

A RACE TO SAVE LIVES

Project on track to deliver COVID-19 vaccine in record time

By Robin Roenker

OPERATION WARP SPEED (OWS) — a joint partnership between the Department of Defense (DOD) and the Department of Health and Human Services (HHS) — was launched by the Trump administration in March. Its stated goal: to produce and deliver a safe and effective COVID-19 vaccine to 300 million people, with initial doses available by January 2021.

It's rare for any vaccine to be developed in under five years, and yet OWS has set its sights on delivering one in less than 12 months.

The scale, difficulty and importance of the challenge cannot be overstated.

As of early December, COVID-19 had claimed the lives of more than 260,000 Americans. Some 13 million cases have been reported nationally, with outbreaks continuing to spike across the country.

President Trump has called OWS "a massive scientific, industrial and logistical endeavor unlike anything our

country has seen since the Manhattan Project." To date, Congress has allocated roughly \$10 billion to the vaccine-development effort. "This is a whole-of-America approach," says Army Gen. Gustave F. Perna, Operation Warp Speed's chief operating officer. "The world's best doctors working beside the world's best military, with the support of American industry and academia — that really is Operation Warp Speed. It is a collective team approach."

EXPEDITING A VACCINE

In addition to leadership roles by DOD and HHS, OWS' scope includes essential work by the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, Food and Drug Administration (FDA) and other federal agencies, plus, from the private sector, six pharmaceutical companies with leading vaccine candidates — Moderna, Pfizer,

AstraZeneca/University of Oxford, Johnson & Johnson, Novavax and Sanofi/GlaxoSmithKline.

Learn more about the Department of Defense's work to combat COVID-19 and secure a vaccine at [defense.gov](https://www.defense.gov).

By funding production of each of the six leading vaccine candidates before they complete clinical trials and receive final approval from the FDA, Operation Warp Speed is on target to dramatically shrink traditional timetables for vaccine development and delivery.

As of mid-October, Perna says he believes "vaccines will come in the tens of millions prior to the end of the year and will expand rapidly to hundreds of millions in the following months, into the new year." At an Oct. 21 press briefing, HHS Secretary Alex Azar concurred, noting that high-risk Americans — including first responders, health care workers and seniors — should be able to receive a vaccine by January, with the

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Jessie Garcia, a sailor assigned to Naval Medical Center San Diego, prepares medication at the clinic in September. Operation Warp Speed continues to oversee ongoing research and testing to screen and treat patients who are already infected with COVID-19.

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Minook Choo, a laboratory manager with the emerging infectious disease branch at the Walter Reed Army Institute of Research in Silver Spring, Md., is studying ways to prevent and treat the coronavirus.

remaining population likely having access to a vaccine by April 2021.

The expedited timeline does not, however, mean that protocols were skipped when it comes to evaluating the safety and efficacy of the vaccines. All standard CDC and FDA guidelines for vaccine development, testing and approval are being followed.

"We will take zero shortcuts with the safety of the vaccine," Perna says. "There are zero shortcuts with respect to the science of what we're doing. We are following protocols with exactness and being led by data that's being driven and approved by the greatest scientists in the world."

By sourcing necessary materials for the vaccine candidates' manufacture, securing and staffing production facilities across the U.S. and funding

production to occur simultaneously with testing, OWS is making it possible "to be ready to distribute (the vaccines) immediately upon (FDA) approval to the whole of America," Perna says. "Everybody is going to have access to this vaccine."

TAPPING THE MILITARY'S LOGISTICAL EXPERTISE

With the goal of a successful vaccine in sight, OWS still has many challenges to address — from securing supply chains for hundreds of millions of glass vials and hypodermic needles to delivering the vaccine, most likely in a required refrigerated capacity, from current U.S. production facilities to tens of thousands of doctors' offices, health departments, long-term care facilities and pharmacies across the

country.

To tackle these potential hurdles, DOD and the various branches of the U.S. military will put their tactical and logistical expertise into play.

"In the nationwide effort to develop a vaccine as part of Operation Warp Speed, the Department of Defense is proud to provide the bandwidth of our tremendous logistical expertise, including program management and contracting proficiency, to the COVID-19 fight," says former Defense Secretary Mark Esper. "With the DOD's augmentation of knowledge and personnel to support and enhance HHS capabilities, together we are expanding the commercial production capacity for vaccines in the United

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Army Gen. Gustave F. Perna delivers remarks during an update on vaccine development at the White House on May 15.

States at a scale that did not previously exist."

While OWS' original stated goal was to develop and deliver 300 million doses of an effective COVID-19 vaccine, several of the leading vaccine candidates require two doses per patient. Therefore, the scope of the project may double to require the production of 600 million doses or more in the coming months.

The task is daunting, but not impossible, says Perna. "In simple terms, what the DOD brings is an expanding capability and capacity to achieve this really Herculean task," he says. "We brought technical experts in to help advise us on how vaccines are manufactured, so that we are not trying to learn it on the go. We take their expertise, and then we manage

it in program form. We have personnel from all the (military) service branches helping us, and they come in with rich program management skills. They know how to look at things and hold people and organizations accountable to execution."

For example, Perna points to the DOD's acumen and experience in acquisition and contracting as one factor helping to facilitate the many government, industry and academic partnerships that have played a role in achieving the expedited vaccine development timeline.

Alongside its work to support vaccine development and delivery, OWS continues to oversee ongoing research and testing for improved COVID-19 diagnostics and therapeutics to improve the health care system's

ability to screen and treat patients who are already infected.

But the end goal for everyone — from laboratory scientists and frontline health care workers to government leadership — is the delivery of an effective vaccine. On everyone's minds is a common hope: A vaccine will not only save lives, it might also signal that life, finally, can slowly regain a bit of normalcy for American businesses, schools and families.

For its part, the U.S. military plans to stop at nothing to reach that goal. "We (the DOD) are very good at planning," says Perna. "We can see beyond today. We can go at different horizons — be it tactical, operational or strategic. And we can put all this together and drive from one event all the way through to the end state."