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Rules for Operating at Warp Speed

On December 11, 2020, the US Food and Drug Administration (FDA) authorized the first COVID-19 vaccine dose for people aged 16 and older. Obtaining an effective vaccine less than a year after the COVID-19 pandemic began was an unprecedented achievement. The vaccine development effort, called Operation Warp Speed (OWS), was co-led by Moncef Slaoui, former head of vaccines at GlaxoSmithKline, and Gustave Perna, a retired four-star general. Since the authorization, OWS has been viewed as a stunning success both inside and outside government.

Making such rapid progress on the COVID-19 vaccine during a public health crisis required deviation from the federal government's usual modes of operation: in particular, temporarily suspending or ignoring some of the usual administrative and scientific guardrails. For instance, accelerated contracting processes replaced the usual federal contracting procedures. And although OWS accessed federal biomedical and preparedness expertise, it did so in ways that deviated from existing policy processes of scientific consensus authorized via advisory committees, systematic merit review, and other established practices.

The justification for suspending these guardrails was speed. The government needed to quickly develop novel modes of detection, treatment, and prevention in response to the public health emergency caused by SARS-CoV-2. The rapid tests, monoclonal therapies, and mRNA vaccines that companies have developed or commercialized have saved lives, prevented suffering, and reduced further economic and other damage from the virus.

OWS could become the template for rapid government response to future crises. Whether it's used in public health emergencies, climate threats, or other disruptions, how this model handles funding accountability and scientific expertise warrants more attention than it has received from policymakers. It clearly contains cautionary lessons: if OWS-type programs become a norm for government—either because they are perceived as an effective way to get results in a crisis or because the government finds itself responding to crisis after crisis—over time important attributes of transparency and deliberation in government may be deemed disposable. But the lessons could also be instructive, because more flexible spending mechanisms that can be deployed quickly in either crisis or normal times are critical to ensuring appropriate use of taxpayers' funds. Likewise, more nimble, expeditious mechanisms for scientific consensus could help the government function more efficiently overall. The key to gleaning these various lessons lies with better understanding how OWS functioned.

Suspension of the administrative state

OWS was an exceptionally large expenditure. In less than a year, its financial cost was $18 billion dollars—on par with the Manhattan Project, which developed the atomic bomb at a cost of $23 billion (adjusting for inflation) over five years.

Spending $18 billion dollars in less than a year meant that the normal guardrails for funding transparency, including congressional oversight of appropriations and contract reporting mechanisms, were not in place. Instead, by March 2021, according to the Government Accountability Office (GAO), $12.5 billion was obligated by the Departments of Defense (DOD), Health and Human Services (HHS), and Homeland Security through flexible contracting mechanisms known as Other Transaction Authority (OTA).

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OTA includes mechanisms for legally binding funding agreements with the government that are much more flexible than a standard federal contract, grant, or cooperative agreement. OTA was first used by NASA, then by DOD to support funding for research and technology prototypes. These agreements are not subject to many regulations that generally govern federal procurement, including the Federal Acquisition Regulations (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS). In fact, the proverbial guidebook for OTA is only 53 pages long—incredibly brief in comparison to the FAR, a whopping 1,988 pages, and the DFARS, which comes in at 1,338 pages.

In 2020 and 2021, I interviewed senior officials at DOD, FDA, the White House, and internationally focused nongovernmental organizations involved in the COVID vaccine development effort as research for my dissertation. These officials, who spoke confidentially—as required by the institutional review board for my dissertation—corroborated the predominant use of OTA-type contracting vehicles during OWS.

In general, the routine use of OTA avoids the government procedures meant to ensure fairness and accountability of federal funding and can permit murky federal funding processes—as has been reported by DOD's inspector general in the past. The widespread use of OTA during the pandemic renewed persistent complaints to the GAO about the limited remedies for procurement disputes when OTA is used. It also provided limited transparency about how money was spent on OWS, particularly when third parties acted as contractors.

Despite questions about accountability and transparency in relation to the use of the OTA mechanism for allocating federal funding, OTA has been proposed as the sort of "flexible contracting" tool that the government could employ even in noncrisis settings. Although OTA was likely an appropriate choice during OWS, given the need for speed and for public-private partnering during the pandemic, its replacement of standard procurement contracts under normal circumstances has been criticized as a "black box" that can potentially subvert the important administrative mechanisms that govern proper allocation of federal funding.

Suspension of the scientific state

Just as the speed required for OWS to be successful entailed moving operations outside the usual contracting mechanisms, the normal bureaucratic processes for federal scientific advice also shifted. As a result, the government's normal consensus mode for science advice contrasted starkly with the mode used by OWS during the pandemic crisis.

One official I spoke with—a senior leader from DOD, who served through several administrations before, during, and after OWS—juxtaposed the two approaches. This official explained procedures when normal channels are used for scientific advice: "It's group. It's consensus. It's you make policy by making sure everybody agrees with something and then with that agreement then you get some sort of approval." The official outlined the H1N1 prepandemic response in the Obama administration, which followed this model and was led by health and medical experts within the government, including the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority, an office located within HHS.

More recently, this official had clearly come to favor the OWS effort, which was characterized by rapid, top-down decision making. During OWS, government action happened concurrently with direct engagement with industrial partners and a strong logistical focus. According to this official, the key was bringing in Slaoui, a former industry executive in research and development, and Perna, a logistician, in place of the leadership of health experts. "We think that was the magic combination because it wasn't the health experts in here … those decisions would be made very quickly, and we would have strategic direction and we would just know."

Officials I spoke with suggested that OWS temporarily rewrote decades of preparedness norms in favor of crisis-driven improvisation. And although many federal scientific advisory committees continued meeting, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the congressionally mandated coordinating body for federal response to biological threats, was not formally involved in OWS. A 2021 consensus study report from a National Academies of Sciences, Engineering, and Medicine (NASEM) committee tasked with rapidly reviewing the public health emergency countermeasures enterprise stated, "During meetings with the committee, government leaders involved in OWS did not refer to PHEMCE. As the committee understands it, OWS became the de facto all-of-government MCM [medical

countermeasures] preparedness and response effort for COVID-19." (I was a science writer for the committee's report.)

A final question is whether the OWS template is likely to be applicable to other public health emergencies. Here it's important to recognize that OWS didn't have to do the science from scratch: the work of the scientific state had, over decades, already created the tools and platforms—such as the pioneering work on mRNA, lipid nanoparticles, spike protein stabilization, and rapid sequencing of the virus—needed to develop the vaccine. According to Slaoui and OWS vaccine lead Matt Hepburn, OWS did not need to do fundamental research to support vaccine development. Instead, the strategy was to select existing vaccine candidates and compress the sequence of vaccine development, testing, regulatory approval, production, and deployment. The fact that the right scientific knowledge and promising new technologies converged with urgent public purpose may have been, in a sense, a lucky break. In another crisis, where the science isn't ready and waiting, the OWS approach could disappoint.

Adapting governance for crisis as well as normal times

Despite concerns about the transparency and replicability of OWS, the effort made clear that slow, complex systems for awarding federal contracts, monitoring spending, and supporting cross-agency scientific consensus are incompatible with the speed and scale required for major crisis response. What's more, these procedures may sometimes be incompatible with what would be ideal for normal government operations as well. Transforming systems to support solutions to urgent problems—be it responding to a pandemic, addressing climate change, or curing cancer—will require a two-fold mission to replicate the speed and efficiency of OWS while reinforcing the scientific-administrative state as a partner rather than an obstacle.

Despite its success in delivering a vaccine, OWS revealed that the standbys that cut government contracting time and paperwork, such as OTA, do not support a robust system of accountability for spending. As crises become more frequent, this problem will only worsen. To address it, federal procurement policies should be revisited with specific attention to governance so that funding accountability and transparency is balanced with the need for expeditious government action. While a 53-page guide is clearly not up to the task, the necessity of contractor guidebooks that run to more than a thousand pages deserves examination.

Future crises will also require faster mechanisms, both internal and external to government, for providing scientific expertise and advice. As with government procurement and contracting, these mechanisms must be consistent across times of both crisis and noncrisis. In normal times, a major pathway for scientific advice in support of federal government policy is the Federal Advisory Committee structure. The Federal Advisory Committee Act (FACA), which became law in 1972, provides opportunity for advice and recommendations on agency operations and activities from experts inside and outside of government. This legislation should be amended to enable processes for rapid scientific response in crisis. The marshalling of FACA committees to quickly produce socially useful scientific recommendations in crisis would be a major accomplishment and a valuable tool for resilience.

In addition to FACA, another tool for external expertise engagement—the rapid response committees developed by NASEM—made important strides during the pandemic. At NASEM, preexisting lengthy timelines for consensus report development were significantly reduced to support the need for expert-based guidance in real time. These rapid response committees could serve both as their own source of expertise and as a model for how cross-agency advisory groups comprised of government scientists and experts, such as PHEMCE, could best work in a crisis.

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Looking to a future in which regular crises become part of the new normal, we must evaluate the trade-offs that these oscillations from crisis to noncrisis require rather than simply accept the ways that crises change the innovation system in Washington. Innovations such as OWS should be explored, and their costs and benefits weighed out, to allow a deliberate approach to positively transforming the innovation system to serve the public good. Put simply, American innovation governance during crisis must evolve to honor the robust systems of transparency and expertise that exist between crises—because COVID-19 will not be the last shock to the system.

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