COVID-19 VACCINE FAQ

Lake Region HEALTHCARE | Prairie Ridge HEALTHCARE | Mill Street RESIDENCE

Many of these Q&A's have been modified or derived from a very thorough document prepared by the North Dakota Department of Health.

Vaccine Development and Approval

Q: When can we expect a vaccine to be available?

A: We anticipate that a COVID-19 vaccine will become available in mid-to-late December 2020. Early on it is likely that vaccine will be limited to certain priority groups. An explanation of how the process has been shortened is available from Operation Warp Speed.

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.

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 types of COVID-19 vaccine are in clinical trials?

A: 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 taken up in cells and then the cell processes it to make proteins. Once the proteins are produced, the immune system will recognize them and 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.*
    - *The Pfizer and Moderna vaccines are both mRNA vaccines.*

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

A: 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 October ACIP meeting, the number of participants in clinical trials and diversity of participants were presented.

Q: Are people from different races and ethnicities being included in clinical trials for COVID-19 vaccines?

A: Yes. Vaccine manufacturers have made special effort to ensure clinical trials are inclusive of people from different races and ethnicities. Both Pfizer and Moderna, two of the manufacturers of COVID-19 vaccines in late stage clinical trials, are reporting at least 30% of participants being from diverse backgrounds (Black, Hispanic, Asian, American Indian). At the October ACIP meeting, the number of participants in clinical trials and diversity of participants were presented.

Q: What will be needed to license a COVID-19 vaccine in the United States?

A: 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. It is likely that at first, COVID-19 vaccine(s) will not be fully licensed but will receive emergency use authorization.

Q: What is Emergency Use Authorization?

A: 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 severe 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.

Q: Who has been identified as priority populations?

A: Priority groups for vaccination have not been solidified; however, at the current time they will mostly likely include:

- Phase 1A: Healthcare workers and long-term care residents
- Phase 1B: Other essential workers (i.e., police, fire, teachers)
- Phase 1C: People 65 and older and people at high risk

The Advisory Committee on Immunization Practices (ACIP) will make recommendations as to who should be prioritized for COVID-19 vaccine. These recommendations will be available after the vaccine is approved for use.

Q: Why was my "group" not considered in a higher tier in the priority groups?

A: Great consideration went into determining priority groups and among other things, the following were considered when determining priority groups:

- Risk and intensity of exposure to COVID-19
- Likelihood of adverse outcome if infected with COVID-19
- Critical role in ensuring survival of infected patients and ensuring the integrity of community function

In considering risk, many factors may fall under the above categories, including living in a congregate setting, known impact of the epidemic on a population, provision of direct or indirect patient care especially to persons at increased risk or known to have COVID-19, having underlying health conditions or being age 65 or older. Separation of one group from another is often determined not just by the presence of a risk factor but by the number of factors each group has. Unfortunately, not everyone can be highest priority for vaccination. For more information on priority groups, please visit the CDC website.

COVID-19 Vaccine Safety

Q: Is the COVID-19 vaccine safety tested?

A: Yes. 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: What is the current safety and efficacy of COVID-19 vaccines in clinical trials?

A: Preliminary data for Pfizer and Moderna are available online.

Full information regarding the safety and efficacy (performance) of COVID-19 vaccines in clinical trials has not yet been released. Information from clinical trials will be available before these vaccines are used.

Q: What is 95% efficacy? Is there a difference between vaccine efficacy and effectiveness?

A: Vaccine efficacy and vaccine effectiveness measures the proportionate reduction in cases among vaccinated persons. Vaccine efficacy is used when a study is carried out under ideal conditions, for example, during clinical trial. Vaccine effectiveness is used when a study is carried out under typical fields (that is, less than perfectly controlled) conditions.

Q: How does the efficacy of the Pfizer and Moderna vaccines compare to other vaccines?

A: Both the Pfizer and Moderna vaccines efficacy is among the best we have available compared to all recommended vaccines. For example, compare the efficacy of COVID-19 mRNA vaccines to a selection of recommended vaccines:

- Pfizer novel coronavirus vaccine (2-doses): 95%
- Moderna novel coronavirus vaccine (2-doses): 94.1%
- Influenza vaccine (1 dose): ~44%
- Chickenpox vaccine (Varicella-2 doses): 90%
- Measles (MMR-2 doses): 97%

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

A: 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, v-safe, is also planned to monitor COVID-19 vaccines using smart phones. 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?

A: 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 before the vaccine is recommended for these populations, 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?

A: 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. 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: Will the mRNA COVID-19 vaccines alter your DNA?

A: No. While the mRNA vaccines are the first of their kind, they cannot alter DNA. The mRNA vaccines work by introducing a messenger RNA molecule into your body, which causes cells to produce a protein that resembles one of the viral proteins that make up SARS-CoV-2. Your immune system recognizes the viral protein and generates an immune response against it.

The mRNA vaccines are unable to change your genetic makeup because the mRNA injected into the tissue to stimulate an immune response does not integrate into the cell nucleus of its recipients, thus genetic modification is not possible. Injecting RNA does not alter the DNA sequence of a human body. It only presents the body with the instructions to build a protein, which builds immunity. When the cells divide, they will only include your natural DNA. Further, the time RNA survives in the cells is relatively brief, usually only a span of hours.

Q: Is the COVID-19 vaccine made with fetal cells?

A: The mRNA COVID-19 vaccines produced by Pfizer and Moderna do not require the use of any fetal cell cultures in order to manufacture the vaccine.

The following organizations assert that the mRNA COVID-19 vaccines are ethically uncontroversial: National Catholic Bioethics Center, Pontifical Academy of Life Statement, Charlotte Lozier Institute, Immunization Action Coalition.

Getting Vaccinated

Q: Who will get the vaccine first?

A: Early on, COVID-19 vaccine will be limited and need to be prioritized.

Priority groups for vaccination have not been solidified; however, at the current time they will mostly likely include:

- Phase 1A: Healthcare workers and long-term care residents
- Phase 1B: Other essential workers (i.e., police, fire, teachers)
- Phase 1C: People 65 and older and people at high risk

The Advisory Committee on Immunization Practices (ACIP) will make recommendations as to who should be prioritized for COVID-19 vaccine. These recommendations will be available after the vaccine is approved for use.

Q: How many doses of COVID-19 vaccine are required?

A:

- ***Pfizer***
  - The Pfizer COVID-19 vaccine requires two doses separated by 21 days.
- ***Moderna***
  - The Moderna COVID-19 vaccine requires two doses separated by 28 days.

There are other COVID-19 vaccines currently in clinical trials. One vaccine requires only one dose, while others require two. It is important to know which vaccine you have received and when/if you need to return for additional doses.

Q: Do I need to get the same vaccine to complete my two doses?

A: Yes. If you receive a vaccine product that requires two doses, the second dose must be the same brand/manufacturer as the first dose.

Q: How will I know which vaccine product I received?

A: Each person will receive a vaccine record card that states the COVID-19 vaccine product that was administered. It is important to keep this card in a place where it will not be lost or misplaced in order to assure the second dose of COVID-19 vaccine is the same brand/manufacturer as the first dose received. Patients who are vaccinated are encouraged to take a picture of their immunization record card with their smartphone.

Doses will also be documented in the MIIC – Minnesota Immunization Information Connection so health care providers across the state and nation will know which type of vaccine a patient received and when.

Q: Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose?

A: No, However, all vaccine recipients should be encouraged to keep their card and show it at their follow- up vaccination appointment.

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

A: At this point, no one can really answer the question as to when everyone in the United States 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: Is there anyone who should not be vaccinated with COVID-19 vaccine?

A: ACIP will provide recommendations for who should and should not be vaccinated – watch for further information.

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

A: No. The recommendation, specific to the Pfizer vaccine, is that an individual should not have received another vaccine within 30 prior to their COVID-19 vaccination.

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

A: 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: What are common side effects after vaccination?

A: Common side effects from vaccination include pain, swelling or redness where the shot was given, a mild fever, chills, fatigue, headache, and muscle and joint aches. These side effects were also noted in COVID-19 vaccine clinical trials.

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

A: 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: Can a COVID-19 vaccine cause COVID-19?

A: No. None of the vaccines currently in development in the United States use the live virus that causes COVID-19. Vaccination with COVID-19 vaccine could cause side effects, such as fever and body aches. These symptoms are normal after vaccination and are a sign the body is building immunity.

Q: Can a COVID-19 vaccine cause you to test positive on COVID-19 viral tests?

A: No. COVID-19 viral tests are used to detect current infection. COVID-19 vaccines cannot cause COVID- 19 infections.

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

A: 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: Does the flu vaccine cause COVID-19?

A: No. The influenza vaccine does not contain the novel coronavirus or any coronaviruses. The influenza vaccine will not prevent or protect against COVID-19. Because the influenza vaccine does not contain the COVID-19 virus, it will not impact results of COVID-19 tests. The PCR test for COVID-19 is specific to COVID-19.

The influenza vaccine will help prevent the flu and serious complications due to influenza. A number of additional benefits from influenza vaccine can be found here. Influenza vaccination will reduce the burden of illness on healthcare providers, including hospitals. Because influenza and COVID-19 are both respiratory illnesses, vaccination will also reduce the burden of disease and need for COVID-19 testing.

Co-infection with COVID-19 and influenza in China led to more severe outcomes according to data presented at the June Advisory Committee on Immunization Practices meeting. A large study in Brazil showed more COVID-19 deaths in people who were not vaccinated against influenza.

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

A: The interval between influenza and COVID-19 vaccines needs to be at least 30 days.

Everyone six months and older should be vaccinated against influenza. Influenza vaccination should ideally occur prior to the end of October each year.

Q: How much will the coronavirus vaccine cost?

A: At this time, coronavirus vaccines are expected to be distributed for free. It is possible that some health care providers may charge a fee to administer the vaccine. Health insurance 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?

A: There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and the ACIP makes recommendations to CDC on how to best use COVID-19 vaccines, we cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Q: Is a COVID-19 vaccine necessary?

A: 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: Why should I get a COVID-19 vaccine?

A: The COVID-19 pandemic has had a significant impact on all of our lives. Although you may not know anyone who has been directly affected by the disease, it is ever-present in our community. While preventative measures like social distancing and masks help to slow the spread, the only truly preventive measure against this virus is to vaccinate.
By vaccinating against COVID-19, you not only protect yourself, but also prevent spread of the disease to your friends, loved ones, and those in your community. COVID-19 can have serious, life threatening complications and there is no way to know how the virus will affect you. COVID-19 vaccines are being carefully evaluated and will be authorized only if they are found to be safe and make it substantially less likely you'll get COVID-19.
For more information on the benefits of getting a COVID-19 vaccine, please see the CDC website.

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

A: 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: If one product has slightly higher efficacy than another vaccine, isn't it better to get the better vaccine with higher efficacy?

A: No. Any COVID-19 vaccine that is authorized for use in the United States has met the FDA's rigorous guidelines regarding EUA and has been reviewed by both VRBPAC and the ACIP (expert committees that provide recommendations and guidance on immunizations). In the last ten months, we have had over 250,000 deaths

associated to COVID-19. While preventive measures like social distancing and masks help to slow the spread, the only truly preventive measure against this virus is to vaccinate. Preliminary data from Pfizer and Moderna is extremely promising. Phase III trial results on both vaccines indicate an efficacy around 95%, rivalling the effectiveness of some of the best vaccines available to us against other viruses such as MMR (97% effective) and Chickenpox (92% effective) vaccines. In addition, efficacy for the Pfizer and Moderna vaccine was consistent across age, gender, race, and ethnicity demographics. There is no reason to wait for a better vaccine when both the Pfizer and Moderna vaccines efficacy is among the best we have available compared to all recommended vaccines.

Q: What happens if I have a problem or bad reaction after getting a COVID-19 vaccine?

A: The CDC and FDA encourage the public and healthcare providers to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS). This national system is not designed to determine if a vaccine caused a health problem but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.
CDC is also implementing a new smartphone-based tool called v-safe to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a v-safe information sheet telling you how to enroll in v-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

Q: I have heard COVID-19 vaccine manufacturers are not liable for vaccine injury. What happens if I have a vaccine injury?

A: To encourage expedient development of medical countermeasures during a public health crisis, the PREP Act was created in 2005. The PREP Act authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act Declaration that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. Previous PREP Act declarations have been issued numerous times, including those for the H1H1 pandemic in 2009.
The PREP Act does provide manufacturers of countermeasures (e.g. COVID-19 vaccine) some immunity from liability, but this does not mean COVID-19 vaccine injuries are not covered or compensated for. They are covered under the Countermeasures Injury Compensation Program (CICP). The PREP Act authorizes CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under the PREP Act declaration.
Although vaccine manufacturers are not liable for unforeseen adverse events; they would be liable for negligence.
For more information on the PREP Act, please see the Public Health Emergency website. For more information on CICP, please see the HRSA website.
Additional information about COVID-19 vaccine is available on CDC's COVID-19 vaccine website.