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HEALTH

Operation Warp Speed promised to do the impossible. How far has it come?

By HELEN BRANSWELL @HelenBranswell, MATTHEW HERPER @matthewherper, LEV FACHER @levfacher, ED SILVERMAN @Pharmalot, *and* NICHOLAS FLORKO @NicholasFlorko
/ SEPTEMBER 8, 2020

Reprints

ALEX HOGAN/STAT

It's called Operation Warp Speed. And — regardless of one's politics, one's level of concern about Covid-19, or one's views of therapeutics and vaccines — it inarguably ranks as one of the most ambitious scientific endeavors in modern U.S. history.

Is it working?

Roughly five months after top U.S. health officials coalesced around the idea of a public-private effort to accelerate the development, manufacturing, and distribution of Covid-19 vaccines, therapeutics, and diagnostics, an answer to that question remains out of reach. But with billions of federal dollars already spent on the effort, it's possible to take stock of the initiative's progress, or lack thereof.

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Here's an assessment of the work so far.

All in on vaccines

If all goes well, the fast-tracking of vaccine development, which normally takes years, will have been telescoped down to about a year. To date, the fastest a vaccine was ever developed was four years.

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Operation Warp Speed, or OWS, has already spent about $10 billion to help vaccine makers develop their candidates and build out production capacity to make vaccines at commercial scale. An innovation of this process: The vaccine makers are already producing doses, before they even know if the vaccines work. The idea is that if a vaccine is shown to be protective, use of it can start immediately. Moncef Slaoui, the scientific head of OWS, told STAT last week that the initiative has already started to stockpile upward of hundreds of thousands of doses.

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"That number will ramp up as the scale goes up, and that machine, if you wish, warms up," he said.

Contracts with six manufacturers have been announced; another one or two may be coming, Slaoui said.

There have been ripple effects, however. In placing itself at the front of the line to receive vaccine doses from the OWS manufacturers, the United States has ignited a vaccine nationalism wildfire, which is reaching conflagration status. Wealthy governments have locked down more than 4 billion doses of vaccines so far, with the United States topping the list with commitments for 800 million initial doses and options on another 1.6 billion doses; new bilateral purchase agreements are announced almost daily.

The World Health Organization and other global health agencies have argued that early access to vaccines should be shared across the nations of the world to help protect health workers, but the U.S. position has been that it will vaccinate Americans first, and share second. "We want to get our oxygen mask on first and then we're going to help the people around us," an unnamed administration official told Science in May.

Richard Hatchett, CEO of CEPI — the Coalition for Epidemic Preparedness Innovations — acknowledged recently that the bilateral purchase agreements could snowball, if countries increasingly fear this is their only option. But he also believes the rest of the world will get vaccine sooner because of the investment the U.S. government has made.

"I don't think you can characterize the behavior of the country as being all one thing or another," Hatchett told STAT. "They have invested … many billions of dollars in terms of funding the basic work and the clinical trials and the development of vaccines that will serve the needs of the world. They have invested more than all the rest of the world in aggregate."

A modest impact on therapeutics

When it comes to therapeutics — which many observers believed would be important tools before the approval of any vaccine — OWS has had a far more modest impact.

The initiative has made only one major investment in manufacturing: a $450 million payment to Regeneron to build up manufacturing for its monoclonal antibody treatment, which is still in clinical trials. OWS has also provided support to studies of a similar medicine being developed by Eli Lilly. It's hoped that the antibodies will be able to be used both for treatment and prevention of Covid-19, but experts still worry about whether pharmaceutical companies can make enough of these treatments should they prove effective.

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A major government-run study begun before OWS was involved showed that remdesivir, a drug developed by Gilead Sciences, shortened the time it took for patients to recover from Covid-19 by four days. This moderate effect is still the best seen by a new drug for Covid. A much older treatment — the steroid dexamethasone — was shown to have a big benefit late in Covid-19 by a study funded not by the United States but by the United Kingdom.

A limited role on diagnostics

The inability to manufacture and provide widespread access to diagnostics has been one of the biggest failures of the U.S. response to the pandemic. Responsibility for that failure is spread across both the public and private sector.

On its site, OWS lists the development and testing of diagnostics as one of its five focus areas. The reality is that the initiative appears to have stayed largely on the sidelines, with the National Institutes of Health taking the lead.

An NIH effort, the Rapid Acceleration of Diagnostics (RADx), is funded with $1.5 billion, a sixth the OWS budget. By the end of the year, that program aims to have its awardees add 6 million tests per day to the number that can currently be conducted.

A big bet on materiel, with some risks involved

Manufacturing hundreds of millions of vaccine doses is a gargantuan challenge in and of itself. But the effort has set off a parallel scramble to avoid a comparatively low-tech bottleneck: potential shortages of the syringes and pharmaceutical-grade glass vials needed to transport and administer the vaccines, once they've been approved for use.

The federal government has doled out several major contracts to companies rushing to ramp up manufacturing capacity for the essential glassware. In May, OWS awarded $138 million to ApiJect, a small company that makes an as-yet-unapproved product that would inject vaccine into syringes before shipment. The contract calls for 100 million prefillable syringes by the end of 2020 and another 500 million by the end of 2021.

The Department of Health and Human Services and the Department of Defense also awarded roughly $350 million in June to two companies already in the business of manufacturing containers for vaccines and pharmaceuticals. Roughly $200 million went to Corning for a capacity expansion that would allow the company to churn out 164 million glass vials each year, and another $143 million went to SiO2 Materials Science to allow for the manufacture of 120 million glass-coated plastic containers each year.

Some announcements have raised questions about the government's procurement process and its methodology for awarding no-bid contracts. Before the Covid-19 pandemic, ApiJect had only manufactured its prefillable syringe in prototype form and limited quantities. And the company's own executives have acknowledged there's no precedent for using the technology en masse — especially not during a pandemic.

Prefillable syringes "have to be precisely manufactured under the right conditions," said Irwin Redlener, the director of the Pandemic Resource and Response Initiative at Columbia University. "It's really unconscionable that a small company is being given this kind of responsibility."

But contracts to expand capacity established manufactures like Corning and SiO2, he said, induce more confidence.

"It's nothing new for them," he said, "and they're well-established companies with good track records."

Major questions on vaccine distribution plans

When it comes to OWS plans to distribute vaccines when they become available, the initiative has not been forthcoming.

Groups that are normally responsible for last-mile planning — getting vaccine doses to the places where they'll be administered — haven't received a lot of information about the role they will or won't play this time around.

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"There are still lots of big questions that remain, and it's getting toward crunch time," said Claire Hannan, executive director of the Association of Immunization Managers.

Some OWS skeptics in the public health world were heartened when the administration announced it had contracted with McKesson, one of the three largest pharmaceuticals wholesalers in the U.S., to be a "central" distributor of vaccines. McKesson plays this same role in the annual distribution of influenza vaccines.

The company's role here has not been clearly defined, but it stands to reason the wholesaler will function as something of a hub in a distribution wheel, shipping containers to facilities around the country. STAT asked McKesson for more information, but has not yet received a reply.

Distribution, of course, is fraught with challenges, including some related to security. Although vaccine makers and wholesalers have long had procedures in place to thwart cargo theft, they will have to invest in additional sensors to track shipments around the country.

Beyond security, some of the pending questions can't currently be answered, like how many vaccine doses will be available for use when the first one or two or three vaccines get approved. And the various groups working to prioritize who should get first access to the vaccines aren't yet finished with their work, so granular planning around priority groups — Who is an essential worker in Omaha, Neb.? Tallahassee, Fla.? — can only go so far.

Planners also have to consider they may first be distributing a vaccine that requires ultra-cold storage. Pfizer's vaccine, if it works, must be kept at -70 Celsius, which pretty much rules out administration in doctors offices. Or they may be distributing a couple of types of vaccines, with different cold-chain requirements.

Low marks on transparency

Basic questions about what is being done and why are often not laid out. It's not crystal clear, for instance, why OWS picked the vaccine projects to fund that it did, or how the process was handled.

The trial protocols for the studies, which would explain what and how analyses are being done, have not been published. However, for the trial of Moderna's vaccine, data on the diversity of the participants are being regularly made public.

Key public health professionals across the country have been in the dark about how Covid-19 vaccines, once available, will be distributed and administered.

Matthew Hepburn, a Defense Department official who heads the vaccines portion of OWS, ruffled feathers in June when he made a presentation to the Advisory Committee on Immunization Practices, an expert panel that develops vaccination guidance for the Centers for Disease Control.

ACIP presentations routinely involve data-rich slides. Hepburn said he hadn't received clearance to present slides, but looked forward to liaising with ACIP in future. The group, which was at that point struggling to find out if — as would normally be the case — it would be tasked with determining which Americans should be at the front of the line for vaccines when they become available, was not impressed. Several members asked Hepburn pointed questions he pointedly did not answer.

A careful balance with regulators

The Food and Drug Administration, which is playing a critical role in the response to the pandemic, has virtually no visibility into OWS — but that's by design.

Two senior FDA officials told STAT the agency couldn't even explain the structure of OWS or when its leaders meet. The FDA has set up a firewall between the vast majority of staff and the initiative to separate any regulatory decisions from policy or budgetary decisions.

FDA officials are still allowed to interact with companies developing products for OWS, but they're barred from sitting in on discussions regarding other focuses of OWS, like procurement, investment or distribution.

Even FDA Commissioner Stephen Hahn is removed from the day-to-day workings of OWS, an FDA spokesperson confirmed to STAT.

Helen Branswell, Matthew Herper, Lev Facher, Nicholas Florko, Ed Silverman, and Damian Garde contributed to this report.

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Former NIH Researcher

SEPTEMBER 9, 2020 AT 4:06 PM

Slightly off topic but very important new information:
Covid tests may be 1000 times too sensitive

From an article in NYT:

"The PCR test amplifies genetic matter from the virus in cycles; the fewer cycles required, the greater the amount of virus, or viral load, in the sample. The greater the viral load, the more likely the patient is to be contagious.

This number of amplification cycles needed to find the virus, called the cycle threshold, is never included in the results sent to doctors and coronavirus patients, although it could tell them how infectious the patients are.

In three sets of testing data that include cycle thresholds, compiled by officials in Massachusetts, New York and Nevada, up to 90 percent of people testing positive carried barely any virus, a review by The Times found.

On Thursday, the United States recorded 45,604 new coronavirus cases, according to a database maintained by The Times. If the rates of contagiousness in Massachusetts and New York were to apply nationwide, then perhaps only 4,500 of those people may actually need to isolate and submit to contact tracing.

One solution would be to adjust the cycle threshold used now to decide that a patient is infected. Most tests set the limit at 40, a few at 37. This means that you are positive for the coronavirus if the test process required up to 40 cycles, or 37, to detect the virus.

Tests with thresholds so high may detect not just live virus but also genetic fragments, leftovers from infection that pose no particular risk — akin to finding a hair in a room long after a person has left, Dr. Mina said."

This means that the number of those who are now tested positive should be divided by 1000, also the dead, of course. They may die from anything and be counted as Covid if they have traces of Covid proteins. That means that there are 27,931 cases in the world, and a total of 905 deaths to date, in the world.

Since the only thing that makes a death a covid death, is the PCR test, they may have died from any of the 150 viruses sirculating at any time or any of the commodities that most have. Only 6% seem to die from Covid alone, but remember even these are flu deaths where SARS CoV 2 is the only virus tested for. All of the symptoms are extremely vague and common to most flus and pneumonias.

With the new information there have been only 194 deaths in the US and 6,529 people really contaminated. This seems ridiculous, but if the testing machine had been stopped at the point the researchers say, the numbers would not have been higher than that. The tests would not have been counted as positive, neither for the contaminated nor the dead.

The whole point is that the false positives are both for cases and for deaths, so case fatality percentages stay exactly the same.

Reply

Former NIH Researcher

SEPTEMBER 9, 2020 AT 4:07 PM

With this counting, we are approaching 200 deaths from Covid in the US.
So where do all the other excess deaths come from?
These could be results of lockdowns, e.g. not getting treatments in hospital for cancers heart attacks etc. I could also be from over treatment of anyone with a positive corona test, e.g. by intubating. Anyway, the deaths are in people at the average life expectancy or older, and may be "low hanging fruits" left over from a very mild flu season. Many old people may have died from neglect and have lost their will to live in the loneliness from lockdown.
See more thoughts on Covid at cividscience.blogspot.com

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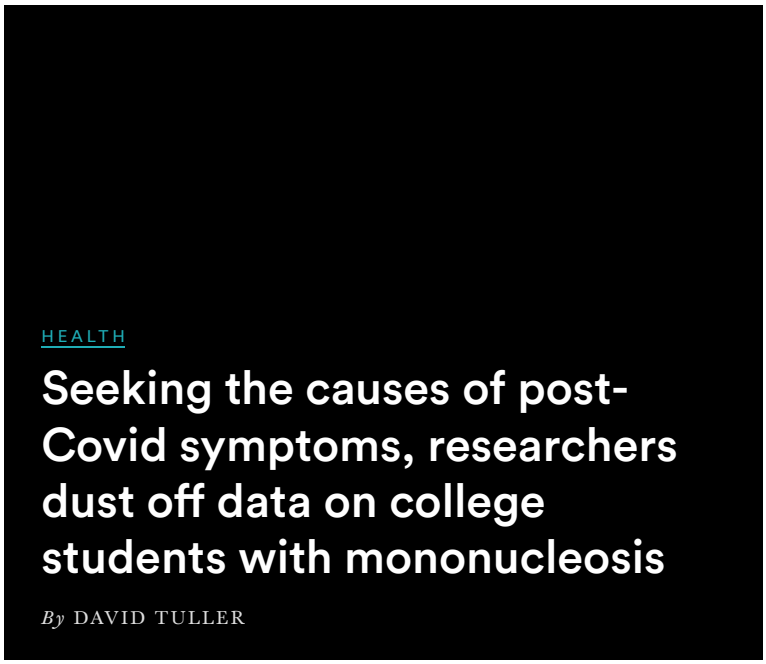

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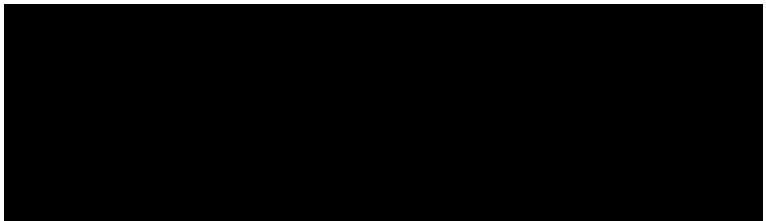

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