to overcome obstacles in the production and procurement of COVID-19 testing kits in 2021. Using the targeted discussion questions, participants can explore the strengths and limitations present in legal frameworks and doctrinal approaches, as well as analyze the application of traditional authorities in the case study. A key focus is the significance of organizational dynamics and individual collaboration skills in problem resolution and strategy development.

Contextual understanding

- What are the key facts and critical issues presented in this case study?
- What are the main problems or challenges presented in the case? Are there underlying issues that were not widely observed or accounted for?

- What would have been the traditional approaches to solving the key issues, and what
 were the limitations inherent in using existing and practiced approaches and
 authorities?
- What were the interacting influences, environments, conditions, and other complicating factors in existence at the time of this situation?
- What assumptions underlie the actions and decisions made in the case?
- Laws, authorities, plans, and attitudes have changed. How would public health outcomes be achieved in the current regulatory and political climate? How would the particular context of this case from 2021 be different today, if at all?

Decision-making

- What decisions by government and industry were made in this case? Were they effective? Why or why not?
- Can you propose alternative strategies or solutions that might have been more effective?

Perspective analysis

- From whose perspective are we analyzing the case? How might the problem look different from other perspectives?
- What were the perspectives, or biases, of different individuals, entities, and areas of interest or influence that were involved in the decision-making and coordination processes?
- What effects did these differing perspectives have on the ultimate result? How could the situation have played out differently if the influence of the perspectives was "weighted" differently?

Collaboration and coordination

- What interpersonal and organizational contexts were at play in the case?
- What effect did these contexts have on the nature of the problems to be solved and the potential solutions?
- How were barriers and challenges overcome? Are these strategies repeatable or unique to this case?

Ethical considerations

• Were there any ethical dilemmas or considerations in this case? How were they addressed?

Future implications

- What can be learned from this case? How can these lessons be applied in future scenarios?
- What are the potential long-term implications of the actions taken in this case?

Module 4. Case Study B: Operation COVIDTest.gov—Delivering Free Rapid Antigen Tests to Every American Home

This case and the culminating summary exercise examine the innovative government policies and actions that were successful in expanding the availability and provision of free COVID-19 tests with direct delivery to the public. This lesson emphasizes the unprecedented policy challenges, public-private coordination, and massive logistical requirements of the pandemic. The summary exercise brings together the key points and lessons that can be derived from the case in its entirety.

Case abstract: How could the US government physically reach the entire US population with delivery of free at-home rapid COVID-19 tests?

Innovative government policies and actions successfully drove expanded production and availability of over-the-counter rapid COVID-19 tests at retail, but accessibility was still limited and the retail cost of tests presented a barrier for a wide range of the public. To combat the winter surge of early 2022, further limit the spread of disease, and protect lives, additional action was necessary; the government needed to expand availability and use by providing tests free of charge and with direct delivery to the public. Reaching a population of more than 100 million households across a continent and oceans away from sources around the globe again presented unprecedented policy challenges and required both public-private coordination and massive logistical efforts. This case study delves into the challenges, players, initial strategies, and pivotal decisions that shaped "Operation COVIDTest.gov."

Introduction

In December 2021, faced with a surge in COVID-19 cases and a soaring demand for tests that far exceeded both retail supply and existing distribution capacity, the US government embarked on an unprecedented mission: to deliver free rapid antigen tests to every home in America. The President grew increasingly concerned about ensuring access to rapid antigen tests during the winter surge. Efforts had already been made to expand production capacity in collaboration with domestic manufacturers and newly FDA-authorized testing companies. However, despite these efforts, the public demand for tests continued to rise dramatically.

Moreover, the government faced a pressing need for reduced test costs. The first company to market over-the-counter rapid tests set a relatively high price point, roughly \$24 per box of two, and most others followed suit. The retail costs were considered high compared to the production costs, which were estimated at roughly \$5 dollars per test or less, and the costs were a significant barrier for many consumers, especially combined with guidance that necessitated frequent retesting. This pricing strategy raised public concerns over the affordability of the tests that were further compounded by the existing scarcity.

Just before the 2021 holiday season, in order to address the issue of high test prices and limited accessibility, the President directed the development of a program to provide free rapid antigen tests to every American household upon request. The task was monumental: the plan involved creating an online ordering platform capable of massive amounts of traffic; finding and buying billions of tests without affecting the availability or price on the retail market; establishing a logistics system to transport, track, and unpack those billions of tests; and building a fulfilment system to take the orders, repackage products, and deliver to virtually any address in the United States. This undertaking, comparable to reinventing a service similar to Amazon, had to be executed within approximately two weeks to aptly respond to the public health emergency and the looming Omicron surge during the winter holidays.

Question prompts

- What were the major components of the test delivery challenge? 1.
- 2. What was the primary objective or desired outcome?
- 3. What were some initial ideas of how the problem might be solved?

Key players

When the President initially tasked the government with this mission, the composition of the key players was uncertain. Several approaches were considered to execute this ambitious project, including outsourcing it to a third-party logistics organization, contracting it to large online ordering and fulfillment services, or managing it entirely through government agencies. None of the individuals involved had prior experience launching an operation of this magnitude from scratch.

Initial outreach was made to large private-sector organizations specializing in high-volume online fulfillment and ordering. The universal sentiment held by these private-sector entities was that the mission was impossible and unachievable within the specified timelines. In addition, federal procurement law and acquisition rules created significant complications. For instance, if a third-party logistics organization or private-sector online retailer had the capacity for such an operation, it would require an extensive and time-consuming competitive bidding process or the use of emergency authorities for sole sourcing and direct procurement. Unlike the previous emergency procurement strategy in which all potential manufacturers were awarded a contract, sole sourcing on this scale with substantial funds involved would almost certainly lead to protests from competitors and further delay the process, which was not feasible given the urgent timeline.

In light of these challenges, an alternative plan was devised: forming a government-based team. This team, coordinated by the White House COVID-19 Response team, would consist of a partnership between top procurement experts from across the DOD, key logistics and testing experts from the HHS's ASPR, the US Digital Service, and critically, the United States Postal Service (USPS).

- 1. Which players are key to solving the challenge of delivering tests to all US households?
- 2. In retrospect, who could have been included in the situation but was not?
- 3. What are the interests, perspectives, biases, and influences of the players?
- 4. What other interests or perspectives had to be considered? Who is, or should be, ultimately "in charge"?
- 5. Are there other similar or analogous problems that you can think of that would present this interagency, multisectoral dynamic?
- 6. Given what you know now about the challenge and the players involved, how would you go about solving the problem?

Initial strategies

When it became evident that collaborating with a private-sector organization for this mission was not possible, the team had to assemble an ad hoc group of governmental experts and various key agencies that had never collaborated before on such a massive project. The goal was to establish a partnership between the USPS, DOD, and HHS with the objective of locating and acquiring a substantial quantity of rapid antigen tests from new manufacturers and vendors worldwide while preventing shortages elsewhere. These tests were to be transported to strategic logistics points within the United States where they would be unpacked, inventoried, and repackaged. Simultaneously, the team would manage online orders from across the United States, ensuring order accuracy and preventing bulk purchases for resale on the gray or black markets.

Although USPS initially expressed concern about the timelines and scale, it ultimately embraced the mission with enthusiasm and a commitment to public health and safety. The postmaster general personally led the USPS efforts, providing necessary resources, eliminating bureaucratic obstacles, and making the mission a top organizational priority. Initially, the primary goal was to be able to successfully launch the program by the end of the second week of January 2022, although the outcome's success remained uncertain.

- 1. What other strategies could have been considered? What would have been the pros and cons of these alternatives?
- What challenges could have been anticipated with the initial strategy? 2.
- 3. What could be some expected challenges and risks? What are some potential unintended consequences?

Challenges and risks

The challenges and risks of this operation were multifaceted. First, the logistics operation was immensely complex, involving the delivery of tests to anyone in America who desired them. A significant concern was the government's track record of building inefficient online systems for such purposes; the experience of the problematic 2013 HealthCare.gov rollout was fresh in the minds of those involved. In fact, many individuals engaged in the COVID-19 response had participated in the remediation effort to fix HealthCare.gov. Therefore, the pressing question was whether a system capable of handling the anticipated high traffic, potentially reaching hundreds of millions of orders, could be developed in just a couple of weeks.

Another challenge was the policy choice of avoiding the creation of additional shortages at retail by not purchasing vast quantities from existing US manufacturers and essentially depleting the entire production capacity. Although the administration prioritized supporting US manufacturers through executive orders, the sheer volume of rapid antigen tests required to meet public demand for this program necessitated sourcing materials globally. Collaborating closely with HHS agencies, including the FDA and the Testing Diagnostics Work Group, the team reached out to global manufacturers with recent FDA emergency use authorizations for sale in the US.

The team identified sufficient production capacity, primarily through key manufacturers in China who could rapidly scale up their production. Tests were also sourced from US manufacturers and manufacturers in Korea and other parts of the world. Once again, acquisition rules posed challenges under this kind of timeline. To support American manufacturers, US procurement has historically included "Buy American" provisions. Acquiring materials from other countries such as China required special authorization under the federal acquisition rules, known as a "nonavailability waiver." Because of the urgency of the public health emergency, this waiver was granted, enabling procurement of rapid antigen tests from various corners of the globe.

- What were the key concerns with this new strategy? 1.
- 2. What were the costs and benefits of the government implementing this approach rather than the private sector?
- 3. In implementing this strategy, what were the key aspects and challenges?
- 4. What critical logistics challenges did the team face?

Execution and logistics

The success of the operation hinged on several key elements, including global acquisition of tests, navigating transport operations amid global disruptions, efficient acceptance and distribution within the US, creation of a robust logistics network, and repackaging of bulk pallets from manufacturers.

The first critical aspect involved the global acquisition of materials from various sources worldwide. Large-scale buying during a shortage would exacerbate the shortage, and the US government acquiring hundreds of millions of rapid antigen tests from the same manufacturers supplying US healthcare and US retail would have caused a massive shortage of the same devices that they were trying to augment. So, the government needed an alternate strategy in which procurement was limited to FDA-approved tests that were not in wide distribution within the US. Fortunately, a number of such tests were available from companies who were in the process of rapid scale up. US law requires that the government procure items made within the United States whenever possible, and it was an administration policy to use the waivers for that requirement in extremely limited circumstances. The public health emergency was, however, deemed to be such a circumstance, and "non-availability" waivers were issued by the secretary of defense for the DOD (who was using their considerable procurement capability to manage the large-scale acquisition in support of the HHS) to procure tests from South Korea, China, and any other available source with an FDA-approved label.

Second, the operation faced the significant challenge of coordinating transportation and logistics to move these materials from manufacturers across the world amid disruptions caused by shipping challenges and widespread COVID-19 lockdowns in various cities, towns, and countries. Procurement and order tracking was being managed by the Department of the Army; the DLA was tracking the movement. Shipments arrived by sea and air from across the globe.

The third element of this operation was the reception and distribution of the acquired products within the United States. These materials were received at distribution points across the country and subsequently distributed to numerous facilities nationwide. The development of an efficient logistics network was essential to ensure prompt delivery. The objective was to achieve delivery times of two to three days to any location in America through USPS.

The fourth crucial component was the establishment of an effective ordering system to receive and process orders swiftly. In addition, the fifth element, known as "pick and pack," involved the meticulous handling of bulk pallets of materials received from manufacturers. This process included opening, breaking down, counting, and inventorying all products, followed by repackaging them into packs of four and placing them in appropriately sized mailers. Using the orders taken by the USPS's online ordering system, postal service personnel printed labels that were then affixed to these packages, enabling seamless entry into the USPS mail stream for delivery.

The operation faced the monumental task of handling potentially hundreds of millions of deliveries within a short time frame. Even seemingly straightforward challenges, such as procuring a sufficient volume of Tyvek envelopes, required creative solutions. In fact, the operation purchased nearly the entire US supply of envelopes, as well hundreds of millions of self-adhering labels and countless printers to meet its needs.

Fortuitously, USPS had recently expanded its capacity through its annual holiday temporary staffing, which allowed them to retain the extra workforce for an extended period. This additional staffing proved to be indispensable in accomplishing the mission and sustaining it over many months.

As planning continued, operation leaders recognized two facts: the project required expertise in air shipment retail logistics, and the US government lacked internal experience in this area. To address this gap, HHS entered into an interagency personnel agreement with FedEx, borrowing one of their senior global air operations executives, who became an invaluable asset to the operation.

Question prompts

- What other strategies might have been used to overcome the execution and logistics challenges?
- 2. Should the government have charged individual households for these tests? Why or why not?
- 3. Was there an overarching principle guiding critical decisions?

Critical decisions

The decision to build the operational capacity through the collaboration of government agencies rather than contracting with private-sector entities was pivotal. It enabled a more agile response by circumventing lengthy procurement processes. In addition, the acceptance of internationally manufactured tests, which required special authorization, demonstrated flexibility in the face of a public health emergency.

During the creation of the operation, difficult decisions arose from efforts to both adhere to the program's core philosophies and values (simplicity, easy user experience, speed, and equity) and achieve the desired policy outcome: tests in the hands of whoever wanted them to hopefully prevent spread of the disease. When policy choices arose, such as collecting additional demographic information from the ordering form for later analysis or charging some minimal fee, the decision would be guided by those principles. From past experiences, including the rollout of HealthCare.gov, the team knew the process must be kept simple to maintain efficiency and reduce likelihood of failures. The more complicated the ordering interface, the more likely something could break. Charging even a small fee would require a payment process system to be connected. Requesting additional demographic information would require additional database services. When the team created the ordering system, they made it straightforward: a user just needs to include a name and address with no need for any extraneous information. USPS would cross-reference the address with its existing systems to prevent repeat ordering. Although there was discussion about charging a nominal amount to prevent abuse of the system, the idea was quickly dismissed because it would 1) add a layer of complexity and point of failure with processing payments and 2) create an inequitable situation for people lacking credit cards or banking. When tenants of large apartment buildings with shared addresses tried to order and found themselves caught up in the USPS duplication checks during the initial days of ordering, USPS turned the checks off for those addresses to avoid disenfranchising individuals. Although this action theoretically may have allowed some people to order twice, the worst-case outcome would be more tests in circulation, without risk of disenfranchising anyone, so the team decided to prioritize public health and safer health outcomes.

Outcome and effect

To achieve a successful project outcome, the team had to overcome initial challenges and form an unprecedented collaboration between government experts and key agencies. This partnership united USPS, DOD, and HHS in the mission to acquire a significant quantity of rapid antigen tests from global sources without causing shortages elsewhere. These tests were

efficiently transported to designated logistics points within the United States where they were unpacked, inventoried, and repackaged.

Simultaneously, the team implemented an online ordering system that enabled the processing of orders from all across the United States while preventing duplicate orders and unauthorized bulk purchases for resale. After considerable debate, the team decided to use the existing USPS online store system to manage the test orders. USPS information technology leadership set load expectation well beyond what was expected to ensure that the system could hold up. Although that precaution was met with skepticism by some technical managers, the leadership concerns were well founded; users placed more than 60 million orders in the first few days.

Under the leadership of the postmaster general, USPS allocated necessary resources, cleared bureaucratic hurdles, and prioritized the mission's success. The result was the successful execution of the project, with tests delivered and lives potentially saved by the first week of January 2022, marking a remarkable achievement in a challenging endeavor.

Question prompts

- In retrospect, what could have been potential failure points or poor decisions? 1.
- 2. What overarching lessons or key attributes made this strategy and execution successful?
- 3. What innovations and nontraditional approaches were necessary? What conditions might make nontraditional approaches necessary in future events?
- Would this strategy be replicable in the future? 4.

Lessons learned

This case study underscores the importance of flexibility, collaboration, and decisive action in responding to unprecedented challenges. The successful execution of Operation COVIDTest.gov demonstrates the government's capacity to innovate and deliver under extreme constraints, providing valuable lessons for future crisis management. Strict adherence to a set of philosophies and values and a consistent focus on the desired policy outcome can lead to success in the most challenging of situations.

Conclusion

Operation COVIDtest.gov stands as a testament to the resilience and adaptability of government agencies in the face of a public health crisis. The integration of key players,

strategic decision-making, and a commitment to a common goal resulted in the successful delivery of free rapid antigen tests to every American home, shaping a model for effective crisis response.

Summary exercise: Operation COVIDTest.gov—delivering free rapid antigen tests to every American home

This exercise is designed to facilitate awareness and understanding of the challenges the government faced in delivering COVID-19 testing kits in 2021, as well as the innovations developed to overcome them. The goal is to guide participants through an exploration of the strengths and limitations present in legal frameworks and doctrinal approaches, encouraging thoughtful discussion on the application of traditional authorities in the case studies. The exercise also seeks to foster appreciation for the vital role of collaboration across a spectrum of stakeholders—including government entities, the private sector, nongovernmental organizations, and community groups—in managing emergency resources effectively. One key focus is the significance of organizational dynamics and individual collaboration skills, recognizing their often subtle yet substantial contribution to the challenges and opportunities inherent in developing innovative and effective strategies. The objective is to equip participants to identify and engage with the critical factors that underpin successful collaboration in future emergency procurement and provision scenarios.

This exercise is designed to facilitate an understanding of the challenges faced in delivering COVID-19 testing kits in 2021 and the innovations developed to overcome those challenges. Using this series of targeted discussion questions, this exercise explores the strengths and limitations present in legal frameworks and doctrinal approaches, as well as the application of traditional authorities in the case study. A key focus is the significance of organizational dynamics and individual collaboration skills in problem resolution and strategy development.

Contextual understanding

- What are the key facts and critical issues presented in this case study?
- What are the main problems or challenges presented in the case? Are there underlying issues that were not widely observed or accounted for?
- What would have been traditional approaches to solving the key issues, and what were the limitations to using existing and practiced approaches and authorities?
- What influences, environments, conditions, and other complicating factors interacted during the time of this situation?
- What assumptions underlie the government's actions and decisions made in the case?
- How would the particular context of this case from 2021 be different today, if at all?

Decision-making:

- What major decisions were made in this case? Was a strictly government operation the right choice? Was making them free the right choice? What else? Were they effective? Why or why not?
- Can you propose alternative strategies or solutions that might have been more effective?

Perspective analysis:

- From whose perspective are we analyzing the case? How might the problem look different from other perspectives?
- What were the perspectives (or biases), areas of interest, and influences of different individuals and entities that were involved in the decision-making and coordination processes? Did these perspectives come from public health officials, White House staff, members of Congress, HHS employees, or procurement officials?
- How did these differing perspectives affect the ultimate result? How could the situation have played out differently if the influence of the perspectives was "weighted" differently?

Collaboration and coordination:

- What might be the interpersonal and organizational contexts at play in the case?
- How did these contexts affect the problems to be solved and the potential solutions?
- How were barriers and challenges overcome? Are these strategies repeatable or unique to this case?

Ethical considerations:

• Were there any ethical dilemmas or considerations in this case? How were they addressed?

Future implications:

- How can the lessons from this case be applied in future scenarios?
- What are some potential long-term implications of the actions taken in this case?

Module 5. Analysis and Integration **Exercise**

This final exercise is designed to contrast lessons learned from each of the two cases previously examined, acknowledging their different context, players, challenges, and solution sets. It is intended to further ingrain understanding of the challenges the government faced in delivering COVID-19 testing kits in 2021 and extract key lessons from the innovations developed to overcome them. The objective is to equip participants to identify and engage with the critical factors that underpin successful collaboration in future emergency procurement and provision scenarios.

This final exercise is designed to contrast lessons learned from each of the two cases, acknowledging their different context, players, challenges, and solution sets. Through this set of targeted questions, participants can identify and engage with the critical factors that underpin successful collaboration in future emergency procurement and provision scenarios.

Comparative analysis

- What are the similarities and contrasts between the two cases in terms of context, approaches, influencers, and solution sets?
- What specific strategies and approaches were employed in each case study? How did the strategies differ between the two cases, and what were the reasons for these differences?
- Who were the key stakeholders involved in each case, and what roles did they play? How did the level and type of stakeholder collaboration and coordination compare between the two cases?
- What were the main challenges encountered in each case, and how were they addressed?
- What were the notable successes in each case, and what factors contributed to these successes?

• What were the short-term and long-term outcomes of each case? How do the different approaches of these cases compare in terms of effectiveness and efficiency?

Synthesis of findings

• Discuss how these case studies could exemplify the integration of differing approaches, drawing lessons and smart practices from each as well as novel possibilities from their combination.

Implications for policy and practice

• Discuss how the insights from these cases can inform future strategies and policies.

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