

OPERATION WARP SPEED (OWS) COVID-19 VACCINES AND TREATMENTS

SHARED BY THE GOP DOCTORS CAUCUS



Key Messaging Ideas

- We are in the process of developing safe, effective vaccines & treatments faster than ever before thanks to American ingenuity
- Operation Warp Speed is safe and sound – due to modern efficiency, technology, and old fashion determination of effort.
- A safe, effective vaccine is the key to restoring our normal way of life
- Vaccines save lives. Vaccines prevent illness. Vaccines prevent the spread disease.
- Vaccines have rendered deadly diseases like polio obsolete. (Share specific, personal examples of how vaccines have helped you, your loved ones, or society)
- In some ways, COVID-19 is like many other flu-like viruses, yet, in many ways, it is unlike any other.
- COVID-19 is new, a never seen before virus. It is different, it is “novel.”
- Like previous influenza-type viruses, certain individuals are more at risk than others, and greater preventive measures must be taken.
- Symptoms from COVID-19 may vary: none, fever, loss of taste and smell, cold-like, flu-like, breathing difficulties, death.

WHAT IS OPERATION WARP SPEED?

Operation Warp Speed is America’s common-sense path forward, in a historic effort, to safely bring COVID-19 testing, treatments, and vaccines to the American people in record time.

Goal:

Develop 300 million doses of a safe, effective COVID-19 vaccine by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).

The Federal government is coordinating with private vaccine researchers in order to draw from the best that each has to offer so that we accelerate the development and production of a safe and effective vaccine treatment.

Current Status of OWS Vaccine Development

Dozens of potential vaccines are already in clinical development testing phases. As of early August, at least three promising vaccine candidates began Phase III trials - the final stage of clinical trials.

These potential vaccines will be tested on thousands of volunteers and evaluated for effectiveness and safety. While there are no guarantees of success with trials, if Phase III trials are successful, we may be only months away from a safe, effective coronavirus vaccine.

The testing standards are the same as any other vaccine developed domestically, however, the speed has been accelerated as the magnitude of the process has been enhanced. There is a path forward and we have reasons to be hopeful. Part of the path forward includes treatments have safely developed.

OWS Treatments

Our medical community continues to develop innovative therapeutics to treat COVID-19 that can improve outcomes and help patients recover faster. Since February, we have made great advances in treating symptomatic COVID patients and we have decreased the mortality rate 40 percent. Best practices are being refined determining when someone should be treated, and how, for best outcomes.

It is better to treat a patient sooner, rather than later. It is better to treat a patient before they are in need of more extensive care.

Through OWS, existing treatments (such as anti-viral, convalescent plasma, and steroids) are showing positive results. Many care regions are showing a smaller percentage of COVID positive patients needing hospitalization and a smaller number of patients needing intensive care.

What is Convalescent Plasma?

Patients who have recovered from COVID-19 have antibodies against the virus in a part of their blood called plasma. Through simple blood donations, antibodies from a patient that has had, and recovered from, COVID-19, can be given to patients to assist in their recovery and help save a life.

Many of the more than two million Americans who've recovered from COVID-19 are eligible to donate and should consider doing so. President Trump has recently launched a nation-wide call to action, encouraging plasma donation.

Why a vaccine?

Vaccines are prevention. It is common sense to aspire to prevent a disease from ever taking hold. While treatments fight disease and the symptoms of disease, vaccines, once administered, are used to block disease.

OWS Vaccines will be safe

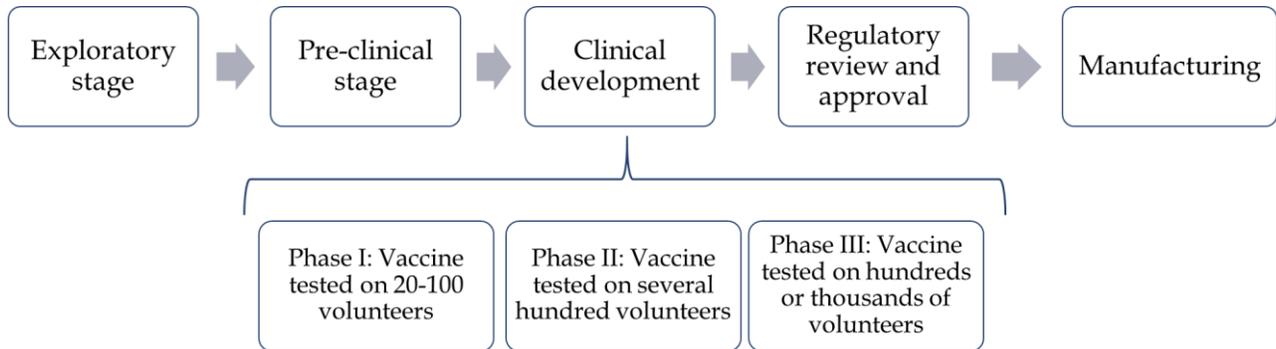
It makes medical and scientific sense, as well as common sense, that COVID -19 vaccines are to go through the same, if not more, rigorous testing as previous vaccines to ensure that they are safe and effective.

Vaccines have helped our society defeat diseases like polio and measles.

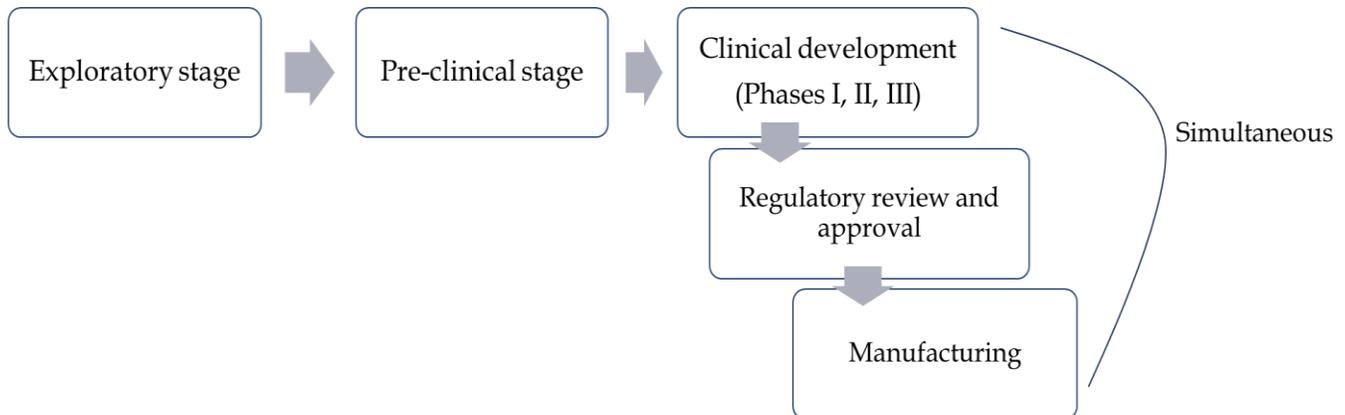
How is OWS different from the typical process?

Typical vaccine development takes 10 to 15 years, and each step occurs one at a time. Under OWS, vaccine testing, regulatory approval, and manufacturing occur simultaneously. This means a possible vaccine could be developed in mere months.

Typical Vaccine Development Process (10 to 15 years)



Operation Warp Speed Process (Less than 12 months)



Our vaccines are showing clear signs of positive results. We will not proceed until proven effective and safe for patient use. Mass production capabilities are already being arranged for the moment that all phases of vaccine development are thoroughly proven to be safe and effective.

DEVELOPING BEST PRACTICES

Operation Warp Speed (OWS) is working with world-leading scientists to develop and inform about best practices in relation to testing, monitoring, and treating COVID-19.

Test, Monitor, Treat

1. **Testing** 6-7 day wait / Point of Contact – no wait

The federal government is working to expand testing capacity and reduce the current wait times and get results faster. This includes funding to develop more accessible point of contact testing so there is no wait for results.

The National Institutes of Health (NIH) launched the [Rapid Acceleration of Diagnostics \(RADx\)](#) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. Accurate, fast, easy-to-use, and widely accessible testing will help us restore our normal way of life.

2. **Monitoring**

- Thermometer to measure temperature.
- Pulse Oximeter to measure O₂ in blood.
 - *Indicates breathing function*
 - *If trending downward with home monitoring, treat sooner rather than later*
- Other physician led monitoring:
 - *CT scan of lungs (infiltrates indicate disease)*
 - *Blood work: inflammatory markers (i.e, IL-6)*

Americans can monitor their health at home, including thermometers to take their temperature and pulse oximeters to measure blood oxygen levels, which indicates breathing function. If either of these vital signs are trending outside normal ranges, they should consult with their doctor and seek treatment sooner rather than later.

If someone is exhibiting symptoms, believes they have COVID-19, and/or is awaiting test results, they should self-isolate and quarantine until they are confident they are not sick and cannot transmit the virus to others.

Additional diagnostic tools your doctor may utilize include a CT scan of the lungs to measure COVID-19 indicators and blood work to measure inflammatory markers, like IL-6.

3. Treatments

We know a lot more about how to treat COVID-19 than we did in March, and Operation Warp Speed is adding to our understanding of how to best treat patients to keep them out of the hospital and recover faster. Treatments that are showing potential include:

- Isolation / quarantine
- Anti-viral medications
- Autoimmune disease treatment
 - *Hydroxychloroquine*
- Antibiotic treatment
 - Azithromycin
 - *(to help prevent secondary bacterial lung infection)*
- Convalescent plasma / hyperimmune globulin
 - *(antibodies from those previously infected)*
- Steroid treatments
 - *(to reduce inflammatory reaction to virus)*
- Monoclonal antibodies

The U.S. Government and Operation Warp Speed are working to both conduct trials and distribute effective treatments as safely and quickly as possible. These efforts include:

- **Remdesivir, an anti-viral drug**, which has been shown to decrease mortality and speed up recovery time.
 - HHS has secured more than 500,000 treatment courses of the drug for American hospitals through September. ([HHS](#))
- **Convalescent plasma & hyperimmune globulin** - antibodies that combat the virus.
 - The plasma of individuals who have recovered from an infection like COVID-19 may contain antibodies made by the immune system that can combat the virus.
 - HHS is promoting a PSA campaign to encourage recovered Americans to donate plasma. ([HHS](#))
- **Steroid treatments - to reduce inflammatory reaction caused by virus.**
- **Hydroxychloroquine / Azithromycin**
 - Hydroxychloroquine is an FDA approved drug for malaria and autoimmune diseases. Hydroxychloroquine, in combination with FDA approved antibiotic azithromycin, *by some preliminary reports*, may benefit COVID-19 patients. Numerous clinical trials are underway, including with NIH. ([NIH](#))
- **Monoclonal antibodies** are manufactured antibodies that can help fight COVID-19.
 - The NIH is studying the investigational monoclonal antibody “LY-CoV555,” which was identified in a blood sample from a recovered COVID-19 patient, through their ACTIV-3 Study as part of OWS. ([NIH](#))

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Additional National Top Lines Messaging

- **THREE KEY WORDS/PHRASES TO USE IN EVERY INTERVIEW:**
 - **PATH FORWARD**—The President is leading the country out of this pandemic
 - **SAFE**—everything we are working on: school reopening, vaccines, treatments, etc. are all about keeping your family SAFE.
 - **COMMON SENSE**—People should exercise caution, everyone can follow common sense guidelines to keep their families, neighbors, and safe.
- **THE WHY:** COVID-19 is an unprecedented global challenge; a pandemic that no one has faced in our lifetimes. As we work together to combat this terrible virus, the Trump Administration is heightening its engagement with 25 cities that are the top “areas of concern” for increasing COVID cases. Under President Trump’s direction, we are calling because we believe if everyone is in this together, **we can prevent your city from becoming the next hot spot.**
- **STILL A GLOBAL CHALLENGE:** New outbreaks continue throughout the world, even for countries who previously through the virus was behind them. COVID-19 is spreads equally in areas. **President Trump urges everyone to be cautious.**
- **UNPRECEDENTED VACCINE AND TREATMENT DEVELOPMENT:** The Trump Administration continues an unprecedented, groundbreaking effort to deliver safe and effective vaccines, therapeutics, and diagnostics at historic speed for Americans. Operation Warp Speed (OWS) has a mandate to begin the delivery of 300 million doses of safe and effective vaccines by early 2021. OWS will consider partnering with any company that can deliver safe and effective vaccines and therapeutics and rapidly scale up manufacturing to meet delivery throughout the United States and its territories. The advancements in vaccine and therapeutic research made through OWS means we are in a better position than ever before to combat the coronavirus, keep Americans safe, and protect vulnerable communities.
- **WHAT DO WE DO?:** It’s time for every individual to re-commit to mitigation efforts that President Trump continues to emphasize: **(1) if you feel sick, stay home, (2) practice social distancing, (3) wear a mask when you cannot social distance, (4) wash your hands frequently and practice good hygiene. (5) Americans should be extra careful in closed or indoor spaces,** like bars and restaurants.
 - **Don’t forget the 3 W’s:**
 - **Wash Your Hands**
 - **Wear a Mask**
 - **Watch Your Distance**
- **WHO TO PROTECT:** President Trump wants to protect all Americans, including our most vulnerable—the elderly and those with underlying health conditions.

- **IT'S NOT TOO LATE:** By acting now, we can contain and manage the spread so that fewer people get seriously sick and the economy stays open.
- **PATH FORWARD:** (1) **We know much more now than we did in March.** We know that if individuals use common sense and are vigilant, we can safely keep the economy open. (2) **Treatments work!** Due to the power of American ingenuity and innovation, we now have therapeutics to better treat COVID, and help more people recover. Also, **Vaccines are progressing** at an incredible, historic pace. (3) **Our medical system is now much more prepared** to handle capacity and testing has increased exponentially, enabling our death rate from COVID to decrease significantly.