

Q.) Is there a vaccine that protects against COVID-19 (SARS-CoV-2)?

No. Currently, a vaccine against COVID-19 is not available, but several are in clinical trials. Six vaccines are currently being manufactured at the same time that clinical trials are occurring, so if approved for distribution, doses are available. If not approved, manufactured doses will be discarded.

Q.) When can we expect a vaccine to be available?

No one knows exactly when a COVID-19 vaccine will be available, although late 2020 or early 2021 are a possibility. Availability will be dependent on the results of clinical trials. Early on, it is likely that vaccine will be limited to certain priority groups.

A COVID-19 pipeline tracker is available [online](#).

Q.) Why is this COVID-19 vaccine process so condensed compared to when other vaccines are licensed?

Some of the approaches that are being employed to shorten the timeline ***without sacrificing quality and safety*** include:

- Utilizing existing technology – Many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.
- Developing vaccines immediately after viral genome sequence is available.
- Financing – The federal government has provided financing for COVID-19 vaccine development.
- Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, they will have large numbers of doses ready. This is not typical because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.
- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:
 - Developing plans for how to distribute the first, limited quantities that will be available
 - Ensuring adequate supplies for distributing and administering vaccine, like vaccine vials, syringes and other equipment needed to vaccinate
 - Establishing mechanisms for distribution to large subsets of the population

A diagram explaining how the process has been shortened is available from [Operation Warp Speed](#).

Q.) The development and production of a COVID-19 vaccine has been called “Operation Warp Speed,” does this mean shortcuts have been taken?

Operation Warp Speed is a partnership between the U.S. Department of Health and Human Services, the U.S. Department of Defense, and the private sector. The goal of Operation Warp Speed is to accelerate the development, manufacturing, and distribution of COVID-19 vaccine.

The Food and Drug Administration (FDA) has a well-outlined regulatory process that assures any licensed vaccine has gone through a rigorous process to assure that it meets a standard for safety and efficacy before being released. All COVID-19 vaccine candidates being studied in the U.S. are in the process of completing these rigorous studies with no compromises in the process.

What has been significantly shortened (i.e. the “warp speed”) is the production process. The federal government has decided to fund the production of the leading vaccine candidates at the same time they are undergoing studies to assure their safety and efficacy. Should the vaccine candidate meet the FDA’s safety and efficacy requirements, supplies would then be ready to start immunizing right away.

A summary of Operation Warp Speed’s Strategy and Approach is found in the [New England Journal of Medicine](#).

Q.) What will be needed to license a COVID-19 vaccine in the U.S.?

Vaccine manufacturers must follow guidance provided by the FDA while developing any COVID-19 vaccine. This includes requirements to share information about how they determined that a vaccine is safe and effective. They will need to provide data for review and information, so the FDA and other scientists can understand how the studies were designed, how many people were evaluated, and how the testing to obtain the data was done.

Q.) What is Emergency Use Authorization?

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. It is likely that a COVID-19 vaccine will be made available using an EUA.

The FDA has established strict safety and efficacy [criteria](#) in order for a vaccine to be approved through EUA. Criteria includes two months post vaccination data, minimum clinical trial size, at least a 50% effectiveness and a certain number of COVID-19 cases in participants. COVID-19 vaccines will also be reviewed by external, independent experts.

Additional information about EUA is available on FDA’s [website](#).

10/16/2020

Some information taken directly from the [Children’s Hospital of Philadelphia Vaccine Education Center](#).

Q.) Is the COVID-19 vaccine safety tested?

All possible vaccine candidates are in various stages of testing in order to ensure they are both safe and effective. We will know more once those studies conclude. If a serious potential adverse event is noted during a clinical trial that trial may be paused while that event is investigated. It's typical for most vaccine candidates to not make it to the final stages of testing. Additionally, it is possible that not all COVID-19 vaccine candidates will come to market.

Q.) How does the size of COVID-19 vaccine clinical trials compare to clinical trials for other vaccines routinely used in the United States.

According to an [article](#) published in *Human Vaccines and Immunotherapeutics* in 2012, phase III clinical trials for vaccines currently being used in the United States included, on average, 29,844 participants. Ongoing phase III clinical trials for COVID-19 vaccine include or plan to include at least 30,000 participants.

At the September ACIP meeting, the number of participants in clinical trials and diversity of participants were [presented](#).

Q.) How will safety of the COVID-19 vaccine be monitored?

COVID-19 vaccine safety will continue to be monitored after it is made available to the public. The [vaccine adverse events reporting system](#) (VAERS) will be used to identify signals that might indicate a safety issue. The [Vaccine Safety Datalink](#) will also be used. VSD is an active surveillance system that monitors electronic health data for adverse events in various healthcare settings. The [Clinical Immunization Safety Assessment Project](#) (CISA) will conduct clinical research and assess complex vaccine safety issues. A new, additional safety monitoring program is also planned to monitor COVID-19 vaccines. Information about this program was discussed at the September Advisory Committee on Immunization Practices (ACIP) meeting. Additional information about safety monitoring is available on [CDC's COVID-19 vaccine website](#).

Q.) Is the COVID-19 vaccine being studied in children or pregnant women?

Recently, [one manufacturer](#) started to include children in COVID-19 vaccine clinical trials. Studies will need to be conducted in children and in pregnant women, but these studies are often done after the vaccine has been shown to work and be safe in healthy adults. It is likely that when COVID-19 vaccine is first available that it will not be recommended for pregnant women or children.

Q.) If vaccine trials do not include people with autoimmune conditions, how will we know if they can be vaccinated?

The requirements related to who can participate in a vaccine trial vary based on the company running them, the disease they are seeking to protect against, and various types of autoimmune conditions. Often the first studies are the most restrictive, so that the data are not influenced by other conditions.

10/16/2020

Some information taken directly from the [Children's Hospital of Philadelphia Vaccine Education Center](#).

Later scientists and healthcare providers will accumulate data for different sub-groups. In some cases, specific trials will be conducted, but often the information on healthy adults can inform what to expect regarding different conditions. About half of the people participating in clinical trials are considered high risk for COVID-19.

Q.) What types of COVID-19 vaccine are in clinical trials?

According to the Children's Hospital of Philadelphia's [Vaccine Education Center](#), several approaches to COVID-19 vaccines are currently being tested. They include both tried-and-true as well as new approaches.

Here is a brief summary of these different strategies:

- Inactivated vaccine — The whole virus is killed with a chemical and used to make the vaccine. This is the same approach that is used to make the inactivated polio (shot), hepatitis A and rabies vaccines.
- Subunit vaccine — A piece of the virus that is important for immunity, like the spike protein of COVID-19, is used to make the vaccine. This is the same approach that is used to make the hepatitis B and human papillomavirus vaccines.
- Weakened, live viral vaccine — The virus is grown in the lab in cells different from those it infects in people. As the virus gets better at growing in the lab, it becomes less capable of reproducing in people. The weakened virus is then used to make the vaccine. When the weakened virus is given to people, it can reproduce enough to generate an immune response, but not enough to make the person sick. This is the same approach that is used to make the measles, mumps, rubella, chickenpox and one of the rotavirus vaccines.
- Replicating viral vector vaccine — In this case, scientists take a virus that doesn't cause disease in people (called a vector virus) and add a gene that codes for, in this case, the coronavirus spike protein. Genes are blueprints that tell cells how to make proteins. The spike protein of COVID-19 is important because it attaches the virus to cells. When the vaccine is given, the vector virus reproduces in cells and the immune system makes antibodies against its proteins, which now includes the COVID-19 spike protein. As a result, the antibodies directed against the spike protein will prevent COVID-19 from binding to cells, and, therefore, prevent infection. This is the same approach that was used to make the Ebola virus vaccine.
- Non-replicating viral vector vaccine — Similar to replicating viral vector vaccines, a gene is inserted into a vector virus, but the vector virus does not reproduce in the vaccine recipient. Although the virus can't make all of the proteins it needs to reproduce itself, it can make some proteins, including the COVID-19 spike protein. No currently licensed vaccines use this approach.
- DNA vaccine — The gene that codes for the COVID-19 spike protein is inserted into a small, circular piece of DNA, called a plasmid. The plasmids are then injected as the vaccine. No currently licensed vaccines use this approach.
- mRNA vaccine — In this approach, the vaccine contains messenger RNA, called mRNA. mRNA is processed in cells to make proteins. Once the proteins are produced, the immune system will make a response against them to create immunity. In this case, the protein produced is the COVID-19 spike protein. No currently licensed vaccines use this approach.

10/16/2020

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Q.) Who will get the vaccine first?

Early on, COVID-19 vaccine will be limited and need to be prioritized. Some groups being discussed for prioritization include health care workers, essential workers, people 65 years of age and older, people who live in long-term care facilities, and people with high-risk conditions, like heart disease, or chronic lung disease.

The [ACIP](#) is currently discussing which groups should be prioritized for COVID-19 vaccine. The National Academy of Medicine, Engineering, and Sciences developed a [Framework for Equitable Allocation of COVID-19 Vaccine](#), which provides priorities for vaccination. Additionally, North Dakota is establishing an Advisory Committee on COVID-19 Vaccine Ethics to inform prioritization of vaccine within the state, if vaccine supply is not adequate to meet federal priorities.

Q.) When will there be enough vaccine for everyone who wants to be vaccinated to get a COVID-19 vaccine?

At this point, no one can really answer the question as to when everyone in the U.S. would be able to be vaccinated. It is possible that there may be enough vaccine in 2021 for anyone who wishes to be vaccinated to have access to COVID-19 vaccine.

Q.) Will I be able to get the COVID-19 vaccine at the same time as other vaccines?

Studies will have to be done to determine whether COVID-19 vaccine can be if given with other vaccines. It is possible that some of the later COVID-19 vaccine trials will be tested with other vaccines, particularly the influenza vaccine, but that will depend on a variety of factors and would have to be approved as part of the clinical trial protocol.

Q.) How long will immunity from the COVID-19 vaccine last?

Because we do not know how long immunity after infection lasts, immunity following vaccination will also have to be determined. Immunity following vaccination will depend on which types of vaccines are licensed or authorized and what part of the immune system responds to the vaccine.

Q.) Will I need to get a COVID-19 vaccine annually like an influenza vaccine?

Currently, the answer is unclear. It is possible that over time, additional doses of vaccine may be needed to provide continued protection. It will take ongoing evaluation over several months and years to understand how our immune systems respond to this virus and COVID-19 vaccines.

Q.) How many doses of a COVID-19 vaccine will be needed?

We will need to wait for the results of the clinical trials to have more information about how many doses will be needed. It is likely that for many of the vaccines, two doses separated by a specific amount of time will be needed.

10/16/2020

Some information taken directly from the [Children's Hospital of Philadelphia Vaccine Education Center](#).

Q.) Will getting the flu vaccine protect me against COVID-19?

No. Influenza viruses and coronaviruses are different, so the flu vaccine does not protect against coronavirus. This fall and winter, both COVID-19 and influenza will be circulating at the same time. Both are respiratory illnesses and have similar symptoms. Influenza vaccination will be important to prevent illness this fall and the burden of influenza illness on health care providers. Additionally, influenza vaccine will prevent you from being sick and having to miss work or school. While it may seem like there is so much out of our control during this pandemic, getting vaccinated against influenza is within our control. This will protect not only those who receive flu vaccine, but also the community.

Q.) How much will the coronavirus vaccine cost?

At this time, coronavirus vaccines are expected to be distributed for free. It is possible that health care providers may charge a fee to administer the vaccine. Health insurance most likely will cover these fees. Those who are uninsured and unable to pay the administration fee cannot be turned away.

Q.) If you had COVID-19 and recovered will you still be able or need to get the vaccine?

Right now, we do not know how long antibodies last after infection or whether they will protect against reinfection. The current vaccine trials will include immunizing people who have never been infected with COVID-19 as well as those who have been previously infected. We will soon know whether vaccination of those who have been previously infected provides more complete or longer lasting protection than those who were previously infected but haven't been vaccinated.

Q.) Is a COVID-19 vaccine necessary?

COVID-19 infections range from asymptomatic or minor illness or can lead to severe disease or even death. While measures such as social distancing, handwashing, and wearing masks offer some help, the best way to stop this virus is to generate COVID-19 specific immunity. The safest way to do that is through vaccination.

Q.) If I get COVID-19 vaccine, do I have to still wear a mask or quarantine if I am exposed?

It is unknown at this time how effective the COVID-19 vaccine will be, so until additional information is available, even if you are vaccinated, you still need to take additional measures to prevent COVID-19.

Q.) Is there an interval between influenza vaccination and receiving COVID-19 vaccine?

It has not yet been determined what the interval between influenza and COVID-19 vaccines will be. Everyone six months and older should be vaccinated against influenza. Influenza vaccination should ideally occur prior to the end of October each year.

10/16/2020

Some information taken directly from the [Children's Hospital of Philadelphia Vaccine Education Center](#).

Q.) Will COVID-19 vaccine be mandated in North Dakota?

COVID-19 vaccine will not be mandated for all North Dakotans. It is possible that certain employers may mandate vaccination. Health care and long-term care facilities often mandate influenza vaccination in an effort to protect their staff and patients.

Q.) Is North Dakota a pilot state for COVID-19 vaccine?

North Dakota was one of five sites selected to participate as a planning pilot site for COVID-19 distribution. North Dakota was able to assist federal partners in planning for when COVID-19 vaccine will eventually be available. Planning topics included vaccine storage and handling, distribution, communications, information technology, data, etc. The Tribes and other partners, including pharmacies, were included in this planning process to ensure that they were able to provide valuable insight into COVID-19 vaccine planning and eventual distribution and administration.

North Dakota will **NOT** receive COVID-19 vaccine before other states.

Additional information about COVID-19 vaccine is available on [CDC's COVID-19 vaccine website](#).

10/16/2020

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