REDESIGNING VACCINE DEVELOPMENT PROCESS FROM A PPP PERSPECTIVE: OPERATION WARP SPEED

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Abstract

Announced on May 15, 2020, Operation Warp Speed (OWS) was a major public-private partnership (PPP) that effectively shepherded the development of two safe and effective COVID-19 vaccines in less than a year. The initiative sought to coordinate an array of government bodies to support private companies in producing COVID-19 medical countermeasures, meaning therapeutics, diagnostics, and vaccines, which were crucial for mitigating the public health and economic distress caused by the virus (Slaoui & Hepburn, 2020). To meet the unique and pressing circumstances, OWS leveraged both public and private capacity to follow traditional vaccine development processes on an accelerated timeline and with a diverse stakeholder group. The initiative met many challenges, including issues with intellectual property rights and the rule of law. It is salient to understand OWS's operational framework and how future projects can mirror its success and learn from its challenges. This paper seeks to clarify the roles of the public and private sectors in shaping the initiative, examine the effective strategies adopted, and describe the challenges.

Introduction

In a race considered to be a marathon, Operation Warp Speed (OWS) sprints. Announced on May 15, 2020, the initiative effectively shepherded the development of two safe and effective COVID-19 vaccines in less than a year (Shulkin, 2021). The development of a COVID-19 vaccine was crucial to mitigate the public health and economic distress caused by the virus. OWS was a public-private partnership (PPP) that sought to coordinate an array of government bodies to support private companies in producing COVID-19 medical countermeasures, meaning therapeutics, diagnostics, and vaccines (Slaoui & Hepburn, 2020). With most of the funding allocated to vaccine development, manufacturing, and distribution, the primary goal was to deliver 300 million effective, FDA-authorized COVID-19 vaccines by January 2021 (Siddalingaiah, 2021).

It is salient to understand OWS's operational framework and explore how future projects can mirror its success. While there are three core aspects of OWS–the development, manufacturing, and distribution of vaccines–this paper focuses on the earlier stages of the initiative: the initial contracting and vaccine development. This paper seeks to clarify the roles of the public and private sectors in shaping the initiative, examine the effective strategies adopted, and describe the challenges. For example, how was the standard vaccine development process adapted to meet OWS's timeline? Given that OWS was implemented in recent years, this paper will utilize relevant agency documents, journal papers, research reports, and credible news.

Literature Review

PPPs are generally defined as "working arrangements based on a mutual commitment (over and above that implied in any contract) between a public sector organization with any organization outside of the public sector" (Bovaird, 2004). PPPs have been adopted to address health care delivery, public health, and global health, often involving public agencies, multinational companies, and research institutions (Thadani, 2014). Initially, they were a tool for the government to close the financial gaps with private funds, in what Bovaird (2004) calls "marriages for money." Increasingly, state government contracts with the private sector to facilitate health interventions by leveraging the industry's resources and expertise in communication, logistics, and marketing.

Derived from strategic management research, Bovaird (2004) summarizes three distinct competitive advantages that partnerships can contribute. First, a partnership can provide "economies of scale" and critical mass in service delivery. Second, they provide "economies of scope," which refers to the ability to exploit partner organizations' complementary capability and competency. Lastly, partnerships create "opportunities for mutual learning between partners" that can foster an environment for long-term dynamic interchange. The following illustrates a couple of PPP examples from the healthcare sector within this framework.

To drive higher COVID-19 vaccination rates, the Centers for Disease Control and Prevention (CDC) collaborated with Walmart to improve vaccine access in low-income communities (Greene et al., 2021). CDC provided Walmart with allocations of vaccines, while Walmart pinpointed vulnerable communities by analyzing demographics, local health needs, and gaps in critical access to medical services. Vaccination sites were set up at Walmart parking lots and in-store locations across 18 states. The public sector took full advantage of the private company's commercial location and workforce for mass vaccination while leveraging the industry's knowledge in logistics and outreach to scale up vaccination efforts. In this partnership, Walmart provided economic scale and scope in health service delivery.

Cancer Moonshot, an effort to accelerate progress in the scientific discovery of cancer launched in 2016, is an example of facilitating mutual learning between partners. The initiative fosters broader collaboration between researchers through creating a network of research communities that encourage communication and the complete sharing of primary data (Sharpless and Singer, 2021). As Sherkow (2018) put it, understanding cancer is understanding cancer information. Recognizing the value of sharing information, the Cancer Moonshot Public Access and Data Sharing (PADS) Policy calls for "releasing publications and sharing the underlying primary data" in an attempt to accelerate cancer research (National Institute of Health, 2021). However, this approach did not go without considerations, raising intellectual property and information policy issues in the structure of a PPP (Sherkow, 2018).

Network management is essential in organizing complex governance processes such as PPP. It emphasizes managing both the individual partners in a partnership and the network within which the partnership is embedded. The literature identifies two effective strategies for network management. Warsen (2000) describes the *exploring strategy,* which seeks to create new solutions, collect joint information, organize research, and combine conflicting opinions, as well as the *connecting strategy,* which focuses on activating actors and resources, linking actors, nurturing inter-organizational relations, and addressing conflicts. The author concluded that network management is associated with perceived performance. In particular, the constant nurturing of partnership, activation of cooperation, and the ability to deal with uncertainty are crucial to making PPPs work. These insights hold in the context of dealing with the COVID-19 pandemic and managing OWS.

Operation Warp Speed

1. Overview

Operation Warp Speed was officially announced on May 15, 2020, by President Trump (Shulkin, 2021). OWS is a PPP that maximizes the government and private sectors' respective capabilities to achieve shared goals. The initiative involved multi-level government agencies, the military, pharmaceutical, manufacturing, delivery, and more. The ultimate goal was to deliver 300 million doses of safe vaccines to the American people by January 2021 (Slaoui and Hepburn, 2020). Despite successfully presenting viable vaccines under a near-impossible time frame, the initiative faced constant criticism regarding slow vaccine rollout and raised questions about patent rights. In February 2021, the Biden Administration renamed and restructured the initiative, transferring the responsibilities of OWS to the White House COVID-19 Response (Siddalingaiah, 2021).

The leadership of OWS reflects the primary objectives of the initiative. The United States Department of Health and Human Services (HHS) and the United States Department of Defense (DOD) were the co-chairs. Moncef Slaoui, former Chairman of the Global Research and Development and Global Vaccines divisions at pharmaceutical company GlaxoSmithKline, was appointed chief advisor. General Gustave F. Perna, an expert in global supply chain and material readiness from his time as a commanding general in the U.S. Army Materiel Command, was the chief operating officer. The expansive team also included stakeholders from other federal agencies, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. It built on existing initiatives by HHS-wide activities, such as the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA (Slaoui and Hepburn, 2020; Shulkin, 2021).

Further, OWS awarded contracts and other transaction (OT) agreements with a variety of private competitors in vaccine development and the production of ancillary vaccination supplies. OWS selected vaccine

manufacturer candidates such as Moderna, Janssen Pharmaceuticals, Sanofi/GSK for federal financial support during vaccine development (GAO, 2021). Though Pfizer-BioNTech did not accept funding from the US government for vaccine development–claiming to maintain its scientific independence and keep its production out of politics, the Trump administration reached a deal with Pfizer to manufacture and deliver 100 million doses of vaccine (DOD, 2020).

2. Strategies and Implications

How did the White House defy the timelines that have governed vaccine development for decades? The fastest record of vaccine development before the COVID-19 vaccine was the mumps vaccine, which took four years to go on the market (Cohen, 2020). It can take up to a decade to complete all development and regulatory processes in typical vaccine development timelines (Shulkin, 2021). Advances in vaccine platform technology (like mRNA), have improved understanding of safe and efficacious vaccine design, and similarities between the SARS virus and COVID-19 set some of the groundwork for developing the COVID-19 vaccine (Corbett et al., 2020). However, several measures boosted the OWS initiative's speed and effectiveness. The following sections illustrate strategies identified in the contracting and vaccine development phases, including strengths and weaknesses.

Contracting. OWS expedited the development process from the start of the partnership by using other transaction (OT) agreements instead of traditional procurement contracts (GAO, 2021). Often used by DOD, OT agreements enable speed and flexibility and are generally exempt from federal procurement laws and regulations. By December 2020, about $8.8 billion of $13 billion in funding dedicated to vaccine development and manufacturing was obligated via OT agreements.

However, OT agreements can be controversial in that they are less transparent and are exempt from regulations designed to protect taxpayers. For example, they can bypass the Bayh-Dole Act, which gave the public access to intellectual property rights from federal government-funded research (Schwartz & Peters, 2019). Further discussion of IP rights will be presented in the next section.

Diverse Project Portfolio. OWS announced support for six candidates on three predetermined vaccine platforms (GAO, 2021). It created a diverse project portfolio by awarding contracts to candidates pursuing different scientific methods to develop a vaccine. This diversification narrowed the risk of pouring significant resources into one method when the outcome involved great uncertainty. It maximized the possibility that the objective would be achieved if one or all approaches proved successful.

Horizontal and Vertical Coordination. Drawing from Warsen (2000), exploring and connecting network management strategies are especially applicable to OWS. The initiative not only facilitated the working relationship between government and private entities but also among public organizations and within the private sector. It used federal authority to guide and resolve deadlocks while not interfering with the research autonomy of private companies.

First, the government utilized the private sector's economies of scale and scope, maximizing private companies' intellectual efficiencies and commercial-scale manufacturing capabilities to the advantage of the government without threatening the autonomy and integrity of science. Second, OWS merged the administrative and budgetary forces of HHS and DOD to achieve its objective. Removing conventional barriers by providing generous funding upfront and clearing the red tape among government agencies, OWS aimed to leverage the total capacity of the government to ensure that no technical, logistic, or financial hurdles obscured vaccine development or deployment. Third, OWS also helped enable, accelerate, harmonize, and advise the private companies involved. For example, HHS's Biomedical Advanced Research and Development Authority helped identify additional manufacturing partners to increase production (GAO, 2021). Additionally, the U.S. Army Corps of Engineers oversaw construction projects to expand capacity at vaccine manufacturing facilities (GAO, 2021).

Results Orientation and Goal Alignment. According to Savas (2000), a project is well-suited for government contracting when a project's goal can be specified in advance, performance can be easily measured and evaluated, there is competition among providers, the demand for service increases over time, and the private sector has more significant economies of scale in producing the services. OWS is a mission-critical project with a clear objective and firm deadline. The articulated goal was to produce and deliver 300 million safe and effective

vaccine doses by January 2021. Under the pressure of the pandemic, the need for a viable vaccine increased by the day; therefore, the interests among different groups of stakeholders were easily aligned and the market was competitive. Moreover, the executive branch gave clear instructions to cooperate and achieve a common objective.

Parallel Vaccine Development and Manufacturing. The OWS vaccine development process followed traditional practices but with few adaptations. According to GAO (2021), the biggest difference was the compressed timeline. To facilitate the rapid development of vaccines, the FDA allowed companies to rely on established knowledge from similar products manufactured with the same platform technology, to the extent legally and scientifically permissible. Moreover, OWS vaccine companies conducted concurrent clinical trials to quickly determine vaccine efficacy. Such approaches were successfully used during the Ebola epidemic in the mid-2010s (GAO, 2021). The COVID-19 process was further sped up by reducing the time it took to review Phase 2 data. Typically, it would take the company six months to review data before moving on to Phase 3; however, it only took three weeks for the companies in OWS to initiate Phase 3 (GAO, 2021). Moreover, the FDA granted Moderna a Fast Track designation to begin Phase 1 and the expanded Phase 3 trial (HHS, 2020). In order to quickly provide drugs to patients, FDA grants Fast Track to drug companies to facilitate the development and accelerate the review of drugs to address unmet medical needs (FDA, 2018). While Phase 3 normally involves several hundred to thousands of volunteers, OWS conducted large-scale clinical trials of 30,000 individuals, enabling the rapid collection of demographically represented efficacy data (GAO, 2021; HHS, 2020).

To expedite the availability of the completed vaccine, the manufacturing and the logistical planning for distribution were happening parallel with vaccine research and development (Slaoui and Hepburn, 2020). The government was willing to undertake substantial financial risk, supporting the companies financially and technically to commence development and scale-up manufacturing while companies were still in preclinical stages. The companies also began commercial-scale manufacturing while still collecting data in clinical trials. The HHS–DOD partnership began the groundwork for vaccine distribution and logistical planning as development and manufacturing proceeded. In addition, the government purchased millions of Pfizer and Moderna vaccines while they were still undergoing clinical trials (Weiland et al. 2020).

Such a compressed timetable and PPP model enabled fast and large-scale distribution of vaccines. However, it also may have contributed to creating a group of vaccine-hesitant people in the American general public. The narrative of OWS, a White House effort "racing" to deliver a vaccine, politicized the initiative and reinforced the public's distrust in the government, and subsequent hesitancy in vaccines (Torreele, 2020; Coustasse et al. 2021). People were skeptical about the safety and effectiveness of COVID-19 shots, which highlights the importance of public conception campaigns, government information dissemination, and public education about initiatives like OWS.

3. Challenges

The Moderna vaccine was a testament to the power of partnership, having emerged directly from a collaboration between Moderna and a laboratory at the National Institute of Health (NIH) led by Dr. Barney Graham (Ledford, 2021). Sixty-six days after the genome of COVID-19 was first published, the first Moderna vaccine was injected into a human during a Phase 1 study in May 2020. Fast forward to November 2021, Moderna and NIH found themselves in a boiling patent dispute when Moderna filed several patent applications but excluded NIH in some of them (Ledford, 2021; Stolberg and Robbins, 2021).

Critics and Congressmembers had expressed concerns that the intellectual property rights of OWS-financed COVID-19 vaccines could restrict vaccine production. IP rights are an essential incentive for manufacturers to invest in research and development because they grant companies a temporary monopoly in the market for any new technology. Since it is a deciding factor for the affordability and accessibility of a vaccine or drug, if the government assumes a more assertive stance on intellectual property, it will have greater control over the prices of pharmaceuticals.

According to the Patent Act, a vaccine developer can secure patents on the manufacturing of vaccines and enjoy a temporary monopoly of the invention (Hickey et al., 2020). However, when a private party receives federal financial support, its allocation and scope of patent rights are affected. Typically, the patent rights will be owned by either the U.S. government or the federal contractor, depending on the form of government support and

the contract. Through purchasing or funding contracts with vaccine manufacturers, the government has upfront guarantees on pricing and distribution (Hickey et al., 2020). Furthermore, in certain reasonable circumstances, funding agencies can enable other producers to manufacture the vaccine with march-in rights for vaccines protected by the Bayh-Dole Act. March-in rights refer to the government's authority to "march in and grant compulsory licenses to third parties in some circumstances" (Hickey et al., 2020). For U.S. patents, the federal government has the authority to exercise the eminent domain power under 28 U.S.C. § 1498 to make and use the invention without a license (Hickey et al., 2020).

In a move considered unprecedented, the U.S. government voiced "support for the waiver of the protection for COVID-19 vaccines" in May 2021, because the extraordinary circumstances of the pandemic called for extraordinary measures (Maxmen, 2021). Some considered the move to be fair and just because it promoted the equitable distribution of vaccines in the U.S. and abroad, while opponents claimed it would undermine "global response to the pandemic and compromise safety" (Maxmen 2021). Such policies have more profound implications for future PPP research and development projects. For example, companies might be more hesitant to partner with the government in a project where the government could potentially curtail profit-making potential.

The accessibility and availability of vaccines do not guarantee a stop to the COVID-19 outbreak unless vaccination rates reach a level high enough to achieve herd immunity. To that end, the government has exercised the authority to impose vaccine mandates, raising challenges to the rule of law. The issue mentioned above brought up the struggle to balance governmental power and individual freedom, which deserves further discussion and close attention (Kettl, 2009). It magnified the socioeconomic disparity in healthcare accessibility. For example, some households, especially in vulnerable communities, simply do not have the time or ability to book appointments (Coustasse et al. 2020). Such circumstances opened new opportunities for PPPs and for the private sector to step in, for instance, the Biden Administration partnered with ride-share companies Uber and Lyft to provide free rides to vaccination sites (The White House, 2021).

Conclusions

Can the vaccine development of OWS be replicated? Scientists have indicated that it depends on the nature of the pathogen and social context (Ball, 2000). One of the advantages of developing the COVID-19 vaccine was its similarity with SARS. Years of research and advances in vaccine platform technology paved the way for fast results. On the other hand, the sense of social and political urgency enabled the government to take the financial risk to initiate large-scale manufacturing before the completion of clinical trials.

However, the lessons from OWS drive further discussions of how the normal process might be reformed. First, OWS is considered a successful case of public-private partnerships as it effectively achieved its overarching objective: delivering 300 doses of safe vaccines to the public. It coordinated a network of public and private actors to pool efforts in developing and delivering vaccines in time. The initiative exploited the respective advantages of the government and the industry. With direct federal support and constant governmental oversight, the initiative managed to enable accelerated processes without micromanaging and interfering with the autonomy of science. Integrating the support of different government agencies, OWS streamlined and accelerated the development process.

Second, vaccine hesitancy and the lower-than-expected vaccination rate highlighted the need for effective communication strategies to deliver transparent information, promote scientific facts, and improve accessibility. The private sector could be a valuable asset to address the challenges of distributing vaccines in the United States and abroad.

Last, OWS's accelerated vaccine development model could have greater implications for future vaccine development, such as the installation of reduced data review periods and relaxed regulations. While in this case, the need for speed was understandable, it does beg the question of whether anything was lost by not going through the typical formal process.

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