Operation Warp Speed and the Countermeasures Acceleration Group—A Twenty-first Century Manhattan Project

Preliminary Observations on the U.S. Department of Defense's Role in the Supply, Production, and Distribution of COVID-19 Vaccines and Therapeutics

John E. Hall, SES; Lieutenant Colonel Nate Packard; and the Countermeasures Acceleration Group (CAG) Team

Abstract: On 15 May 2020, Operation Warp Speed, later renamed the HHS-DOD COVID-19 Countermeasures Acceleration Group (CAG), was a collaboration between the Department of Health and Human Services, the Department of Defense (DOD), and the private sector to accelerate development, production, and distribution of effective vaccines and therapeutics to counter COVID-19 for the American people. The CAG was the nucleus of the "whole-of-America" effort to defeat COVID-19, and DOD's contribution was essential to the success of the CAG. This article highlights the contributions made by DOD, with a focus on innovative solutions and best practices that might apply to other DOD activities.
Keywords: pandemic response, Operation Warp Speed, Countermeasures Acceleration Group, CAG, COVID-19

> Operation Warp Speed was a bright spot: one of the greatest public health achievements in modern times. . . . The success of Operation Warp Speed proved what government can accomplish when it functions well, to improve our preparedness and protect the Nation.[1]
>
> ~ Dr. Scott Gottlieb,
> former Food and Drug Administration commissioner

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Introduction

The coronavirus disease of 2019 (commonly known as COVID-19 or SARS-CoV-2) pandemic, declared a national emergency on 13 March 2020, was the greatest threat the United States has faced since World War II. The country reported nearly 80 million confirmed cases and more than 950,000 deaths as of 3 March 2022.[2] Officially announced by the Donald J. Trump administration on 15 May 2020, Operation Warp Speed (OWS), subsequently renamed the Health and Human Services (HHS)-DOD COVID-19 Countermeasures Acceleration Group (CAG) by President Joseph R. Biden Jr.'s administration, was a collaboration between the Department of Health and Human Services (HHS), the DOD, and the private sector to accelerate development, production, and distribution of effective vaccines and therapeutics to counter COVID-19 for the American people.[3] The CAG was instrumental in vaccine development and a vaccination program of historic proportions. DOD's contribution of manpower and logistics expertise was essential to its success. By mid-2021, the CAG accomplished its mission of delivering enough safe and effective vaccines to vaccinate every American. The CAG was dissolved on 31 December 2021, per its memorandum of understanding (MOU). The HHS Coordination Operations and Response Element (HCORE) assumed responsibility for all functions performed by the CAG.

The CAG was the nucleus of the "whole-of-America" effort to defeat COVID-19. It arrived at several hard-earned innovative solutions and best practices in that capacity. COVID-19 proved to be an elusive adversary, as evidenced by the rapid spread of the Delta and Omicron variants. The CAG had to be just as adaptive in meeting the challenge, thus providing a case study of rapid organizational adaptation in a crisis. Furthermore, the CAG represents one of the few bright spots in what many would agree has been one of the great tragedies in American history.[4] With nearly a million American lives lost and countless disrupted to varying degrees, the United States must learn and apply lessons learned from the experience.

This article is not intended to be a definitive account of the CAG's activities. Instead, it is an effort to provide an overview of the CAG's activities and share observations made by those DOD members directly involved in the operation. The intent is to highlight best practices applicable to other DOD endeavors. To paraphrase the CAG's director of COVID-19 vaccine development, a retired Army colonel and infectious disease specialist, it would be a shame if the United States did not learn from an effort of historic importance.[5] This article is a first step toward what the authors hope will be a more comprehensive effort to understand and learn from the CAG experience.

Two caveats are in order. First, the authors' focus on DOD is in no way intended to diminish the contributions of other institutions. The success of the vaccine program would not have been possible without the contributions of all stakeholders. The authors focused on DOD because that is what they know best. Again, the authors hope that this effort will be followed by a comprehen-

sive effort to better understand the CAG in its entirety. Second, the CAG was not resource constrained. The White House and Congress put its full weight behind the effort because of the scale of the crisis. Some of the best practices described below were only possible because the nation was responding to a national emergency and may not be feasible when conducting steady-state operations. Caveats aside, the CAG's successes show that the U.S. government—and America as a whole—can still accomplish big things.

OWS/CAG Timeline

13 March 2020	Declaration of national emergency concerning COVID-19
15 May 2020	Formation of Operation Warp Speed
5 June 2020	MOU signed by the secretary of HHS and secretary of defense to expedite vaccines to 300 million Americans
July 2020	Large-scale efficacy trials begin
11 December 2020*	First vaccine receives emergency use authorization (EUA)
24 February 2021	National emergency declaration extended for one year
1 May 2021	OWS was renamed the HHS-DOD COVID-19 Countermeasures Acceleration Group (CAG); new MOU takes effect
10 May 2021*	First vaccine receives EUA for adolescents (ages 12–15)
September 2021*	CAG assigned mission of managing distribution of therapeutics
1 November 2021*	EUA issued for pediatrics (ages 5–11)
19 November 2021*	Booster dose authorized for all vaccinated individuals 18 and older
31 December 2021	CAG dissolved, and mission transitioned to the HHS Coordination Operations and Response Element (HCORE)

*The issuance of each EUA and the assumption of the therapeutics mission involved planning and executing the production, delivery, and administration of tens of millions of doses to tens of thousands of individual locations.

Measures of Effectiveness

The most important factor in assessing a military organization is whether it accomplished its assigned mission. The CAG's initial objective was to deliver 300 million vaccine regimens, enough to vaccinate every American. Critical tasks included: (1) contracting at risk for large-scale production of vaccines across

a diversified vaccine portfolio; (2) leading the public-private partnerships necessary for rapid vaccine development; (3) assembling ancillary kits to support vaccine administration; (4) establishing logistics relationships and distributing doses; (5) assuring security of the domestic COVID-19 countermeasure production ecosystem; (6) developing an IT architecture for vaccine allocation, distribution, and administration; and (7) supporting public confidence in the national distribution of COVID-19 vaccines.

In a little more than a year, the CAG accomplished its mission of delivering enough safe and effective vaccines to vaccinate every American. Furthermore, as one expert observed, "Delivering a vaccine in a year or less was perhaps the most challenging task in the pandemic response."[6] The rapid development of multiple safe and effective vaccines was one of the few bright spots in what many would agree had been one of the great tragedies in American history.[7] The CAG's achievements were some of the biggest successes of both the Trump and Biden administrations, one of the only topics on which the two gentlemen agree.[8]

Leveraging DOD and HHS expertise, the CAG and supporting Army acquisition professionals used a variety of DOD acquisition authorities to rapidly bring six vaccine candidates to clinical trials and begin large-scale production. The CAG delivered the first Food and Drug Administration (FDA) authorized vaccine in December 2020, less than seven months after forming. During the following year, the CAG delivered seven years' worth of vaccines to the American people and 150 million excess domestic vaccine doses to 101 nations, a vaccine effort of unprecedented speed and scale.[9]

Metrics

- 1.6 billion doses procured
- 582 million doses delivered domestically; 150 million internationally
- Distribution to more than 91,000 sites
- 86 percent of 18+ population received one shot; 207 million Americans fully vaccinated
- 87 percent of ≥65 population, the most vulnerable demographic, fully vaccinated
- 75 million booster doses administered
- 7 million pediatric (ages 5–11) doses administered between 1 November and December 2021
- Managed allocation and ordering of 3.9 million courses of monoclonal antibodies[10]

At the time that the CAG was dissolved, the entire U.S. resident population had available and equitable access to a COVID-19 vaccine. The COVID-19 domestic countermeasures production ecosystem was more robust and secure; vaccine waste had been minimized; an IT architecture that provided data on

allocations, distribution, and administration was in place; and booster, adolescent, and pediatric vaccine campaigns were ongoing.

Most importantly, the vaccines and therapeutics produced and delivered by the CAG averted an estimated 1.1 million additional COVID-19 deaths and more than 10.3 million additional COVID-19 hospitalizations in the United States as of November 2021.[11] This achievement supported and nested with the recovery outlined in the *National Strategy for COVID-19 Response and Pandemic Preparedness* (January 2021).[12] The CAG's efforts arguably saved more American lives than any other DOD effort in U.S. history.

Observations of Interest

A "Whole-of-America" Approach

No single government or private organization had the capacity, capability, or expertise for this mission. No playbook or standard operating procedures existed to do so during a global health pandemic. The shortest timeline to bring a vaccine to market prior to the COVID-19 pandemic was the mumps vaccine, which took more than four years, and the U.S. government's annual vaccine distribution effort—known as Vaccines for Children—typically distributes 80 million vaccines in a year, in much lower quantities and longer timelines than required for this mission.[13]

As the nucleus of the federal COVID-19 response, the CAG leveraged existing networks, processes, and partnerships and maximized the use of existing pharmaceutical production, distribution, and administration infrastructure. HHS and DOD CAG leaders built the unit to be truly interagency, incorporating a more whole-of-government approach. Key partners included HHS, the Departments of Commerce, Justice, Homeland Security, and State; vaccine and therapeutic producers Sanofi, Moderna, Janssen, Novavax, Pfizer, AstraZeneca, and Merck; and distributors CVS, FedEx, UPS, AmerisourceBergen, and McKesson. CAG leadership ensured unity of effort through interagency collaboration, communication, and integration.

The DOD was uniquely positioned to serve as the integrator at scale in a crisis, with the tools, staffing, and experience necessary to coordinate multiple disparate entities at the national level during crisis. Two organizations within the CAG—the Vaccine and Therapeutics Operations Center (VTOC) and the Vaccine Coordination Center (VCC)—served to synchronize efforts across the enterprise. The VTOC was the center of gravity of the CAG. Staffed and managed by uniformed CAG members along with representatives from every interagency and industry partner, it brought all stakeholders together to ensure real-time information sharing and a common understanding of the operation. The VTOC held a meeting every morning, referred to as the daily stand-up, in which all parties, including every jurisdiction, had the opportunity to speak to each other and to senior leaders within the CAG. In so doing, it integrated, coordinated, and synchronized the movement of domestic vaccines and eventually therapeutics across the country daily.

For its part, the VCC was how the CAG coordinated at the jurisdictional and regional levels. Working closely with the CDC, the VCC ensured that stakeholders at the local level had the information they needed to order and receive vaccine shipments.

Leadership/Personnel

DOD senior leaders, as well as acquisition, logistics, medical, strategic planning, legal, and security personnel, both uniformed and civilian, played a central role in the success of the CAG. Throughout, DOD provided high-quality, technically proficient personnel capable of building and leading teams. Agility was essential. Over time, the original mission evolved to include booster and pediatric campaigns, global donation of vaccine doses, and the distribution of therapeutics. Military officers proved particularly well-suited to operating in a fluid environment.

Leaders designed the CAG to be fast and flat without a formal, linear staffing process. Collaborative decisions were made on the spot based on input from all stakeholders. The CAG overcommunicated and overshared. Leaders instilled a crisis mindset and a sense of urgency. CAG leadership had both decision-making authority and, for more senior-level decisions, could access senior leaders at the touch of a phone.

Leadership also insisted that everything be auditable and pass the test of public scrutiny. CAG personnel provided unredacted copies of all contracts related to COVID-19 vaccines and therapeutics to the Government Accountability Office (GAO) and congressional committees as requested. The CAG also proactively worked with contractors to release minimally redacted copies of contracts to the public while protecting proprietary information and trade secrets to preempt numerous Freedom of Information Act (FOIA) requests. This process allowed most high-value contracts to be publicly posted online, which enhanced transparency and public support and confidence in America's COVID-19 response.[14]

The CAG was committed to accountability and transparency, providing regular updates to Congress, GAO, and the media. The CAG responded to hundreds of requests for information from various Senate, House, and state offices. CAG pursued an aggressive campaign participating in bicameral and bipartisan information sharing activities, working together with the White House legislative and external engagements team, and participating in more than 100 state and regional touchpoint sessions providing real-time sensitive information. In addition to GAO, congressional, and media engagements, CAG leaders supported and participated in more than 50 external affairs engagements with civic, academic, business, and industry organizations.[15] These engagements not only represented a commitment to transparency but directly led to improved vaccine confidence in the American people.

Vaccine Development

The Vaccine Development Team, led by a DOD civilian and augmented by five DOD program managers, rapidly and innovatively selected vaccine candidates for federal support based on four established criteria determined in coordination with the scientific and pharmaceutical community. The team researched, funded, and supported candidates within four vaccine-platform technologies expected to most likely yield a safe and effective COVID-19 vaccine: the mRNA platform, the replication-defective live-vector platform, the recombinant-subunit-adjuvanted protein platform, and the attenuated replicating live-vector platform. This approach mitigated the risk of mission failure and yielded the largest number of effective doses possible.

Once federally supported candidates were identified, CAG coordinated funding and led the most aggressive clinical trials in history, governed by the highest ethical standards for science and safety. CAG leveraged the Logistics Civil Augmentation Program contract to support clinical trial site setup at 61 locations, preparing for all phases of trials simultaneously, which allowed companies to move seamlessly through the phases with little or no additional waiting time. The operation also harmonized and increased the size of Phase 3 clinical trials to more than 30,000 people each to speed efficacy. Overall, across five Phase 3 trials, more than 160,000 volunteers were enrolled, yielding immense amounts of data to prove safety and efficacy across diverse populations.[16]

CAG leaders and team members maintained daily contact and coordination with six federally supported vaccine candidates, closely monitoring progress and enabling rapid issue escalation and resolution. OWS team members also coordinated and collaborated across the government with the FDA, National Institutes of Health (NIH), National Institute of Allergy and Infectious Disease (NIAID), Centers for Disease Control and Prevention (CDC), and multiple professional scientific and medical associations. In less than nine months, the team's efforts resulted in three vaccines receiving FDA EUA, two candidates nearing completion of Phase 3 clinical trials, and the final candidate progressing through Phase 2/3 trials. The idea of having a single vaccine developed by the end of 2020 was initially viewed with great skepticism. As of 31 December 2021, the CAG had generated two vaccines approved for emergency use by the FDA and a third with full approval. The three remaining vaccine candidates continued development for potential use as boosters, vaccines for children, and international donations.

Additionally, DOD logistics and engineering capabilities were employed to scale up the clinical trials' size and accelerate the process. The CAG leveraged the U.S. Army Corps of Engineers (USACE) for support on construction activities, designed to increase the industry base expansion activities, valued at $1.2 billion, throughout the COVID-19 vaccine supply chain. USACE's support included a wide range of services such as working with the local government to expedite permits, providing recommendations on condensing manufacturing's construction schedule, and directly providing project management advice with

our industry partners. This effort reduced multiple construction schedules by months while allowing CAG to remain on schedule to meet its vaccine production goals. USACE supported the manufacturing expansion efforts for six technology investment agreements by providing expert engineering, scheduling, and program management advice. In addition, USACE provides an additional layer of governmental oversight on other construction efforts.

Therapeutics Development

The CAG's Therapeutics Team pursued a two-pronged strategy, focusing on therapeutic candidates to attack the virus and manage complications. The CAG therapeutics development team rapidly advanced with DOD leaders who provided structure, aligned the team's goals, and instituted a battle rhythm for progression and distribution of COVID-19 treatments.

The therapeutics team streamlined efforts within 12 manufacturers and multiple government agency stakeholders to assess more than 50 potential drug compounds. To date, these public-private partnerships resulted in three EUAs for monoclonal antibody treatments, which have demonstrated a decrease in the risk of hospitalization by 70 percent in high-risk patients. In concert with these intra-agency teams, the CAG has delivered more than 2.52 million monoclonal antibodies, resulting in more than 1.32 million patient courses used during the past six months. In addition to partnering with pharmaceutical manufacturers, DOD leaders successfully accelerated COVID-19 convalescent plasma collection and distribution efforts to treat hospitalized patients. The CAG distributed nearly 600,000 units, reducing the severity and shortening the length of the COVID-19 illness in more than 400,000 hospitalized patients throughout the country, preventing an estimated 20,000 intensive care unit (ICU) admissions and cost avoidance of up to $2 billion in nationwide acute care. Based on results from ongoing clinical trials, 12 additional candidates, including small molecule antivirals, immune modulators, and additional monoclonal antibodies, have demonstrated potential for EUA submissions as early as the first quarter of fiscal year (FY) 2021. Subsequently, CAG team members also led outreach efforts with the White House Health Equities Initiative by incorporating capabilities for 63 monoclonal antibody infusion sites with 19,853 therapeutic patient courses delivered to underserved and underprivileged communities.[17]

Therapeutics efforts resulted in contracting actions valued at more than $10 billion, covering product development, research, and manufacturing costs resulting in more than 3.3 million courses of therapeutics secured by the U.S. government on EUA for distribution to the American public at no cost.[18]

Supply Chain Management, Production, and Distribution

DOD personnel in the CAG provided leadership and coordination throughout the COVID-19 medical counter measures (MCM) supply chain from development to final distribution. This logistics expertise allowed for (1) proactively identifying and solving production bottlenecks and delays, (2) the pivoting of

existing, proven technologies to expedite the availability of MCMs, (3) the establishment and scaling of domestic-based manufacturing capabilities, (4) the minimization of risk through advanced purchase agreements, and (5) the creation of a flexible distribution model that is scalable for future needs. Supply chain experts and analysis were used to determine when to use the Defense Production Act (DPA) or other measures to relieve anticipated shortages and bottlenecks without adversely impacting other areas.

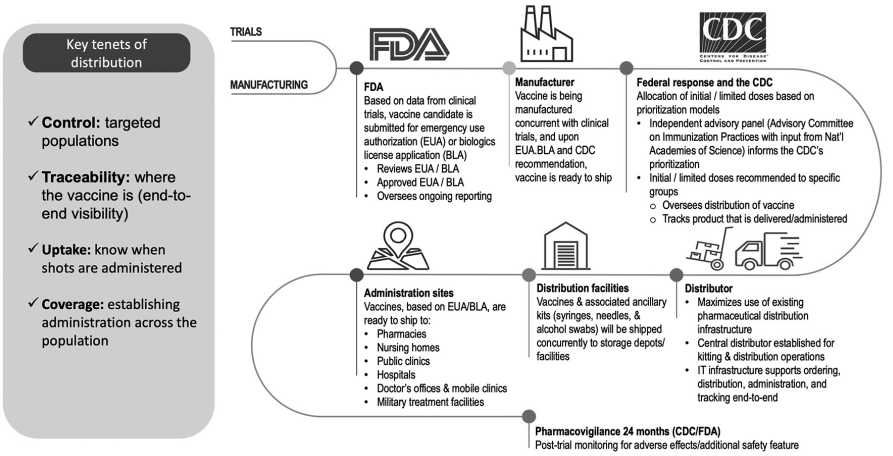
The supply chain management team provided oversight of vaccine manufacturing and enforced the DPA initiative for the critical supply chains across the U.S. pharmaceutical industrial base. Six experienced military logisticians were strategically embedded at key points within the vaccine manufacturing and supply chains to expedite key supplies and to enable rapid identification and resolution of supply chain challenges before they impacted the mission. Strategic placement of these military officers was critical to ensuring an unprecedented level of coordination of common supply chain resources across more than 90 sources of supply for six vaccine and three therapeutic manufacturers, ensuring all demands were met.

To protect U.S. interests and enable rapid development and manufacture of vaccines, diagnostics, and therapeutics, the CAG initiated an effort to apply DPA priority ratings to key contracts and secure the supply chain. Initial efforts focused on enabling manufacturing capacity expansion efforts using DPA authorities. The CAG coordinated the priorities and allocations authority of the DPA through the Department of Commerce. The CAG-led manufacturing efforts resulted in the successful and rapid development of a U.S.-based network that can produce more than 1 billion doses of vaccine per year once a steady state is achieved, a significant increase to national capacity.

Additionally, the CAG initiated a planning cell with CDC and the Strategic National Stockpile (SNS) to design, assemble, and supply ancillary kits that contained all supplies necessary to administer vaccines, funded by the U.S. government. As part of that effort, the team identified the need to gain additional access to needles and syringes to administer primary series, booster, and pediatric vaccine doses. In partnership with SNS, the CAG awarded contracts to procure and deliver critical components such as alcohol swabs, face masks, and vaccination cards to support 1.15 billion vaccinations and ancillaries. Contracts were also executed with distribution partners enabling the assembly and distribution of the kits to thousands of administration sites worldwide. More than 6 million kits were built and distributed with zero failed deliveries.[19]

One best practice was the "personnel-in-plant" (PIPs) initiative. PIPs were military officers embedded with industry partners at their manufacturing locations across the country. They worked with manufacturing leadership to manage progress and work through problems when they occurred. PIPs supported all equipment deliveries to all supply nodes throughout the supply chain. They maintained communication with all necessary raw materials, consumables, and equipment suppliers. Additionally, they coordinated, monitored, and partici-

Figure 1. Key tenets of distribution



Source: CAG Group.

pated in manufacturing productivity studies. PIPs analyzed the impact on delayed supplies and equipment and provided recommended courses of action.

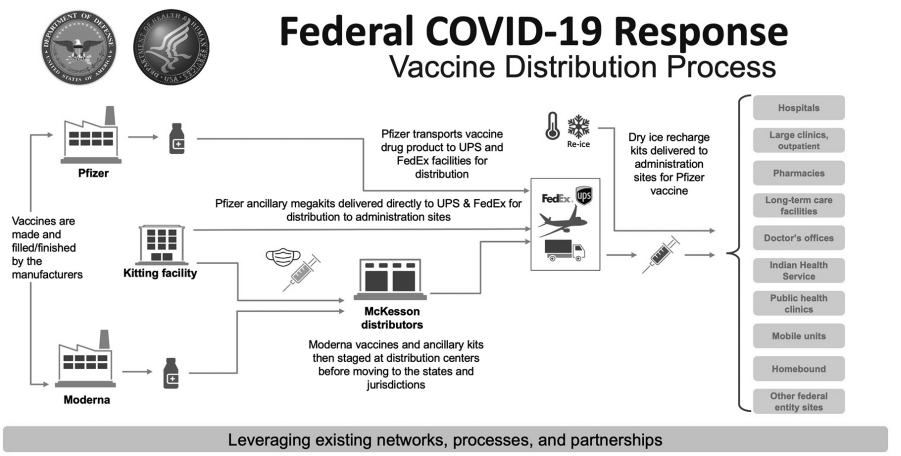
Ultimately, the development and protection of supply chains is a top national security concern. DOD could leverage CAG lessons learned for the Defense Production Act and supply chain management to improve military readiness. From a logistics perspective, the techniques outlined here could be of great importance in force modernization and in increasing wartime production.

Information Technology and Data Analytics

Accurate data was foundational to the success of the CAG. No single federal data system existed to manage and track vaccine distribution across 64 jurisdictions. OWS led information technology collaboration with five U.S. government agencies, academia, and more than 50 industry partners to construct a comprehensive architecture of IT systems capable of supporting the distribution and administration of COVID-19 vaccines. The efforts resulted in an unprecedented IT system architecture comprised of more than 110 system-to-system interconnections or data exchange mechanisms, made operational in under seven months. The IT architecture served as the backbone of OWS's nationwide operations, hosting the authoritative databases, processing orders for millions of doses per day, and tracking shipping and inventory information from the manufacturers to the point of vaccine administration.

OWS also led the nation through the most unique and challenging component of the IT architecture—the data platform systems, data exchange arrangements, and data reporting specification developed to support the receipt, safe storage, visualization, and analytics of critical vaccine administration data. Never in U.S. history had data systems and agreements been established to

Figure 2. COVID-19 response and vaccine distribution process



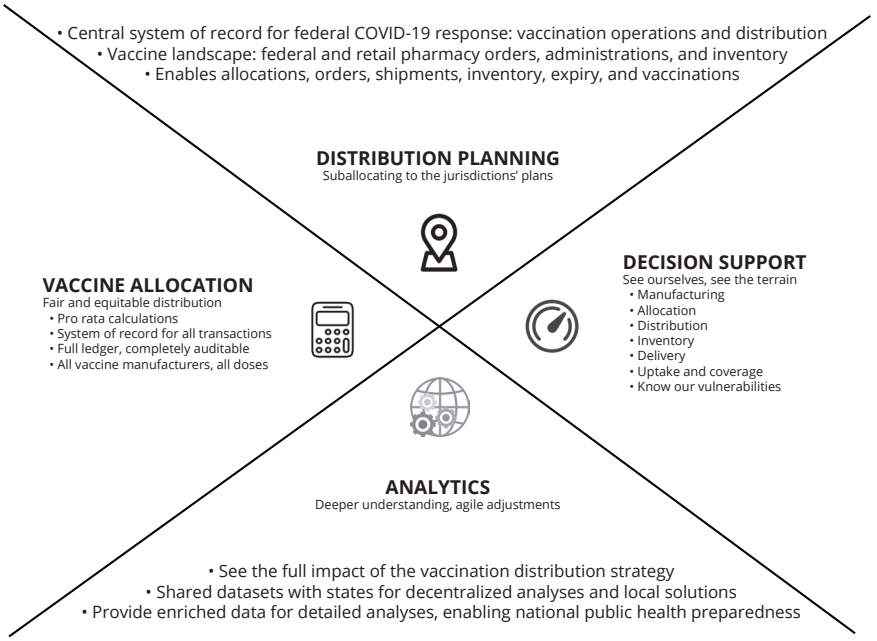
Source: CAG Group.

receive daily vaccination administration data from providers across the nation. By mid-February 2021, more than 90 awardees were reporting a daily average of 1.5 million vaccination records to the federal data systems, with vaccination records averaging less than 60 hours from administration to reporting, all while safeguarding personal health information through encryption and anonymizing data links.

Recognizing the need for a single system to integrate and synthesize information from many disparate lines of effort, the CAG leveraged DOD and HHS IT capabilities to build Tiberius, the national IT architecture that ensured responsive distribution of all COVID-19 medical countermeasures. Tiberius is an end-to-end data management, visualization, and analytical platform that facilitates a common operating picture across clinical trials, manufacturing, kitting, allocations, jurisdictional microplanning, distribution, inventory, and vaccine administration. DOD and HHS analysts used Tiberius to integrate, synthesize, and analyze large amounts of data supporting senior-leader decision making in rapidly evolving situations. The system employed scientific and mathematical problem-solving methods to generate and evaluate alternatives over the range of the enterprise. Neither Tiberius nor a similar capability existed in May 2020. The data analytics team used Tiberius to facilitate shared understanding and a common operating picture; it enabled the CAG and all entities involved in the process to "see ourselves" in the words of Army general Gustave F. Perna, the chief operating officer from May 2020 through June 2021.[20]

Cutting-edge data analytics drove planning and operations. Of note, agile product development was the key to the success of the data analytics effort. Agile practices included requirements discovery and solutions improvement through the collaborative effort of cross-functional teams of developers and key stakeholders; adaptive planning, evolutionary development, early delivery, and

Figure 3. Analytics and Tiberius scope and overview



Source: CAG Group.

continual improvement; and flexible responses to changes in requirements, capacity, and understanding of the problems to be solved. Leaders needed accurate and timely information of the entire supply, production, and distribution network to make sound decisions.

Security and Assurance

Open-source research has exposed Chinese and Russian targeting of biotechnology research.[21] Leadership was also concerned about criminal activities targeting the vaccine effort. DOD personnel and authorities were critical in ensuring the cybersecurity and industrial security of the operation. The CAG Security and Assurance Directorate (S&A) actively synchronized multiple interagency partners, including the Federal Bureau of Investigation (FBI), U.S. Marshal Service, Cybersecurity and Infrastructure Security Agency from the Department of Homeland Security, Defense Counterintelligence and Security Agency, as well as strategic elements of the intelligence community to secure the integrity of the federal COVID-19 response mission and key aspects of the U.S. bioeconomy.

Led by an Army brigadier general, the S&A team's dynamic and persistent efforts effectively integrated several exquisite tools and capabilities of the interagency and intelligence community, ensuring protection against state and nonstate actor attempts aimed at stealing or disrupting CAG procedures. For example, the S&A team coordinated the efforts of U.S. Marshals charged with executing more than 400 armed escort security missions, traversing all U.S.

states and jurisdictions with zero losses or disruption to vaccine distribution. S&A expanded the vaccine transportation security mission beyond domestic distribution to include protection of White House prioritized international donations. U.S. Marshals escorted more than 114 million doses of lifesaving vaccine for more than 85 recipient nations in support of international donations.[22] The S&A team also developed and implemented a unique effort to safeguard all EUA data via armed federal agents physically escorting encrypted hard drives in lieu of the previous standard electronic submission. This novel methodology ensured the uncompromised integrity and timely delivery of manufacturer documents to the FDA without risk of data interception, theft, or corruption.

DOD provided technical assistance and advice to all partners in biosecurity, and the CAG made a great deal of progress securing the U.S. bioeconomy. Defense Counterintelligence and Security Agency, industrial security representatives (ISRs) continued expanding S&A's teach-coach-mentor partnership with industry. Since 15 May 2021, ISRs completed 20 site visits throughout the United States, affecting lasting change in the security culture of critical partners. ISR site visits emphasized supply chain risk management: physical, operational, informational, personnel, and cyber security. As required, ISRs integrated interagency partners and counterintelligence assets into site visits to offer holistic security training and support to a critical segment of the U.S. bioeconomy.[23] At present, DOD may be the only entity with capabilities and authorities sufficient to protect the U.S. bioeconomy and protect critical intellectual property and infrastructure from foreign threats. While the bioeconomy and supply chains are primarily nongovernmental, there are significant national security implications.

Interagency Assisted Acquisition and Dedicated Legal Support

The CAG coordinated the award and administration of contracts and agreements worth more than $46 billion for vaccines, therapeutics, diagnostics, ancillary enablers (needles, syringes, fill/finish, swabs, etc.), distribution of countermeasures, program support, and other activities (including industrial expansion) to support numerous aspects of the aforementioned areas.[24] The contracting offices worked closely with the interagency, leveraging HHS-allocated Coronavirus Aid, Relief, and Economic Security (CARES) Act funds to award contracting actions.[25] CAG personnel ensured that the American taxpayer received the best value and most effective use of their funds by ensuring strict compliance with federal acquisition authorities and that rigorous contract negotiations were conducted by a premier team of DOD professionals. This strict compliance led to such faultless procurements that not a single GAO protest was filed against a CAG contract. Moreover, this strict compliance did not detract from the speed of the acquisition work, as these actions were awarded in a fraction of the time which would have typically been allotted for traditional acquisitions.

The DOD acquisition workforce, specifically the Joint Program Exec-

utive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and Army Contracting Command (ACC), executed the contracts for the vaccines developed by the CAG. The DOD contracting offices exercised historic speed while maintaining quality and thorough oversight. Each contract withstood scrutiny from media, Congress, and public interest groups. The OWS team within the JPEO-CBRND received the 2021 Defense Acquisition Workforce Packard Award for the importance, quality, and volume of the acquisition work performed in support of the CAG mission and innovation in acquisition strategy.

The acquisitions team leveraged two innovative acquisition approaches. The first, other transactional authorities (OTAs), are flexible agreements used in a range of research and prototype activities. OTAs allow DOD the flexibility to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments. The second, technology investment agreements (TIAs) (32 CFR Part 17), enabled DOD to partner with nontraditional suppliers to invest in mission-relevant research and development projects, offer greater contracting flexibilities relative to the federal acquisition regulation (e.g., intellectual property rights and accounting), and allowed DOD a more involved program management role.

Another reason the acquisition process moved so expeditiously was because legal counsel was proactively embedded throughout the process, identifying and mitigating legal hurdles and thereby significantly reducing the time needed to execute contracting actions. CAG leadership identified senior counsel and a dedicated legal cell as a critical enabler of success. Based on the high dollar value of CAG contracts, unprecedented engagement with industry, interagency collaboration, flat and fast decision making, use of novel or seldom-used authorities, congressional oversight, and media and public interest, ubiquitous legal support was essential to proactively identifying and mitigating various risks for leadership.

Early staffing of CAG attorneys allowed the CAG legal team to locate and shape governing authorities. The CAG assigned dedicated legal counsel to key personnel, such as the director of S&A, to attend all meetings with industry, oversee acquisition efforts, ensure protection of procurement sensitive or proprietary information and ensure various agencies collaborating on security matters understood and did not exceed their unique agency intelligence authorities. Additionally, CAG legal counsel closely and proactively coordinated legal advice with DOD and HHS Offices of the General Counsel and other agencies as required to ensure consistent legal counsel was provided to interagency clients. Similarly, the senior counsel established direct relationships with industry general counsel to resolve disputes or misunderstandings quickly.

CAG legal counsel also provided two other important functions. First, they worked closely with CAG, OSD, and HHS legislative liaison and public affairs staff to ensure myriad responses to Congress and media were legally unobjectionable, accurate, and consistent with various laws and regulations. Second,

the senior counsel served as the CAG ethics counselor to help create and manage a comprehensive ethics program including financial disclosure, training, documentation, and close monitoring of policies and staff actions to avoid unlawful conflicts of interest. The importance of embedded legal counsel cannot be overstated. Having legal counsel readily available to all CAG members dramatically reduces the time associated with the legal review of contracting and other key functions.

Strategic Communications and the Information Environment

Although not a DOD responsibility in this case, the CAG and the federal COVID-19 pandemic response in general highlighted the importance of strategic communications and the degree to which the information environment impacts everything DOD does. Early in the operation, public relations, strategic communications, and information operations personnel were not deemed critical and were not assigned to the team. However, it became apparent that such personnel were required to maintain situational awareness about the media landscape, handle public announcements impacting CAG activities, and to maintain confidence in the CAG's ability to deliver safe and effective vaccines and therapeutics to the American public.

In General Perna's view, "Our communication strategy was ineffective, and it was poorly executed strategically, operationally and tactically."[26] For example, the CAG did not expect that vaccine roll out during a pandemic would be a political issue—the planning assumption was that public health was apolitical. Also, the speed of the vaccine roll out, rather than being viewed as an achievement to be celebrated, contributed to vaccine hesitance in some cases. In both examples, the CAG's ability to accomplish its objectives were negatively impacted by its inability to foresee and mitigate potential risks in the information space. The CAG would have benefited from a more concerted effort to understand the information environment.

Planning Capabilities and Transition

DOD's deliberate and crisis planning approaches were essential to achieving desired end states. COVID-19 threw curveballs that required rapidly shifting from one mission to the next. The planning team applied multifunctional expertise—medical, logistics, intel, legal, etc.—to identify potential risks and resource constraints due to simultaneous resource-intensive operations; help leaders make informed decisions; understand problems and develop solutions; task organize the force and prioritize efforts; direct, coordinate, and synchronize action; and anticipate events and adapt to changing circumstances. Throughout, DOD planning processes allowed the CAG to remain mission focused. Ultimately, the planning culminated in the historical interdepartmental transfer of authority from DOD to HHS with H-Core postured to assume the mission.[27]

DOD planners initiated a series of battle rhythm events, reviews, and exercises to rehearse distribution plans and allow the various government and

industry partners involved in the effort to define roles and responsibilities, synchronize movements, identify gaps, and plan for potential challenges at every stage of the distribution process. In total, five vaccine distribution and administration tabletop exercises were planned, developed, and executed with representation from 64 jurisdictions, 24 U.S. government agencies, and 13 industry partners that enabled OWS to identify, monitor, and direct 84 distinct actions for each vaccine candidate from the moment of EUA submission to vaccines arriving at the point of administration.[28] Of military officers, General Perna noted,

> We know how to put a plan together. . . . We use the military decision-making process—something on which we're trained as young officers. We come up with courses of action and we assess risk against them. We decide and we move out, and when they don't work out, we adjust. It's probably the greatest attribute we have because we have never done this in the country before.[29]

Another critical planning effort was the transition effort between CAG and HHS. Per the MOU, the desired end state was that HHS and its various entities assume the entirety of CAG's mission by 31 December 2021. Plans developed and led to a multiphased approach to achieve all five culmination criteria and four transition criteria per the MOU and transfer each CAG workstream to HHS. Plans also drove the contracting effort to support a CAG-like capability once DOD had departed. Leveraging JPEO-CBRND and DOD's assisted acquisition, this contract filled necessary gaps in current HHS capability within workstreams, especially supply, production, and distribution.

As part of the MOU requirement, plans worked closely with the chief of staff's team to develop a records distribution plan to record and compile lessons learned efficiently. These records were made available for HHS counterparts and other governmental agencies as they continued with the COVID-19 pandemic response mission and prepare for future pandemics.

The transition of the CAG's responsibilities from DOD to HHS during an ongoing national emergency was unprecedented. There were no established processes for transferring a critical mission from one federal agency to another. Best practices included establishing an agreed-on end state that everyone can drive toward. The end state can, and should, be revisited and revised as needed. Also, interdepartmental transitions require longer lead times to account for the different processes of each department. The CAG established aggressive target dates and timelines but was prepared to adjust if necessary. Leaders also emphasized the establishment and maintenance of a common understanding. In this case, not only HHS and DOD needed to appreciate the transition process but also the White House and Congress. Ultimately, for the transition to occur, the White House had to be convinced that it could take place with no degradation to the mission.

All parties recognized the complexity of an interdepartmental transition and that unanticipated obstacles would arise. Senior leaders remained calm and

built partnerships to work through emerging challenges. At multiple points in the process, unforeseen events such as the rapid spread of the Delta variant threatened to delay the transition. Leadership, recognizing that the risk to transition was more psychological than anything else, instilled confidence by trusting the process and continuing to execute the plan. They resisted the tendency to allow anxieties about the emergency of the day to derail progress toward the desired end state.

Conclusion

On 7 December 2021, the HHS and DOD deputy secretaries determined that the CAG had accomplished all key transition tasks. The CAG was dissolved effective 31 December 2021, per its MOU. HCORE assumed responsibility for all functions performed by the CAG. As of 1 January 2021, HHS/H-CORE is the lead agent for current pandemic response and future pandemic preparedness.[30]

In a recent report, GAO concluded that a better understanding of the CAG experience would go far in positioning H-CORE for success in the future.[31] For their part, General Perna and other members of the CAG's leadership team recommended a comprehensive bipartisan review.[32] Additional research would provide a more complete understanding of areas where the CAG was successful and opportunities for improvement. The identification of best practices would inform ongoing and future vaccine work specifically and the federal government's crisis response capabilities more broadly. Research should also be done on the perspectives of key external stakeholders, such as industry partners. In April 2020, DOD was the only federal entity with the planning, logistics, and acquisitions capabilities needed to execute the CAG mission. This need not be the case in the next pandemic.

The COVID-19 pandemic represents one potential future threat landscape that the U.S. government and DOD should prepare for. It illustrates the intersection of a transnational threat leading to a national emergency, with bio- and cybersecurity and great power competition. In the current international environment defined by competition among nation-states, all players will seek to take advantage of any opportunity, including natural disasters and pandemics. The nature of the next crisis will be different; however, some of the ways the CAG solved problems in a rapidly evolving national emergency will apply.

Endnotes

1. Scott Gottlieb, *Uncontrolled Spread: Why COVID-19 Crushed Us and How We Can Defeat the Next Pandemic* (New York: HaperCollins, 2021), 10.
2. "COVID Data Tracker," Centers for Disease Control and Prevention, accessed 3 March 2022.
3. For consistency and readability, the acronym CAG will be used for the remainder of the article to cover events that occurred under both OWS and CAG. It was the same organization and mission, just under a different name. CAG was chosen because it was the name of the organization when it was dissolved.

4. Yasmeen Abutaleb and Damian Paletta *Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic that Changed History* (New York: HarperCollins 2021), 425.
5. Interview with Dr. Matthew Hepburn, 8 October 2021, notes in author's possession.
6. Abutaleb and Paletta, *Nightmare Scenario*, 379.
7. Abutaleb and Paletta, *Nightmare Scenario*, 425.
8. Maegan Vazquez and Nikki Carvajal, "Biden Offers Rare Praise of Trump during Covid Speech," CNN, 22 December 2021.
9. Statistics compiled in *Countermeasures Acceleration Group Final Report*, 28 January 2022. Copy in authors' possession. Document not currently available to the general public.
10. Metrics as of 31 December 2021, "CDC Covid Data Tracker." See also *Testimony before the Senate Committee on Health, Education, Labor, and Pensions, Hearing Titled Addressing New Variants: A Federal Perspective on the COVID-19 Response*, 117th Cong. (11 January 2022) (statement of Dawn O'Connell, assistant secretary for preparedness and response), hereafter O'Connell statement.
11. Eric C. Schneider et al., *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?*, issue brief (New York: Commonwealth Fund, 2021), https://doi.org/10.26099/3542-5n54.
12. President Joseph R. Biden Jr., *National Strategy for COVID-19 Response and Pandemic Preparedness* (Washington, DC: White House, 2021).
13. "Vaccines for Children Program (VFC)," Centers for Disease Control and Prevention, 18 February 2016.
14. "FOIA Library/Electronic Reading Room," HHS.gov, accessed 15 March 2022.
15. For representative examples, see "News Conference on Vaccine Development and Distribution," C-SPAN, 30 December 2020; and "Senate Hearing on Defense Department Response to Coronavirus Pandemic," C-SPAN, 25 February 2021.
16. See "CAG Historical Project" folder in CAG Lessons Learned File. Folder in authors' possession. File not currently available to the general public.
17. Figures found in "CAG Historical Project" folder and "Therapeutics" folder in CAG Lessons Learned File. Folders in authors' possession. File not currently available to the general public.
18. Figures found in "CAG Historical Project" folder and "Therapeutics" folder in CAG Lessons Learned File. Folders in authors' possession. File not currently available to the general public.
19. See "CAG Historical Project" folder in CAG Lessons Learned File. Folder in authors' possession. File not currently available to the general public.
20. Jen Judson, "What the Army Can Learn from Operation Warp Speed—An Interview with General Gustave Perna," *Defense News*, 13 March 2022.
21. See Ellen Nakashima, "U.S. Officials Caution Companies about Risks of Working with Chinese Entities in A.I. and Biotech," *Washington Post*, 22 October 2021; and Conor Finnegan and Luke Barr, "U.S. Accuses Chinese Tech Firms, Research Institutes of Weaponizing Biotechnology, Creating 'Brain-Control Weaponry'," ABC News, 16 December 2021.
22. See "CAG Historical Project" folder and "Security and Assurance" folder in CAG Lessons Learned File. Folders in authors' possession. File not currently available to the general public.
23. See "Industrial Security," Defense Counterintelligence and Security Agency, accessed 15 March 2022. For an example of products developed, see "Operation Warp Speed and Beyond Toolkit: An Industry Partners Toolkit for the Pharmaceutical and Biotechnology Sectors," Center for Development of Security Excellence, accessed 15 March 2022.
24. See "CAG Historical Project" folder and "Contracting" folder in CAG Lessons Learned File. Folders in authors' possession. File not currently available to the general public.
25. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116–136 (2021).
26. Judson, "What the Army Can Learn from Operation Warp Speed."

27. Lawrence Wright, *Plague Year: America in the Time of Covid* (New York: Alfred A. Knopf, 2021), 263–65.
28. See "CAG Historical Project" folder and "Plans and Transition" folder in CAG Lessons Learned File. Folders in authors' possession. File not currently available to the general public.
29. Judson, "What the Army Can Learn from Operation Warp Speed."
30. O'Connell statement.
31. *COIVD-19: HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues* (Washington, DC: Government Accountability Office, 2022).
32. Judson, "What the Army Can Learn from Operation Warp Speed."