What Health Care Can Learn from Operation Warp Speed

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Operation Warp Speed was remarkably effective in shepherding the development of two Covid-19 vaccines in less than a year. Its “RAPID” process for problem-solving can be applied to other problems in health care.

The delivery of two commercial vaccines in less than a year is nothing short of miraculous. Solutions to many other medical problems remain elusive after decades of work. So why was the U.S. government’s Operation Warp Speed (OWS) so effective in achieving many of its goals?

Other medical miracles have been achieved, but few with the speed and success of developing the Covid-19 vaccines. Historically, you need to go back decades to recall other missions of such importance. Project Apollo was the National Aeronautics and Space Administration (NASA)’s project to land a man on the moon.1 From 1961 to 1969, thousands of government workers focused on achieving this goal at a cost of $28 billion (inflation-adjusted). Prior to Apollo, the most famous large-scale research undertaking arguably was the Manhattan Project. Starting in 1939, and receiving its first funding of $6,000 in 1940, the project took 5 years to develop an atomic bomb. The final cost was approximately $23 billion (inflation-adjusted).2

In contrast, OWS, a name borrowed from Star Trek, took just over 8 months to complete at a cost of approximately $18 billion. OWS was first publicly revealed on April 20, 2020, and officially announced on May 15, with the first dose of vaccine authorized by the U.S. Food and Drug Administration (FDA) on December 11.

There are important lessons from the work of OWS, many of which can be applied to addressing other problems in health care. Many efforts to address complex problems in health care are considered marathons. They involve serial steps of planning, hypothesis generation, financing, data collection, analysis, presentations, and reporting. However, in solving urgent and complex problems, a sprint may be more appropriate, where all energy and resources available are fully
expended until the objective is achieved. It was this commitment to urgency that helped OWS achieve its amazing results in vaccine development.

In examining the essence of OWS, the elements of a successful process for problem-solving, demonstrated in OWS, can be broken down into the acronym “RAPID”:

**R. Results Orientation**

Everyone involved in a mission-critical project, from the top down, must be clear and engrossed in achieving the goal. Often it is this laser-like focus that is most important in accomplishing a successful outcome. When projects don’t go well, it can be commonly traced back to lack of clarity of the objective, different perspectives on what success looks like, or a lack of understanding of purpose.

When a results orientation is present among the entire team, it is powerful. Recall the now-famous story of when President Kennedy toured NASA in 1961. He stopped to introduce himself to one of the janitors working there and asked him what he did. The janitor responded, “I’m helping sending a man to the moon.” That’s clarity of mission.

The goal of OWS was clear: to develop millions of doses of an effective and safe vaccine, approved or authorized by the FDA, in as short a period of time as possible. Complex problems are often better tackled by establishing big or “stretch” goals, rather than targeting incremental improvements.

Besides setting the right goals, OWS faced a flood of ideas and proposals from so many people who wanted to help. If OWS had engaged with each idea and supported all the companies desiring to participate, it likely would have considerably slowed the process. OWS needed to make some educated bets on which companies and which scientific methods were most promising. This is not easy to do when little preliminary data exists on which to make these determinations. After all, Covid-19 was a novel virus, and many of the vaccine development methods had not been studied before. OWS narrowed the field by focusing on established criteria. These criteria included having some preliminary clinical or preclinical data, and the ability to enter phase 3 trials within a few months. Candidates had to utilize one of the four vaccine platforms that were predetermined to have the ability to scale and be reliably manufactured. Without narrowing the focus of these efforts, OWS would not have been as likely to have so quickly achieved their objectives.

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At the onset, OWS created an integrated command structure, headed by Moncef Slaoui, PhD, that allowed for singular accountability and oversight. This structure was critical in ensuring that timelines were maintained, issues surfaced early, and decisions were made promptly. This project infrastructure helped eliminate redundancies, overcome barriers, identify needed resources, create collaborations, and ensure the project’s ultimate success.

**Agile Development**

Achieving extraordinary results often requires doing things differently. In the software development ecosystem, which has become increasingly competitive and time sensitive, there have been new methods introduced to improve speed and efficiency. As a result, agile development has become popular in the technology and business worlds, yet it has been slow to be adopted in the research and medical communities. The core of agile development is to embrace changing requirements, something that is often unwelcome in the mind of a disciplined researcher.5

Agile development allows complex projects to be broken down into manageable chunks of work. It also requires a highly collaborative team environment, continuous review of progress, and open and candid interactions among all involved. An agile approach allowed OWS to perform essential tasks in parallel, rather than sequentially. For example, conducting safety and efficacy testing at the same time allowed for rapid clinical trial data to be completed. The decision to start industrial-scale manufacturing before study results were available or FDA authorization was given shaved many more months off the process. This type of parallel processing offers great opportunities to speed research and operational mission-critical programs.

Agile development can be associated with taking additional risk in order to achieve a quicker result. The OWS initiative required a willingness to publicly declare a goal, set a strategy, and prepare for the possibility of failure. Most great accomplishments are usually accompanied by significant risk. It is the ability to learn and adapt to failure that ultimately is responsible for achieving success.

**Public-Private Partnerships**

OWS represented a new breed of public-private partnership (PPP). The OWS initiative involved eight pharmaceutical companies, multiple government agencies, including the military, and numerous other companies. Not all PPPs are the same. At one end of the spectrum, the government maintains all accountability for the production and delivery of services, while at the other extreme of PPPs, the government divests all this responsibility. OWS broke new ground from traditional PPP models by creating a unique distribution of responsibilities that ultimately contributed to the success of the effort. OWS largely made these decisions based upon core competencies rather than on political or financial considerations.

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Not much has been reported on the role of technology in bringing the Covid-19 vaccines to market, but it clearly played an important role. OWS focused its efforts on four vaccine technologies: the mRNA platform, the replication-defective live-vector platform, the recombinant-subunit-adjuvanted protein platform, and the attenuated replicating live-vector platform. These each represented potential breakthrough technologies in discovering new methods of vaccine development. Technology, including data analytics, artificial intelligence, and numerous others can be an integral part of improving the time and effectiveness of finding solutions to future problems in health care.

**Interest Alignment**

Research and discovery traditionally occur in silos. Rarely do multiple organizations, companies, agencies, and individuals come together. Part of OWS’s secret sauce was finding an aligned interest among these various groups to work together. In the case of federal agencies, this alignment was created by directives from the Executive Branch, where clear instructions were given to cooperate and achieve a common objective. The Department of Health and Human Services, the Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health, the Biomedical Advanced Research and Development Authority, the Department of Defense, the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs all contributed to the effort. Similar efforts were deployed in the Obama Administration with the Cancer Moonshot that was led by Vice President Biden. Directed from the top, the Moonshot also included federal agencies, academic institutions, and private companies. PPPs create a forum in which entities can individually and collectively contribute to a common objective.

Another part of the success of OWS was the willingness of the federal government to pre-fund many of the project expenses. Often, too much time is spent by project leaders in obtaining the required funding and justifying these investments. Funding limitations also slow the ability to move quickly and to pursue multiple strategies.

Projects that seek to achieve results quickly are typically viewed as expensive. But what is often not accounted for in return-on-investment decisions is the cost of not finding a solution. For OWS, the $18 billion invested was just a fraction of the devastating worldwide economic and human impact of Covid-19. The economic impact on the U.S. economy alone may be as high as $8 trillion, so each day that a vaccine is delayed is costing the economy billions of dollars. This is not to mention the cost of thousands of lives that are being lost each day in the pandemic.

**Diversification**

A big part of the success of OWS laid in selecting a number of potential vaccine candidates with different mechanisms of action. This allowed for the possibility that the project outcome would be achieved if one, some, or all approaches had proved successful. OWS selected companies that were pursuing different scientific methods to develop a vaccine. Moderna and Pfizer/BioNtech utilized mRNA, AstraZeneca and Janssen worked with replication-defective live vectors, and Novavax and Sanofi/GSK utilized a recombinant protein. Merck is working on a live attenuated virus that may
be given orally. This diversification of mode of action is essential to achieving results quickly. The alternative of sequential testing is to wait, and if failure occurs to then start over.

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Competition is one of the great motivators of all times and is one of the successful ingredients of a modern economy. OWS’s enablement of competition in the development of the Covid-19 vaccines was no doubt part of its success. Not only were the eight official participating companies in competition to deliver a vaccine, but hundreds of other companies were involved around the world. This type of serial competition is rare. It was as if the research world stopped in 2020 and everyone turned their attention to a single issue: to find a cure for Covid-19. It was an unusual type of competition that at times took on a cooperative and collaborative spirit.

Lessons Learned

The lessons from OWS can be helpful in finding solutions to other big problems in health care, such as suicide prevention, identifying cancer cures, finding alternatives to opioids for effective management of chronic pain, and addressing neurologic disorders that impair cognition. The “RAPID” process can be applied to problems facing basic researchers, hospitals and health systems, payers, and local, state, and federal health agencies. There is no shortage of problems, only a commitment and willingness to tackle them. With the model of success of OWS, it would be a missed opportunity to not achieve additional medical triumphs.

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Disclosures: David Shulkin is President of Shulkin Solutions and previously served as the Ninth Secretary of the U.S. Department of Veterans Affairs as well as the Under Secretary of the Veteran’s Health Administration. The views expressed in this article are those of the author and do not necessarily reflect the position or policy of the Department of Veterans Affairs.

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