COVID-19 Lessons Learned: Collaboration Needed at All Levels, and a Path to Getting There

Tevi Troy, in Collaboration with UIDP

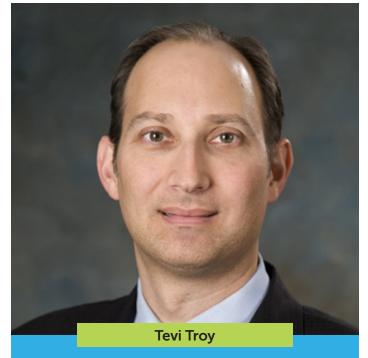
Going into the COVID-19 pandemic of 2020, it would be inaccurate to say that the U.S. was completely unprepared.

The truth is that U.S. policy makers long had plans for how to respond to a dangerous new pathogen, and three layers of defense – international monitoring, testing, and stockpiling of countermeasures — for protecting America and Americans from a pandemic. Unfortunately, all three of these layers failed the test. As such, the disastrous outbreak of 2020 was not a failure of planning but a failure to execute and to collaborate.

These failures were costly. The United States lost over 600,000 lives and trillions of dollars as a result of the outbreak. And yet the country has come through the worst of it, largely as a result of its collaborative approach to address COVID-19, including the rapid development of a number of successful vaccines.

Operation Warp Speed

The COVID-19 vaccines came to fruition via Operation Warp Speed. OWS was a government directed project that encouraged the far more rapid development of vaccines than ever before seen in human history. Under OWS, the federal government agreed to partner with industry by providing financing and expediting review processes, but also laying out a series of expectations in return. OWS capitalized on the power of triple helix collaboration – the ingenuity of scientific researchers in both the private and academic sectors, the directional and financial support of the U.S. government, and the vaccine and logistical know-how of the top American biopharmaceutical companies - to create multiple effective vaccines in record time. Typically, the development of a vaccine can take four to five years; OWS did it in nine months. Regardless of the manifest vaccine distribution challenges - an area where, once again, more collaboration would have been useful – the nine-month development period is an achievement worth celebrating and learning from. Furthermore, once the distribution challenges were worked out, the United States by the end of spring of 2021 had reached a state where everyone who wanted a vaccine was able to get it.



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Yet even in the successful area of vaccine development and distribution, more collaboration could have been useful at an earlier stage. Jason McClellan, a University of Texas at Austin molecular biologist who was instrumental in some of the scientific research that led to the rapid development of a number of SARS-COVID-2 vaccines, said that he had been working on coronavirus since 2013 with little interest from the wider scientific world. In 2016, he and two colleagues submitted a grant application to work on the "Structure-based immunogen design of a pan-betacoronavirus vaccine." They proposed to develop a universal vaccine for coronavirus, something that would have been incredibly useful at the beginning of 2020. Unfortunately, the applicant reviewers gave their proposal a low "Impact score" of 47, judging that "The application does not adequately justify the need for developing a vaccine for a pan-coronavirus. It is thought that the significance for developing a pan-coronavirus vaccine may not be high, as major coronaviruses known to infect humans are geographically distinct."

It is hard to justify this determination. While coronavirus may not have been a household word at the time. MERS and SARS had already emerged, and many in the pandemic preparedness space were already concerned about our lack of tools to cope with a larger coronavirus outbreak. In fact, in 2016, this author wrote in the book Shall We Wake the President that "One specific area that could stand improvement is the development of coronavirus countermeasures. Both MERS and SARS were worrisome pathogens, and the world lacked the countermeasures to combat them. Fortunately, science has advanced to the point where effective vaccine platforms will typically allow us to develop vaccines for new strains of an existing disease. With respect to flu, for example, we have the ability to develop new vaccines to inoculate against rapidly evolving new strains. With coronaviruses, we do not yet have those platforms."

Despite advance warnings and nascent research efforts such as McClellan's, when coronavirus struck in the form of SARS-COVID-2 in early 2020, the United States was unprepared. As noted above, the first two lines of defense failed, and the Strategic National Stockpile lacked the necessary countermeasures to respond. As a result, the only strategy the most technologically and medically advanced nation in the world could initially offer was to tell its citizens to shelter in place and wash their hands frequently. Initially, even masks were not recommended, and would not have been available even had they been recommended. Yet shortly after the disease shut down our society, the spirit of collaboration took

hold, and started to lead to vital innovations that would begin to show the pathway to the end of the pandemic.

Academic Collaborations

To be successful, the development of a vaccine required collaboration from government, business, and academia, with academia providing some crucial collaborations and innovations. American institutions that were particularly helpful in the development of countermeasures were the University of Pittsburgh, the University of Texas at Austin, and the University of Pennsylvania.

The academic collaborations took place at many levels. In the earliest days of the outbreak, entire campuses were shutting down, which had the potential to shut down vital research efforts as well. This potential shutdown led to some of the earliest necessary collaborations. In Pittsburgh, for example,



operations shut down in March of 2020 at the outset of the pandemic, but they made an institutional decision to keep research going. According to Cynthia Sweet, the University of Pittsburgh's associate vice chancellor for economic partnerships, the way Pitt did this was to "dedensify," to take active steps "to reduce the number of people in the labs."

According to Sweet, the de-densification efforts were led by the central administration team but with cooperation from a significant number of players across the university system. As Sweet put it, "The thought was to get things done with as few people as possible, but they recognized the priority to keep COVID research going." This decision paid significant dividends, as – thanks to the decision to keep 'dedensified' labs open – Pitt





had a dozen technologies developed in response to COVID-19. Among those technologies were two vaccine candidates that are still active, including a micro needle technology that could solve the problem of needle-phobic people being reluctant to get the vaccine via traditional injection.

The University of Texas faced a similar situation when it came to shutdowns at the outset of the pandemic. In March, UT shut down most of its operations, including all labs that were not working on COVID-19. This shutdown did not apply to McClellan, who had been looking at coronaviruses since 2013, but it did apply to the molecular bioscientist Ilya Fisher and the chemical engineer Jennifer Maynard. Maynard had previously worked with McClellan on pertussis, so she and Fisher emailed McClellan and offered to help him with his work on coronavirus. McClellan was happy to get the help, especially given the time pressures he was under, and all three scientists worked together and suggested six amino acid changes to the coronavirus spike protein.

This joint effort allowed McLellan and NIH researcher Barney Graham to generate what McClellan called a "great molecule" that they then "distributed to 100 labs around the world." The collaboration was, as McLellan noted, out of the ordinary, but time was of the essence in the effort to make better spikes and, working together, they succeeded.

KEY LEARNING

 Collaboration and widespread distribution of the "great molecule" was an essential step in the development of a COVID-19 vaccine. McClellan and Graham's work fit into a larger framework of collaborative work that was necessary to make successful vaccines. The University of Pennsylvania's Drew Weissman and Katalin Kariko helped develop the mRNA idea itself – that injecting mRNA coding could teach cells to combat the virus rather than the standard practice of using a version of the virus itself to generate an immune response. For that concept to work, though, vaccines required a lipid bubble to house and transport the mRNA into the body's cells. The University of British Columbia's Pieter Cullis was one of a team of researchers who had been working on that concept for over two decades. Graham and McClellan's work isolated the spike protein. And then the testing of the vaccines themselves was undertaken by the NIH and the companies, with approvals in an expedited but not less rigorous fashion coming from the FDA.

KEY LEARNING

 Operation Warp Speed both accelerated the research and streamlined rapid—but no less rigorous—FDA vaccine approval.

Through all this, the scientists on the ground also received unprecedented assistance from the federal government. In late March, federal officials at HHS realized they had an opportunity to leverage federal assistance to expedite vaccine development. According to former senior HHS official Paul Mango, the eureka moment came when he and other senior officials were reviewing a request from Johnson & Johnson for a \$450 million vaccine contract. This proposal led former HHS Secretary Alex Azar to ask, "we're gonna invest almost a half a billion dollars in this company. What are we getting in return? And because of this, how much are they accelerating their ability to develop a vaccine?" That conversation led to the initial development of Operation Warp Speed.

KEY LEARNING

3

• Operation Warp Speed enabled different pharmaceutical companies to work with the federal government in different ways, which is the essence of collaboration.

This OWS initiative had implications at many levels. It is primarily discussed as a collaboration between the federal government and the pharmaceutical companies, and that was certainly a key element. But even here, things were not as simple as often portrayed. OWS enabled different pharmaceutical companies to work with the federal government in different ways, which is the essence of collaboration. Government is often accused of having a "my way or the highway" approach to working with the private sector, but in this case, it was willing to be nimble and flexible to get the results it wanted and that the American people – and the rest of the world – needed.

The government provided funding in the form of direct assistance to companies that met its criteria for likely ability to get the job done, including AstraZeneca, Johnson & Johnson, Merck and IAVI, Moderna, Sanofi, and GlaxoSmithKline. Yet other companies, such as Pfizer and BioNTech, took no funds from the government for vaccine development, although the government agreed to provide manufacturing and distribution assistance upon approval. This approach meant



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KEY LEARNING

• Government can collaborate with the private sector in a nimble and flexible manner to get the results it wants.

The assistance from the government accelerated university research as well. According to the University of Pittsburgh's Sweet, the plentiful nature of federal funding available for coronavirus countermeasures – over \$100 million for Pitt projects alone – had tangible effects. Sweet spoke of one government-funded Pitt project that found blood thinners as a cheap and effective treatment option for moderately ill COVID-19 patients. According to Sweet, "this treatment option came about directly as a result of OWS funding." She further explained that while the federal government had supported their research before, it had never before done so at OWS levels. The speed and integration were remarkable. As she put it, "everything from conception of it to the distribution of the funding to the development of the therapies happened in under a year."

KEY LEARNING

 Working with multiple pharmaceutical companies to get to the same goal meant that the government provided the cooperation and assistance the companies felt they needed instead of a one-size-fits-all approach.

This unprecedented federal support brought about unprecedented results. Moncef Slaoui was a private-sector vaccine expert at Glaxo-Smith Kline who volunteered his time to the government to head the OWS effort. Slaoui understood the opportunity that the effort created. As he noted in an interview on CBS' Face the Nation, "the operation has helped accelerate the development of a number of vaccines, by either creating more financial incentive for a company like Pfizer or for the other five companies by actually accelerating, participating operationally into the development of the vaccine. And also, of course, financing the research and development."

Furthermore, Slaoui explained, the effort brought the vaccines to market at a remarkably cost-effective price. According to Slaoui, "The U.S. taxpayer money has indeed participated in the financing of all the expenses, the research and development, the buildup in manufacturing. But in exchange for that, of course, this was the cost to acquire a hundred million – with options to more hundreds of millions of doses as we are experiencing. So it's part of the cost. I mean, ultimately, \$20 per dose of vaccine is actually a good cost for a vaccine dose. Most vaccines in the private market are sold for a hundred or \$200 a dose."

Other Collaborations

The collaborative spirit that Slaoui brought to the job as vaccine coordinator (with no salary) was reflective of the approach that many Americans brought to addressing the pandemic. The University of Pittsburgh's Sweet appreciated the variety of collaborations that took place as well. She recalled that

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in March and April, companies were calling and offering to help in any way they could. These offers included businesses that were willing to retool their manufacturing processes to develop needed goods like personal protective equipment and hand sanitizer. According to Sweet, "these companies were worried about making payroll but were more interested in contributing." Interestingly, UIDP, a non-profit membership organization focused on facilitating university-industry research collaboration, also shifted gears rapidly to strengthen cross-sector partnerships, moving proactively to enable research connections via virtual networking and collaboration channels during the pandemic. As Sweet recalled, "this platform, with weekly and monthly meetings, kept the conversation going on key research ideas."

Collaboration: A winning formula

The effort to develop countermeasures for SARS-COVID-2 was a nationwide endeavor, requiring multiple players working in concert to bring a vaccine from a concept into millions of arms in less than a year. Despite a number of missteps in the early going – largely based on problematic failures to collaborate – once America's scientific community awakened to the enormity of the challenge, it accomplished great things through collaboration in a record time. Sweet summed it up best: "The response between university, industry, and government all going in the same direction are awe inspiring – they made it possible for America to respond in a rapid manner." The SARS-COVID-2 pandemic taught us many things, but most important among them was reminding Americans of the benefits of collaboration in solving thorny problems

Tevi Troy is a senior fellow at the Bipartisan Policy Center and a best-selling presidential historian. His latest book is Fight House: Rivalries in the White House from Truman to Trump, named as one of 2020's top political books by The Wall Street Journal.

On August 3, 2007, Troy was unanimously confirmed by the U.S. Senate as the deputy secretary of the U.S. Department of Health and Human Services. Troy has extensive White House experience, having served in several high-level positions over a five-year period, culminating in his service as deputy assistant and then acting assistant to the president for domestic policy.

From 1998 to 2000, Troy served as the policy director for Senator John Ashcroft. From 1996 to 1998, Troy was senior domestic policy adviser and later domestic policy director for the House Policy Committee.

From 2014 to 2018, Troy was the founder and CEO of the American Health Policy Institute. Before that, he was senior fellow at Hudson Institute, where he remains an adjunct fellow. He has also been a researcher at the American Enterprise Institute.



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4