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PLEASE NOTE: This document is updated as new information becomes available.

Vaccine Development and Approval

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

Yes. Currently, there are three vaccines available to prevent COVID-19 in the U.S. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unlicensed but authorized products (Pfizer-BioNTech, Moderna, and Johnson & Johnson [Janssen] COVID-19 vaccines) for active immunization to prevent COVID-19 in individuals 16 years of age and older (Pfizer) or individuals 18 years of age and older (Moderna and Johnson & Johnson) in the United States.

Several other COVID-19 vaccines are in clinical trials but have not been approved. Some of the vaccines in clinical trials 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.

2) When did COVID-19 vaccines become available?

The Pfizer COVID-19 vaccine and the Moderna COVID-19 vaccine both became available in December 2020. Johnson & Johnson's COVID-19 vaccine was authorized for use in February 2021 and became available in March 2021.

As of March 29th, 2021, anyone 16 years of age and older is now eligible for COVID-19 vaccine in North Dakota.

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

3) Why is the COVID-19 vaccine development timeline 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

An explanation of how the process has been shortened is available from [Operation Warp Speed](#).

4) 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](#).

5) What types of COVID-19 vaccines 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.
 - ***The Johnson & Johnson (Janssen Pharmaceuticals) vaccine is a non-replicating viral vector vaccine.***
- 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.***

For more information on the most recent updates on COVID-19 vaccines being developed, undergoing clinical trial, and approved/authorized for use, please see [The New York Times Coronavirus Vaccine Tracker](#).

6) 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.

Pfizer enrolled more than 43,000 individuals in their Phase III clinical trial. Moderna enrolled approximately 30,000 people in their Phase III clinical trial. Johnson & Johnson also enrolled more than 44,000 people.

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

Yes. Vaccine manufacturers have made special effort to ensure clinical trials are inclusive of people from different races and ethnicities. Both Pfizer and Moderna reported that at least 30% of participants are from diverse backgrounds (Black, Hispanic, Asian, American Indian). [Johnson & Johnson](#) reported that 26% of participants in the U.S. and 31% of its participants globally are from diverse backgrounds.

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

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. At first, COVID-19 vaccine(s) will not be fully licensed (Biological License Application) but will receive Emergency Use Authorization.

9) 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. Currently available COVID-19 vaccines have been made available through 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](#).

10) Can you explain the difference between an EUA and a Biological License Application (BLA)?

- An EUA is granted by the FDA and can be completed in a short amount of time (weeks). An EUA allows 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. The FDA must determine, among other things, that the ***known and potential benefits of a product outweigh its known and potential risks***.

- A BLA is also undertaken by the FDA but can take up to a year to complete. A BLA can only be approved if FDA determines there is **substantial evidence of safety and effectiveness** from adequate and well-controlled trials.
- Both EUAs and BLAs require data showing the vaccine is safe and effective.
- For both an EUA and a BLA, the FDA receives advisement from the Vaccines and Related Biological Products Advisory Committee (VRBPAC). VRBPAC is an external, expert committee (i.e. scientist, physicians, biostatisticians, and a consumer representative) that reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products.
- Because vaccines are given to millions of **healthy** individuals, the requirements for vaccine EUAs are **much stricter** than requirements for those drugs that have received EUA thus far during the COVID-19 pandemic for treatment of the ill.

11) Why did the FDA issue an EUA before a BLA for a COVID-19 vaccine?

- A vaccine for COVID-19 was first approved under EUA to promote more *rapid and widespread* deployment and administration of COVID-19 vaccine.
- A vaccine may be issued under an EUA with the *ultimate goal* of receiving a BLA.
- A vaccine issued under EUA will continue to be monitored and evaluated by multiple agencies in the United States (e.g. the Center for Disease Control and Prevention [CDC] and the FDA), to assure any vaccine authorized under EUA is safe and effective.

COVID-19 Vaccine Safety and Efficacy

12) Is the COVID-19 vaccine safety tested?

Yes. All COVID-19 vaccine candidates are being studied in large groups of people in order to ensure they are both safe and effective. After vaccines are approved for emergency use or full licensure, they will continue to be monitored for safety through the robust vaccine safety monitoring system in the U.S.

If a serious potential adverse event is noted during a clinical trial, that trial may be paused while that event is investigated. Because of high safety standards for vaccines, it's typical for most vaccine candidates to not make it to the final stages of testing. For COVID-19 vaccines in clinical trials, it is possible that not all vaccine candidates will come to market.

13) What is the current safety and efficacy of COVID-19 vaccines approved for emergency use?

Pfizer, Moderna and Johnson & Johnson have all indicated that their COVID-19 vaccines are safe and effective in clinical trials. These vaccines will continue to be monitored through our country's safety monitoring systems to assure their safety and effectiveness.

In clinical trials, Pfizer's COVID-19 vaccine showed no serious safety concerns, and there were no serious adverse events reported for Moderna's COVID-19 vaccine. The FDA's analysis of Johnson & Johnson's COVID-19 vaccine is that it has "a favorable safety profile with no specific safety concerns."

Pfizer reported 95% efficacy for those who received two doses, while Moderna reported 94.1% efficacy for those who received two doses. The COVID-19 vaccine made by Johnson & Johnson requires one dose, and was 66% effective at preventing moderate to severe COVID-19 in clinical trial participants worldwide. This vaccine is also 85% effective at preventing severe disease and it offered complete protection against COVID-19-related hospitalization and death 28 days after vaccination.

Full safety and efficacy information is available in the FDA briefing documents ([Pfizer](#), [Moderna](#), and [Johnson & Johnson](#)). Information from other clinical trials will be available and reviewed before vaccines are administered.

14) What is efficacy? Is there a difference between vaccine efficacy and effectiveness?

Vaccine efficacy and vaccine effectiveness measure the proportionate reduction in cases among vaccinated persons. The term vaccine “efficacy” is used when a study is carried out under ideal conditions, for example, during clinical trials. Vaccine “effectiveness” is used when a study is carried out under real-world conditions.

A COVID-19 vaccine with 95% efficacy means that it has the ability to *prevent* 19 out of 20 COVID-19 infections in *those who are vaccinated*. In other words, the vaccinated group experienced 95% fewer COVID-19 cases than they would have if they had not been vaccinated.

15) How does the efficacy of the Pfizer and Moderna vaccines compare to other vaccines?

The Pfizer, Moderna and Johnson & Johnson vaccines’ efficacy is among the best we have available compared to routinely recommended vaccines. For example, compare the efficacy of COVID-19 mRNA vaccines to other routinely recommended vaccines:

- Pfizer novel coronavirus vaccine (2 doses): 95%
- Moderna novel coronavirus vaccine (2 doses): 94.1%
- Johnson & Johnson novel coronavirus vaccine (1 dose): 66%
- Influenza vaccine (1 dose): ~44%
- Chickenpox/Varicella vaccine (2 doses): 90%
- Measles (MMR-2 doses): 97%

16) Is there any information on COVID-19 vaccine effectiveness in real-world conditions?

Yes. There have been a number of studies conducted in the U.S. and globally that show the effectiveness of COVID-19 vaccines under real-world conditions. The results are promising and indicate that vaccines are effective at protecting against a wide range of COVID-19-related outcomes; this is consistent with clinical trial findings.

[Recent research](#) conducted among healthcare workers has indicated that currently available COVID-19 vaccines reduce the risk of all SARS-CoV-2 infections, not just symptomatic infections. This is incredibly

important because preventing both asymptomatic (no symptoms) and pre-symptomatic infections can help prevent the spread of COVID-19 to others.

17) I heard the Johnson & Johnson COVID-19 vaccine has been reported to be only 66% effective. Why would I want this vaccine when Pfizer and Moderna's vaccine effectiveness is so much higher?

Johnson & Johnson's (J&J) COVID-19 vaccine was reported to be 66% effective in preventing moderate to severe disease globally in clinical trials. This vaccine is incredibly valuable in our fight against COVID-19 and here's why:

- **The vaccine was highly effective at preventing severe disease, hospitalization and death from COVID-19.** The vaccine was 85% effective at preventing severe disease and it demonstrated *complete protection against COVID-19 related hospitalization and death* in clinical trials.
- **Clinical trial data indicates the vaccine protects against more contagious variants.** Unlike the clinical trial for Pfizer and Moderna COVID-19 vaccines, J&J's vaccine was tested when variants of the COVID-19 virus have emerged and are widely circulating. Although slightly less effective at preventing moderate to severe illness in South Africa, Brazil and Britain (areas with known variants), it was still 82% effective at preventing severe disease and prevented all hospitalizations and deaths associated with COVID-19 28 days following vaccination.
- **It requires one dose.** Because it is one shot, it does not require a follow-up visit for an additional dose to complete the series, like Pfizer and Moderna's COVID-19 vaccines.
- **Differences in clinical trial design make it difficult to compare currently available COVID-19 vaccines.** Pfizer, Moderna, and J&J's clinical trials all had different outcomes they were measuring. Pfizer and Moderna's trials both tested for any symptomatic COVID infection either seven days (Pfizer) or 14 days (Moderna) following receipt of the second dose of vaccine. While J&J sought to determine whether one dose of its vaccine protected against moderate to severe COVID illness beginning from 14 or 28 days after receipt of a single dose of vaccine. Comparing the vaccines is the equivalent of comparing apples to oranges.
- **It is easier to store and administer.** The J&J vaccine can be stored in a refrigerator for at least three months, making it simpler to use than other vaccines that must be kept frozen.

Since the beginning of the pandemic we have had over 567,000 deaths from COVID-19 and it was [listed](#) as the third leading cause of death in the U.S. in 2020. A vaccine that is highly effective at preventing severe disease and death from COVID-19 is an incredible tool to protect our community and vaccinating is the only way we can get back to normal.

18) What is the efficacy of a COVID-19 vaccine if I only receive one dose of a two-dose series?

There is very limited data on the efficacy of Pfizer's and Moderna's COVID-19 vaccines when only one dose is given. Pfizer has indicated that the efficacy of their COVID-19 vaccine after one dose is at least

52%. Moderna has noted 80.2% efficacy after one dose. For best protection, it is recommended that individuals receive two doses.

19) Why was the Johnson & Johnson clinical trial paused? Does this mean the vaccine is not safe?

In October of 2020, Johnson & Johnson announced that their COVID-19 vaccine clinical trial was paused because of an unexplained illness in a study participant. In this instance, the study paused the recruitment of new participants while the event was investigated by an independent safety monitoring board and medical experts. Based on information gathered from their investigation, Johnson & Johnson found no evidence that the vaccine caused the illness and the study resumed enrollment approximately 2 weeks later.

It is not uncommon for clinical trials to be paused. When/if a serious adverse event occurs during clinical trials, the event is reviewed by medical experts and the clinical trial is paused. Pauses in clinical trials should be reassuring to the public; pauses tell us that safety monitoring systems work and safety is a top priority.

20) The administration of the Johnson & Johnson COVID-19 vaccine was paused in the United States. What does this mean?

On April 13, the FDA and CDC recommended a pause in the administration of the Johnson & Johnson COVID-19 vaccine.

As of April 13th, there were over 6.8 million doses of the Johnson & Johnson (J&J) vaccine administered and reported in the U.S. The CDC and FDA had received six reports of a rare and severe type of blood clot in individuals who had received the vaccine. (Breakdown: that means the blood clot is extremely rare and currently estimated to occur at a rate of 1 event per 1.13 million doses administered.) The type of blood clot is called a cerebral venous sinus thrombosis (CVST), and it was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred in women between the ages of 18 and 48, and symptoms occurred 6-13 days after vaccination. Of these cases, one has died, and one is in critical condition.

The CDC, FDA and the ACIP (The Advisory Committee on Immunization Practices - a 15-member expert committee that provides recommendations on immunizations in the U.S.) have recommended a pause for use of the J&J vaccine to:

- ***Determine if these events are causally related to the vaccine*** – We need to determine if vaccination is causing the events. In these six events, the event happened very shortly after vaccination. But remember, correlation is not causation. Causality will be assessed by vaccine and medical experts.
- ***Alert healthcare providers to assure proper diagnosis and treatment*** – This type of blood clot should not be treated with the usual treatment for blood clots (heparin), so the CDC and

FDA needed to get the information out to clinicians ASAP so they could properly detect, PROPERLY TREAT, and properly report the adverse event to CDC and FDA for further investigation.

- **Maintain transparency** – The FDA and CDC have said all along that the safety of COVID-19 vaccines is of utmost importance. These vaccines are being given to millions of HEALTHY people every day. If a safety signal is detected, the American people should be alerted.

It is important to understand that this pause on J&J's vaccine administration in the U.S. shows that our vaccine monitoring systems *are working*. The CDC and FDA are committed to transparency throughout this process and the safety and efficacy of COVID-19 vaccines. The ACIP is meeting on April 23, 2021 to further discuss the Johnson & Johnson vaccine and any additional safety information.

21) The Johnson & Johnson COVID-19 vaccine was paused for use in the United States due to a potentially rare side effect. Why was this not detected in the clinical trial?

First and foremost, we don't yet know if the vaccine causes this rare side effect. If it does, the event is extremely rare.

The clinical trials for the Johnson & Johnson (J&J) vaccine included over 44,000 people. The clinical trials did see some "embolic and thrombotic events" (not necessarily CVST), 15 in the vaccine group and 10 in the placebo group. This indicates a slight imbalance in events (15 vs. 10), but the FDA said the data there was not enough evidence to determine whether there was a true safety signal. They did say they were going to continue to monitor the vaccine for safety.

It would be extremely unlikely that an event that occurs at a rate of 1 in a million doses administered to be picked up in a clinical trial of 44,000 people. An event so rare would likely only be picked up once the vaccine is administered to enough people. This is why we continue to monitor vaccines for safety, even after they get authorized or approved by the FDA.

22) If I recently received a Johnson & Johnson COVID-19 vaccine, what should I do?

It is important not to panic, as these events appear to be a very rare side effect if they are related to vaccination. Additionally, it is important to monitor for symptoms. If you develop a severe headache, abdominal pain, leg pain, or shortness of breath within three weeks of receiving the Johnson & Johnson vaccination you should contact your healthcare provider and seek medical treatment. Make sure you let them know you have recently received a Johnson & Johnson COVID-19 vaccine. To see the latest updates regarding the Johnson & Johnson vaccine, please see the CDC [website](#).

23) Is it true that people in the COVID-19 vaccine clinical trials died?

According to data released by COVID-19 vaccine manufacturers, clinical trial participants did pass away during the safety monitoring period following vaccination. Deaths occurred in participants in the vaccinated and the unvaccinated groups. However, it is important to note that the **deaths that occurred in the vaccinated group were not caused by the vaccination.**

In the [Pfizer](#) briefing document for Emergency Use Authorization (EUA), six deaths were noted in the study population; 2 in the vaccine group and 4 in the placebo group (placebo group = those who did not get the vaccine). In the [Moderna](#) briefing document for EUA, 13 deaths were noted; 6 in the vaccine group and 7 in the placebo group. In the [Johnson & Johnson](#) briefing document for EUA, 25 deaths were noted; 5 in the vaccine group and 20 in the placebo group.

- For those in the vaccine group, none of the deaths were related to vaccine administration.
- **The rate of deaths in the study group occurred at a similar rate to that which would be expected in the general population.**

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

COVID-19 vaccine safety will continue to be monitored after a vaccine 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](#) (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 being used to monitor COVID-19 vaccines using smartphones for health surveys.
- Additional information about safety monitoring is available on [CDC's COVID-19 vaccine website](#).

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

Yes. [Pfizer](#) has fully enrolled its COVID-19 vaccine trial in children ages 12-15. [Preliminary data](#) indicates that the vaccine demonstrated 100% efficacy and was well tolerated in participants aged 12-15 years old in clinical trial. Pfizer [requested](#) expansion of the Emergency Use Authorization (EUA) for their COVID-19 vaccine for this age group in the United States on April 9, 2021. [Pfizer](#) has also started enrolling children 6 months - 11 years in clinical trials.

Moderna has [fully enrolled](#) their clinical trial for children ages 12 and up, and they are currently enrolling a clinical trial for children 6 months - 11 years.

Johnson & Johnson has expanded [clinical trials](#) to include adolescents 12 and older for their COVID-19 vaccine.

[Pfizer](#) has begun enrolling pregnant women in a clinical trial. The Moderna and Johnson & Johnson COVID-19 vaccines have not been formally studied in pregnant women yet. Before vaccines are studied in pregnant women, developmental and reproductive toxicity (DART) studies, which use animal models, are conducted to ensure safety of vaccines in pregnant women. Pfizer DART studies have been reported in Europe and there were no safety signals generated. Moderna and Johnson & Johnson's DART studies found no safety concerns in pregnant animals. Pregnant women who opt to receive the vaccine should report their pregnancy in V-SAFE to be followed for safety monitoring and pregnancy outcomes.

26) 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. 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.

27) Do COVID-19 vaccines cause people to faint?

Fainting, also called syncope, is a common event surrounding vaccination. It is not caused by a vaccination itself; fainting is thought to be caused by the vaccination process (ex. anxiety associated with vaccination). Fainting is usually not serious and has no long-lasting effects.

Because fainting is a common occurrence for vaccinated individuals, we expect to hear reports of individuals who faint when they receive their COVID-19 vaccine. Fainting is not a sign of a vaccine reaction. To help minimize the risks associated with fainting, everyone who receives a COVID-19 vaccine is recommended to be monitored for 15 minutes following vaccination.

28) Will the mRNA COVID-19 vaccines alter your DNA?

No, **mRNA vaccines 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 (where DNA is located), thus genetic modification is not possible**. 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.

29) I've heard that COVID-19 vaccines were developed to control the population through microchip tracking. Is this true?

No. There is no vaccine microchip, and the vaccine will not track people. This myth started after comments made by Bill Gates about a digital certificate of vaccine records. The technology he was referencing is not a microchip, has not been implemented in any manner and is not tied to the development, testing or distribution of COVID-19 vaccines.

30) Can I receive the COVID-19 vaccine if I am allergic to latex?

Yes. People with a latex allergy can receive the COVID-19 vaccine. There is no latex in the vaccine and the vaccine vial's rubber stopper does not contain latex.

It is still important to let your healthcare provider know about any latex allergies so they can ensure they do not use any latex containing products (ex. gloves) when administering the vaccine.

31) Can individuals with an egg allergy receive a COVID-19 vaccine?

Yes. People with a history of egg allergies can receive COVID-19 vaccines, as these products do not contain egg.

32) Do COVID-19 vaccines contain pork products?

No. There are no pork products in the Pfizer, Moderna, or Johnson & Johnson COVID-19 vaccines.

33) I heard reports of anaphylaxis following receipt of Moderna and Pfizer COVID-19 vaccines. Should I be concerned about an allergic response from the vaccine?

Anaphylaxis is an acute and potentially life-threatening serious allergic reaction that rarely follows vaccination. There have been some reports of anaphylaxis following receipt of COVID-19 vaccine, however, it is rare. The CDC has recently updated the estimated rates of anaphylaxis to 2-5 cases per million doses of COVID-19 vaccine administered. The CDC recommends that all individuals be monitored for at least 15 minutes following vaccination to monitor for anaphylaxis.

COVID-19 vaccines were studied thoroughly in clinical trials prior to receiving EUA. The phase 3 trial results indicated **that vaccines were generally well tolerated with no serious safety concerns reported**. However, it is possible for vaccines to cause allergic reactions. As quoted by Dr. Paul Offit, a vaccine expert, "Certainly, vaccines can cause severe allergic reactions. In the U.S., roughly one of every 1.4 million doses of vaccines is complicated by a severe allergic reaction." The CDC advises telling a provider if you have any severe, life-threatening allergies before taking any vaccine, including the COVID-19 vaccine.

The FDA and CDC have included a history of severe allergic reactions to the COVID-19 vaccine or any COVID-19 vaccine ingredient as a reason not to receive a COVID-19 vaccine. Additionally, individuals who have had an immediate allergic reaction to COVID-19 vaccine or a COVID-19 vaccine ingredient should not receive the vaccine.

Individuals who have a history of anaphylaxis to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) may receive a COVID-19 vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. They should also be monitored for 30 minutes following vaccination.

The Johnson & Johnson vaccine has not observed any cases of anaphylaxis in their clinical trial, suggesting that anaphylactic events would likely be rare.

The CDC has posted guidelines for managing anaphylaxis at vaccination sites [here](#).

34) I heard the head of Pfizer research said the vaccine could cause female sterility? Is this true?

This claim is false. Experts say there is no evidence that the Pfizer vaccine would result in sterilization of women.

If you look into the original claim on social media, you will discover it is full of misinformation.

- First, the person who made the claim is not the head of Pfizer research. **The truth:** the individual worked at Pfizer nearly a decade ago in a division that was not directly involved in vaccinology.
- Second, the claim says the COVID-19 mRNA vaccine produces a protein called syncytin-1, which is vital for placental formation. If the body creates an immune response to syncytin-1, the immune system may inadvertently attack the placenta during future pregnancies and lead to infertility. **The truth:** the vaccine works by forming an immune response to the SARS-CoV-2 spike protein. The SARS-CoV-2 spike protein does share a very small genetic sequence with syncytin-1. However, there is little concern about the possibility of the anti-spike protein antibodies attacking the syncytin-1 protein because the immune system recognizes the surface of target proteins, and this is rarely confined to a short genetic sequence (like the genetic sequence shared between the SARS-CoV-2 spike protein and syncytin-1).
- Finally, if this claim was true, those who have had natural infection with COVID-19 would also produce antibodies to the syncytin-1 protein and would experience infertility. Currently, we have no evidence that natural infection is leading to infertility in women.

For more information, feel free to check out the NDDoH [handout](#) and [video](#) created to address this topic.

35) Will getting the COVID-19 vaccine affect a woman's menstrual cycle?

There have been anecdotal reports of menstruation changes following COVID-19 vaccination, but there is currently no scientific evidence to say the vaccine itself causes a change in menstruation patterns. Changes in menstruation following vaccination could be linked to the body's stress response to the immunization or the pandemic; the changes could also be a coincidence. Researchers are currently exploring this question in further detail.

It is also not possible for the vaccination of one woman to affect the menstrual cycle of another woman. Additionally, the menstrual cycle of one woman cannot affect the menstrual cycle of another. This concept came from a study conducted in 1971 and is referred to as the McClintock Effect - which suggested that pheromones or other factors can influence and shift periods for women who live together or are in close proximity to one another. Recent research does not support this finding and further suggest that menstrual cycles don't align reliably and it is just coincidence when a woman's period happens to occur at the same time. It does not have anything to do with close proximity,

pheromones, or moon phases - let alone COVID-19 vaccination. Things that do affect menstrual cycles include birth control pills, extreme stress, chronic illness, and anorexia/bulimia.

The NDDoH suggests that any concerns about changes to a woman's menstrual cycle should be discussed with their gynecologist and/or primary care provider, who has the benefit of access to the person's medical history and current situation to help sort out what might be going occurring.

36) I've heard of people having a delayed reaction with pain, irritation, redness and/or swelling at the injection site following a COVID-19 vaccine dose (up to 7-10 days after vaccination). Should they return for the second dose of COVID-19 vaccine?

Yes, they should return for the second dose of COVID-19 vaccine. This reaction is **not** a contraindication (e.g. condition in which a vaccine should not be administered) or a precaution (e.g. situation in which a vaccine may be administered if the benefits from vaccine are judged to outweigh the risk). It is not known whether individuals who experienced a delayed-onset reaction after the first dose will experience a similar reaction after the second dose. However, these reactions are not believed to represent an increased risk for anaphylaxis after a subsequent dose. Persons who have a delayed-onset location reaction around the injection site area after the first vaccine dose should receive the second dose as the same vaccine product as the first dose and at the recommended interval, preferably in the opposite arm.

37) Do COVID-19 vaccines cause Bell's palsy?

At this time, Bell's palsy does not appear to be associated with COVID-19 vaccination. In the Pfizer clinical trial data, four cases of Bell's palsy were noted in the vaccine group while zero cases were noted in the placebo group. In the Moderna clinical trial data, three cases were noted in the vaccine group and one case was noted in the placebo group. In the Johnson & Johnson trial data, two cases were noted in the vaccine group and two cases were noted in the placebo group. In these instances, **the cases in the vaccine group did not represent a frequency above the rate of Bell's palsy that is expected in the general population.** This was further substantiated regarding Moderna and Pfizer's vaccines with data presented at the March 1, 2021 [ACIP meeting](#). Data from the Vaccine Safety Datalink showed no increased risk of Bell's palsy in vaccinated individuals. Surveillance for cases of Bell's palsy will continue as the vaccine is administered to the general population to determine if vaccination is associated with increased risk of Bell's palsy.

38) Do COVID-19 vaccines cause Guillain-Barré Syndrome (GBS)?

There were no cases of Guillain-Barré Syndrome (GBS) reported following vaccination in the Pfizer and Moderna COVID-19 vaccine clinical trials. Additionally, the Advisory Committee on Immunization Practices (ACIP) shared safety data in March 2021; the data showed no association between GBS and COVID-19 vaccination.

There were single reports of GBS in a vaccine recipient and a placebo recipient in the Johnson & Johnson COVID-19 vaccine clinical trial. In FDA's assessment the events are unlikely related to the

vaccine but a causal relationship cannot be definitively excluded. Safety monitoring systems will continue to monitor for cases of GBS to determine if vaccination is associated with onset of GBS.

39) If I have previously had Guillain-Barré Syndrome (GBS), can I receive a COVID-19 vaccine?

Yes. Persons who have previously had GBS may receive COVID-19 vaccines. With few exceptions, the ACIP general best practice guidelines for immunization do not include a history of GBS as a precaution to vaccination with other vaccines.

40) Do COVID-19 vaccines cause immune thrombocytopenia (ITP)?

ITP is a disorder that can lead to easy or excessive bruising and bleeding. The bleeding results from unusually low levels of platelets — the cells that help blood clot. Thus far, there have been some reports of ITP following vaccination. However, we must remember that association is not causation.

According to the FDA, 1 in 35,000 people in the U.S. present with ITP each year. As millions of COVID-19 vaccines are administered across the country, inevitably some of the vaccinated will be diagnosed with ITP within days of receiving the vaccine. It is human nature to draw a connection between events, especially when they happen close together, but it doesn't mean vaccination caused ITP. The United States has the most comprehensive vaccine safety monitoring program in the world to detect adverse events following vaccination and investigate any adverse events that follow vaccination to determine if a vaccine could have caused a particular outcome. Thus far, there is no evidence to suggest that COVID-19 vaccination is associated with an increased risk of ITP.

41) Is the COVID-19 vaccine made with fetal cells?

- 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](#), [The Vatican - Congregation for the Doctrine of the Faith](#), [Pontifical Academy of Life Statement](#), [Charlotte Lozier Institute](#), [United States Conference of Catholic Bishops](#), and the [North Dakota Catholic Conference](#).
- The non-replicating viral vector COVID-19 vaccine made by Johnson & Johnson did require the use of fetal cell cultures to develop and manufacture the vaccine.
 - The [Catholic Church](#) and the [Southern Baptist Ethics & Religious Liberty Commission](#) have both stated that receiving a COVID-19 vaccine that required fetal cell lines for production or manufacture is morally acceptable.
 - Individuals should not delay vaccination because of product preference.
- For more information on this topic please view the [NDDoH handout](#).

42) Is there antifreeze (e.g. ethylene glycol) in the COVID-19 vaccine?

No. The Pfizer and Moderna COVID-19 vaccines contain polyethylene glycol. This is NOT an ingredient in antifreeze. Polyethylene glycol is actually an ingredient found in common products, such as Miralax, and it is widely used in pharmaceutical and cosmetic products.

Getting Vaccinated

43) Who is currently eligible to receive a COVID-19 vaccine in North Dakota?

As of March 29, 2021, COVID-19 vaccination is open to the entire general public 16 years of age and older. You can find providers offering COVID-19 vaccine in your area at [VaccineFinder.org](https://vaccinefinder.org).

44) What is considered an underlying medical condition for COVID-19 vaccination?

Adults of any age with certain underlying medical conditions are at increased risk for severe illness from the virus that causes COVID-19. It is important to note that the underlying medical conditions listed below are not an exhaustive list and only include conditions with sufficient evidence to draw conclusions. Individuals with any underlying medical conditions (including those NOT on the list below) should consult with their healthcare provider about their own personal risk factors associated with illness from COVID-19.

The following are considered underlying medical conditions that put you at increased risk for potential severe and life-threatening outcomes from COVID-19 infection:

- Cancer
- Chronic lung disease, including COPD
- Serious heart conditions
 - e.g. heart failure, coronary artery disease or cardiomyopathies (also known as heart muscle disease)
- Obesity with a body mass index (BMI) of 30 or more
- Type 2 diabetes
- Chronic kidney disease
- Conditions that cause you to be immunocompromised
 - e.g. HIV infection or those with weakened immune systems due to other illnesses or medication
 - This group should be aware of the potential for reduced immune response to the vaccine and currently limited safety data of vaccine in this population
- Sickle cell disease
- Pregnancy
- Smoking
- Down Syndrome

The following are considered underlying medical conditions that **might** put you at increased risk for potential severe and life-threatening outcomes from COVID-19 infection:

- Asthma (moderate to severe)
- Cerebrovascular disease (affects blood vessels and blood supply to the brain)
- Cystic fibrosis
- Hypertension (high blood pressure)
- Neurologic conditions, such as dementia
- Liver disease
- Overweight (BMI of 26-29)
- Pulmonary fibrosis (having damaged or scarred lung tissue)
- Thalassemia (a type of blood disorder)
- Type 1 diabetes

To see more information on underlying medical conditions and COVID-19 please see the NDDoH [website](#) or the CDC [website](#).

45) If I am from another state, can I still receive a COVID-19 vaccine in North Dakota?

Yes. You can receive a COVID-19 vaccine in North Dakota (ND) regardless if you are a resident of the state or not. Everyone 16 years of age and older is eligible for COVID-19 vaccine in the state.

Find COVID-19 vaccine in your area by visiting [VaccineFinder.org](https://www.vaccinefinder.org).

46) Is it mandatory for teachers to be vaccinated in order to return to in-person learning?

No, it is not mandatory for teachers to be vaccinated in order to return to in-person learning. The [CDC recommends](#) implementing mitigating strategies to reduce transmission of SARS-CoV-2 in schools. Further, while vaccination for teachers and school staff is listed as an additional layer of COVID-19 prevention in schools, the “access to vaccination should not be considered a condition for reopening schools for in-person instruction. Even after teachers and staff are vaccinated, schools need to continue mitigation measures for the foreseeable future, including requiring masks in schools and physical distancing.”

Educators and those working in the school setting should weigh the risk and benefits of vaccination with the risk of COVID-19 infection when determining whether or not they will choose to be vaccinated. This includes the amount of COVID-19 circulating in your community, the use of masks in school, and any personal risk factors.

47) How many doses of COVID-19 vaccine are required to complete the vaccine series?

Two dose vaccine series

The Pfizer COVID-19 vaccine requires two doses separated by 21 days. The Moderna COVID-19 vaccine requires two doses separated by 28 days. Ideally, individuals would also receive both doses from the same facility.

One dose vaccines

The Johnson & Johnson COVID-19 vaccine requires only one dose.

There are other COVID-19 vaccines currently in clinical trials. It is important to know which vaccine you have received and when/if you need to return for additional doses.

48) If the COVID-19 vaccine I receive requires two doses, do I need to get the same vaccine to complete my vaccine series?

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

Ideally, individuals would also receive both doses from the same facility.

49) What if I do not receive the second dose of COVID-19 vaccine of a two-dose series at the recommended interval (e.g. 21 days for Pfizer and 28 days for Moderna)?

While it is [recommended](#) that the second dose of Pfizer or Moderna COVID-19 vaccines should be administered as close to the recommended intervals as possible, there is some flexibility regarding timing. Specifically, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Further, both Pfizer and Moderna's COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. If a second dose is given beyond the 42-day interval, the series does not need to be restarted. While it is important to follow the recommended interval between doses as much as possible, what is of utmost importance is to *be fully vaccinated* and complete the vaccine series.

50) How will I know which vaccine product I received?

Each person will receive a vaccine record card that states the COVID-19 vaccine product that was administered and the date it was received. 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 (if you receive either Pfizer or Moderna). 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 North Dakota Immunization Information System (NDIIS), so health care providers across the state will know which type of vaccine a patient received and when.

51) For vaccines that require two doses, will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose?

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

52) Where can I sign up for COVID-19 vaccination?

There is currently not a way for the general public to sign up for COVID-19 vaccination on the state level. Some COVID-19 providers do have a waitlist for COVID-19 vaccine for their locations, but this varies by COVID-19 vaccine provider. To find COVID-19 vaccine, the NDDoH recommends using [VaccineFinder.org](https://vaccinefinder.org).

If you are 65 years of age or older and have not received a COVID-19 vaccine, call the NDDoH Hotline at 1.866.207.2880 and press #2 for vaccine registration assistance when you hear instructions. The NDDoH has individuals ready to help you find which healthcare providers are offering COVID-19 vaccine in your area and help you register for vaccine. Be aware that this service *only* provides guidance on registering and finding vaccine, not directly providing COVID-19 vaccine.

53) Where can I find COVID-19 vaccine in my area?

[VaccineFinder.org](https://vaccinefinder.org) can help members of the general public find COVID-19 in their area. The free website allows users to enter their zip code to find vaccine. You can also choose whether you want to narrow your search to a particular COVID-19 vaccine (e.g. Pfizer, Moderna, and/or Johnson & Johnson). This website provides information on:

- Provider sites in their area administering COVID-19 vaccine
- If COVID-19 vaccine is currently available at each location
- What COVID-19 vaccine are currently being offered at each location
- How they can contact the provider and/or express interest in receiving COVID-19 vaccine
- Additional Information on each location- business hours, contact information, address, link to Google maps providing directions to the location

54) What are common side effects after vaccination?

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. For vaccines that require two doses, side effects are more common after the second dose for both Pfizer and Moderna.

55) Can I take pain medicine (e.g. acetaminophen or a non-steroidal anti-inflammatory) to manage the side effects of COVID-19 vaccination?

The CDC has [stated](#) that patients can take pain medication (e.g. non-steroidal anti-inflammatory or acetaminophen) *after* their vaccination *if* they feel side effects (e.g. pain, headache, or fever that cannot be tolerated).

There has been debate on whether or not taking pain medication *prior* to vaccination may dampen an individual's immune response to the vaccine. Until we know more, it is not recommended for individuals to take pain medication in anticipation of potential side effects prior to their vaccine. If you have to take pain medication to alleviate side effects, it is advised for you to take it *after* you have been vaccinated.

56) Is there anyone who should not be vaccinated with COVID-19 vaccine?

COVID-19 vaccine should not be given to individuals with a known history of a severe allergic reaction (e.g. anaphylaxis) or immediate allergic reaction to a previous dose of COVID-19 vaccine or any component of a COVID-19 vaccine.

57) Can people with underlying conditions receive the vaccine?

Yes. People with underlying conditions are at a higher risk for severe COVID-19 disease. Vaccine may be administered to these individuals unless otherwise indicated. Pfizer and Moderna's phase 2 and phase 3 clinical trials demonstrated similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19.

58) Can people who are immunocompromised receive COVID-19 vaccine?

Yes. These individuals may be at increased risk for severe COVID-19. They may receive COVID-19 vaccine unless otherwise indicated.

59) Can people who have had COVID-19 receive the COVID-19 vaccine?

Yes. Vaccination should be offered to all eligible individuals, regardless of their history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus, persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.

60) Should people who currently have COVID-19 be vaccinated?

Vaccination should be postponed until the person has recovered and criteria have been met to end isolation.

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus, persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.

Since supplies of COVID-19 vaccine are limited, healthcare providers may choose to prioritize those who previously had COVID-19 at a lower priority.

61) Should people who are currently in quarantine present for vaccination?

No. People who are quarantined because of exposure to COVID-19 should wait to be vaccinated until their quarantine period has ended. This is to prevent spread to COVID-19 vaccinators.

Your local public health authorities make the final decisions about how long quarantine should last based on local conditions and needs. Follow the recommendations of your local public health department if you need to quarantine. Options they will consider *if you remain symptom free* include stopping quarantine after:

- Day 10 without testing
- Day 7 after receiving a negative test result (test must occur on day 5 or later)

Please check out the [CDC](#) and [NDDoH](#) recommendations on quarantine following exposure to COVID-19.

62) Should I get a COVID-19 vaccine even if I have had a positive antibody test?

Yes. Due to the severe health risks associated with COVID-19 and the fact that reinfection with COVID-19 is possible, you should be vaccinated regardless whether you have received a positive antibody test or not.

It is [not recommended](#) to conduct serologic testing to assess for prior infection for the purpose of vaccine decision-making.

63) Should individuals who have previously received passive antibody therapy for COVID-19 be vaccinated?

Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

64) I have recently tested positive for COVID-19. My healthcare provider recommended I receive monoclonal antibody treatment to help prevent severe disease, but that means I can't get the COVID-19 vaccine for at least 90 days. What should I do?

If your healthcare provider has recommended monoclonal antibody treatment, it means you have an increased risk for severe disease. You should strongly consider receiving the monoclonal antibody treatment, as **it may save your life**. If you receive the treatment, you will be eligible to receive your COVID-19 vaccine in 90 days, and until that interval is met, it is very unlikely that you will become reinfected with the virus.

65) Should people who have had a known previous COVID-19 infection receive a single dose of a COVID-19 mRNA vaccine versus completing the two-dose series?

A [recent study](#) has shown that the antibody response to the first vaccine dose in individuals with pre-existing immunity is equal to or even exceeds the titers found in naive individuals after the second dose. But at this time, there are no recommendations related to giving a single dose of COVID-19 vaccine to those who have recovered from a known COVID-19 infection. Those who are able and qualified for COVID-19 vaccination and have received a first dose should complete the vaccine series, regardless of a previous COVID-19 infection. The NDDoH will keep healthcare providers updated on any changes regarding COVID-19 vaccine recommendations.

66) Can pregnant women receive COVID-19 vaccine?

Yes. Pregnant women may choose to be vaccinated and should discuss vaccination with their healthcare provider. They should weigh the risk of COVID-19 with the risks and benefits of vaccination; pregnant women are at an increased risk for severe COVID.

The American College of Obstetrics and Gynecology has published guidance [here](#). The NDDoH has compiled information on COVID-19 vaccine and pregnancy [here](#). The [CDC](#) and World Health Organization ([WHO](#)) have aligned their recommendations for receipt of Pfizer and Moderna vaccines during pregnancy and have advised that *"based on what we know about this kind of vaccine, we don't have any specific reason to believe there will be specific risks that would outweigh the benefits of vaccination for pregnant women."* As of April 21, 2021, more than 94,000 pregnant women have received a COVID-19 vaccine and enrolled in V-SAFE (a COVID-19 vaccine safety monitoring system). No pregnancy-related safety concerns have been detected via vaccine safety monitoring systems.

Considerations for vaccination include: 1) level of COVID-19 community transmission, 2) her personal risk of contracting COVID-19, 3) the risks of COVID-19 to her and potential risks to the fetus, 4) the efficacy of the vaccine, 5) the known side effects of the vaccine, 6) the lack of data about the vaccine during pregnancy.

Pregnant women who experience a fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes.

Johnson & Johnson's COVID-19 vaccine platform has been shown to be safe in pregnant women in a previous large-scale Ebola vaccine trial. Further Johnson & Johnson, like mRNA vaccines, is not a live vaccine and is non-replicating and unlikely to provide risk to the mother or the unborn child.

67) Can women who are breastfeeding receive COVID-19 vaccine?

Yes. Women who are breastfeeding may choose to be vaccinated. mRNA and non-replicating viral vector vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. The American College of Obstetrics and Gynecology (ACOG) has stated "Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine." [Recent research](#) has demonstrated that mRNA COVID-19 vaccines can confer protective immunity from vaccinated mothers to newborns through breast milk and the placenta. View ACOG's published guidance [here](#).

Recommendation regarding Johnson & Johnson's COVID-19 vaccine for women who are breastfeeding has not yet been decided or released. We will update this information as it becomes available.

68) Should individuals who have received dermal fillers be vaccinated?

Infrequently, persons who have received dermal fillers may develop swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy. mRNA COVID-19 vaccines may be administered to persons who have received injectable dermal fillers who have no contraindications to vaccination. No additional precautions are needed. However, these persons should be advised to contact their healthcare provider for evaluation if they develop swelling at or near the site of dermal filler following vaccination.

69) Can children be vaccinated against COVID-19?

Pfizer's COVID-19 vaccine has been authorized for adolescents 16 and 17 years of age. Emergency Use Authorization of the Pfizer vaccine does not include use in individuals younger than 16 years of age.

Moderna's COVID-19 vaccine is only approved for individuals 18 years and older.

Johnson & Johnson's COVID-19 vaccine is also only approved for individuals 18 years and older.

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

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.

71) I have received my first dose of COVID-19 vaccine that requires two doses, how do I schedule my second dose?

If you have received the first dose of COVID-19 vaccine of a two-dose series, it is highly recommended that you receive your second dose from the same location in which you received your first dose, if possible. Many of the sites offering COVID-19 vaccine in the state will contact you when it is time to schedule your second dose, if you received your first dose from their location. If you received Pfizer's COVID-19 vaccine you should receive your second dose 3 weeks after your first dose. If you received Moderna's COVID-19 vaccine, you should receive your second dose 4 weeks after your first dose.

If you are unable to receive your second dose of vaccine from the same COVID-19 vaccine provider you received your first dose from, the NDDoH recommends using [VaccineFinder.org](https://vaccinefinder.org) to determine where vaccine is being provided in your area.

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

COVID-19 vaccines should not be given at the same time as other vaccines. The CDC recommends a 14-day interval between COVID-19 vaccine and other vaccines.

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

At this time, we do not know how long immunity following vaccination will last. Pfizer, Moderna, and Johnson & Johnson noted that there **does not** appear to be evidence of waning protection during the follow-up time of approximately 2 months following the completion of series (1 dose for Johnson & Johnson and 2 doses for Moderna and Pfizer) of the vaccine, and it likely lasts for at least 6 months.

What we do know is that COVID-19 vaccines will be continuously monitored to determine duration of immunity after vaccination. 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.

74) 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.

75) Can a COVID-19 vaccine cause COVID-19?

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. This is not COVID-19. These symptoms are normal after vaccination and are a sign the body is building immunity.

76) Can a COVID-19 vaccine cause you to test positive on COVID-19 viral tests?

No. COVID-19 viral tests will not show a positive result after receipt of the COVID-19 vaccine.

77) 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.

78) Does the flu vaccine cause COVID-19?

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.

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

The CDC recommends a 14-day interval between COVID-19 vaccine and other vaccines, including influenza vaccines.

80) 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 will cover these fees. Those who are uninsured and unable to pay the administration fee cannot be turned away.

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

Yes. Vaccination should be offered to all eligible individuals, regardless of their history of prior infection.

82) If a vaccine recipient has tested positive since their first dose of COVID-19 vaccine, should they receive their second dose?

For people who have received one dose of COVID-19 vaccine and subsequently test positive before receiving dose #2, they should complete the series as soon as they have met the minimum interval for vaccination and once they have completed their isolation period.

83) Why should I get a COVID-19 vaccine?

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. Further, more than 1 in 500 North Dakotans have died from COVID-19. 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](#).

84) What might be the long-term side effects from COVID-19 vaccination?

Since COVID-19 vaccines are new, some people have wondered about the long-term side effects of these vaccines. Because this data is not available, we need to study the evidence we have available regarding long-term side effects from vaccination. The evidence shows that it is unlikely that these vaccines would have long-term side effects.

Pfizer, Moderna and Johnson & Johnson had ***large*** Phase III clinical trial sizes ranging from 30,000 to 44,000 participants. The size of these trials helped to establish the ***safety and efficacy*** of the vaccines. Vaccine safety data shows us that over 90% of adverse events associated with vaccination occur within six weeks of receiving that vaccination. Knowing this, the FDA said that any vaccine approved for Emergency Use Authorization had to have at least two months of safety monitoring data on 50% of clinical trial participants. Pfizer, Moderna, and Johnson & Johnson reported that during the 2-month follow-up period, there were no serious safety concerns found. This tells us the vaccine appears to be safe and that if there are any adverse events associated with vaccination, they are probably extremely rare.

Theoretically, side effects from vaccination could show up at any time, but again, history tells us they almost never happen after six weeks. This makes sense. We would expect any vaccine side effects to occur close to vaccination – as this is when the immune response is most active and working hard to

build protection. Once your body has built that protection, the only thing that remains is your body's own ability to provide protection should you ever encounter the virus in the future.

Should a question about vaccine safety arise down the road, the United States has powerful vaccine safety monitoring systems to help us detect adverse events and assess whether they are associated with vaccination. So far, data from our safety monitoring systems is reassuring and tells us that COVID-19 vaccines are safe. The safety of these vaccines will continue to be monitored for years to come.

Finally, COVID-19 vaccines are much safer than getting COVID-19. COVID has had lasting impacts on many people, and we may just be scratching the surface of what the disease can do and what its long-term impacts are. Thousands of people are dying each week from COVID-19. COVID impacts our lungs, heart, kidneys, and nervous system, just to name a few. Recent studies indicate that 10% of COVID-19 patients may become "long-haulers" and have symptoms of the disease for months. Recent research has suggested that one-third of COVID-19 vaccine survivors were diagnosed with a neurological or mental health condition within 6 months of their COVID-19 diagnoses. To put this into perspective, these conditions were 44% higher after COVID-19 than after the flu.

Without a vaccine, we would all likely get COVID at some point, and you don't know how it will affect you. Any theoretical long-term risk of the vaccine is still to be determined, and while it's understandable to want to see long-term safety data, getting vaccinated is the only way to prevent COVID-19. To the best of our knowledge, the vaccines are safe and people should strongly consider taking one for themselves, for their loved one, and so we can get back to our new normal as soon as possible.

85) If I get a COVID-19 vaccine, do I still have to 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. This includes social distancing, wearing a mask, and observing quarantine recommendations.

Recent CDC [recommendations](#) have stated that fully vaccinated persons (in both healthcare and public settings) with an exposure to someone with COVID-19 (i.e. close contacts) are NOT required to quarantine if they meet ALL of the following criteria:

- Are fully vaccinated (i.e. ≥ 2 weeks following receipt of the second dose in a 2-dose series [Pfizer or Moderna COVID-19 vaccines], or ≥ 2 weeks following receipt of one dose of a single-dose vaccine [Johnson & Johnson COVID-19 vaccine])
- Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet the above criteria should continue to follow current quarantine guidance after exposure to someone with COVID-19. For further guidance, please refer to the [NDDoH What To Do If You Are A Close Contact](#).

Fully vaccinated persons who do not quarantine should still watch for symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated. To read further on CDC's recommendations regarding fully vaccinated people, please visit the CDC [website](#).

86) What things can I do safely if I have been fully vaccinated against COVID-19?

If you are fully vaccinated (e.g. 2 weeks after 2nd dose of 2-dose series OR 2 weeks after single-dose vaccine), the CDC has said you can:

- Visit inside a home/private setting without a mask with other fully vaccinated people of any age
- Visit inside a home or private setting without a mask with one household of unvaccinated people who are not at risk for severe illness
- Travel domestically without a pre- or post-travel test
- Travel domestically without quarantining after travel
- Travel internationally without a pre-travel test depending on destination
- Travel internationally without quarantine after travel

However, it is still recommended to continue to mask and socially distance in public, during gatherings with unvaccinated people from multiple households, and visiting those who are at increased risk of severe illness or death from COVID-19 or those who live with a person at increased risk. For greater detail on CDC recommendations, please see their [website](#).

87) Why do we have to continue to wear PPE and practice social distancing following a COVID-19 vaccination?

Before we can take off our masks and stop social distancing, we need to get disease rates down in our community. We can do this in a few ways. We can do things that reduce our exposure to the virus, like wearing a mask and social distancing. We can also prevent the disease, by getting vaccinated. Until we have enough people immune to the virus that causes COVID-19, we will need to continue to use public health measures for a few reasons:

- ***Vaccination does not provide immediate immunity.*** Both the Pfizer and Moderna vaccines require two doses, weeks apart. The Johnson & Johnson vaccine only requires one dose. It takes time for your body to build protection after any vaccination. It typically takes a week or two following completion of the series (either after 1 dose for Johnson & Johnson or 2 doses for Moderna and Pfizer) to build immunity. During this time, it is still possible to contract an infection and fall ill.

- ***We don't know how well vaccines prevent transmission of COVID-19.*** The Moderna, Pfizer, and Johnson & Johnson vaccines have shown to prevent symptomatic and severe COVID-19 infections remarkably well, but we still do not have enough data to make conclusions regarding their effectiveness at preventing asymptomatic infections. Preliminary data is promising for COVID-19 vaccines, showing they prevent asymptomatic and symptomatic COVID-19.
- ***We don't know how much protection COVID-19 vaccines will provide under real-life conditions.*** While the Moderna, Pfizer, and Johnson & Johnson vaccines have been shown to be efficacious in clinical trial, we have yet to determine how effective the vaccines will be in real-life. Under the controlled and ideal setting of the clinical trial, these vaccines were found to be highly effective at preventing severe disease, hospitalization, and death associated with COVID-19, but real-world factors (e.g. how vaccine is stored, transported, administered) doesn't mimic a controlled clinical trial. [New data](#) has shown promising results that vaccines are maintaining effectiveness in real-world settings.
- ***The herd immunity threshold for COVID-19 is unknown.*** It is still uncertain when enough of Americans will be vaccinated to reach a threshold of protection, also known as herd immunity. The more transmissible a pathogen is, the more people must become immune in order to stop it. It is also important to understand that as cases caused by variants emerge and persist that are more easily and quickly spread, it is of even more importance that we vaccinate. The percentage of the population requiring immunization to acquire herd immunity against COVID-19 is not entirely known, but is estimated to be between 70-90%.
- ***It will be impossible to know who is and isn't vaccinated in your community.*** Vaccine is being allocated in a phased approach, and although you may want to get vaccinated, your priority group may not be able to get vaccinated right away. It is going to take time for vaccine to be distributed and enough of the population to be vaccinated to reach potential herd immunity.
- ***We don't know the duration of vaccine protection.*** Information regarding the length of protection from Pfizer, Moderna, and Johnson & Johnson vaccines are still being studied.

88) Can vaccinated individuals asymptotically transmit SARS-CoV-2?

The currently available COVID-19 vaccines are around 66-95% efficacious at preventing *symptomatic COVID-19*. [Recent research](#) suggests that mRNA COVID-19 vaccines also reduce *asymptomatic COVID-19*. It is [estimated](#) to reduce risk of asymptomatic infection among fully vaccinated individuals by 80% compared to people who have not been vaccinated.

Preliminary data from Johnson & Johnson's clinical trial suggests the vaccine could be 74% efficacious against asymptomatic COVID following day 29 after vaccination. More data are needed to substantiate these findings. Studies are expected in the coming months that better answer this question. It is

important to note that even if the vaccine does not prevent asymptomatic COVID and only prevents symptomatic COVID, it is still extremely valuable.

89) I have heard someone tested positive for COVID-19 after they were fully vaccinated, is this possible?

Yes, it is possible. Here are a few reasons why:

- **No vaccine is 100% effective.** While the currently available COVID-19 vaccines are highly effective, the protection is not perfect. A small percentage of people are not protected after vaccination and for others the protection may wane over time.
- **The vaccine has been shown to be highly effective at preventing COVID-19 disease.** The clinical trials only looked at whether the vaccine prevents disease, not infection, so a vaccinated person could still become infected and/or potentially spread the virus to others. Currently available COVID-19 vaccines are highly efficacious at preventing severe disease. But, we are still learning how well these vaccines prevent asymptomatic disease and transmission.
- **Current vaccines may not be as effective against new strains of the virus.** With the virus still widely circulating globally, we have seen a rise of variants in places such as the U.K., South Africa, and Brazil. We have even seen the presence of these variant strains in the U.S. (including in [North Dakota](#)), and while the vaccines appear to still provide protection, it may not be as effective at preventing infection from these variant strains.
- **Vaccines don't provide immediate protection.** It takes a few days to a few weeks for vaccines to provide protection. Our body needs time to build an immune response to the vaccine. If someone is exposed to the virus during this time, it is possible they still may become sick from the virus.
- **The test may be a false positive.** False-positive test results can occur. It may be that the test detected antibodies to a coronavirus closely related to the COVID-19 virus or that the test quality was flawed.

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

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 year, we have had approximately 567,000 deaths associated to COVID-19 and it is now the leading cause of death in the United States. While preventive measures like social distancing and masks help to slow the spread, **the only truly preventive measure against this virus is to vaccinate.**

Both the Pfizer and Moderna COVID-19 vaccines have reported 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.

Clinical trial data on the Johnson & Johnson COVID-19 vaccine has been shown to be 85% effective at preventing severe disease and it demonstrated ***complete protection against COVID-19 related hospitalization and death***. This vaccine is incredibly valuable in our fight against COVID-19.

It is important for everyone to be vaccinated when it is their turn so we can return to normal sooner.

91) Is the Pfizer vaccine better than the Moderna vaccine for older patients?

Clinical trial data for both Pfizer and Moderna showed strong vaccine efficacy for older populations. Elderly individuals should not delay vaccination because of product preference. Any vaccine that has been approved for use in the United States has met FDA standards for safety and efficacy. Further, vaccine supply is extremely limited and people may not be able to choose which vaccine they would like to receive.

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

Serious adverse events from vaccination are extremely rare. In the event of a serious injury following vaccination with COVID-19 vaccine, the PREP Act provides immunity from liability to the vaccine manufacturer, and the Countermeasures Injury Compensation Program (CICP) provides benefits to individuals who sustained the injury. More information on the PREP Act and CICP is below.

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 H1N1 pandemic in 2009.

The PREP Act does provide manufacturers of countermeasures (i.e. 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](#).

93) I have heard there are new strains of coronavirus circulating worldwide and have even been detected in North Dakota. Will the COVID-19 vaccines provide protection against it?

It is unknown whether the new virus strains (caused by mutations) will affect the efficacy of vaccines in the long run. While COVID-19 variants have been detected and confirmed in [North Dakota](#), both [Pfizer](#) and [Moderna](#) have reported that their vaccines produce immune responses that recognize and neutralize variant strains, although there was a reduction in antibodies that neutralize some variants. We also know that the [Johnson & Johnson](#) vaccine was 64% efficacious against moderate to severe disease and 81.7% efficacious against severe disease 28 days following vaccination in clinical trials in South Africa with 94.5% of the cases identified as the B.1.251 variant. In Brazil, the Johnson and Johnson vaccine was found to be 68.1% efficacious against moderate to severe disease and 87.6% against severe disease 28 days following vaccination with 69.4% of cases identified as the P.2 variant.

It is possible a variant of the virus may someday make current vaccines ineffective. The manufacturers anticipated potential mutation of the virus, as this is common in coronaviruses. Because of this knowledge, vaccines have been designed to target the entire spike protein on the surface of SARS-CoV-2. Vaccinated individuals produce antibodies that recognize many different parts of the spike protein, so even if one portion of the protein changes or mutates, there will be antibodies to other parts of the protein, which makes it harder for the virus to completely evade our immune systems.

94) I have heard reports of people dying following COVID-19 vaccination. Is the vaccine responsible for these reported deaths?

There have been reports of death following COVID-19 vaccination; however, to date, no link has been established between COVID-19 vaccination and any post-vaccination death.

It is important to note that nearly 8,000 people die every day in the United States. As millions of COVID-19 vaccines are administered across the country, inevitably some of the vaccinated will die within a few days of receiving the vaccine. It is human nature to draw a connection between events, especially when they happen close together, but it doesn't mean vaccination caused the death. The United States has the most comprehensive vaccine safety monitoring program in the world to detect adverse events following vaccination and investigate any death that follows vaccination to determine if the events could be connected. Thus far, there is no evidence to suggest that COVID-19 vaccination is associated with an increased risk of death.

95) I heard that VAERS has many reports of people who were vaccinated and then died. Is this true?

While there have been deaths reported to VAERS following COVID-19 vaccination, the CDC has determined that the deaths were not caused by the COVID-19 vaccine. It is important to note that anyone can report to VAERS, and any adverse event following a vaccination is encouraged to be reported so it can be investigated. While these reports may be temporally related (e.g. happened close together) that does not mean they are causally related (e.g. one event caused the other). The fact that

we are seeing these events following COVID-19 vaccine being reported through VAERS, shows us that our vaccine safety monitoring system is working.

Whenever a death or any serious event is reported to our monitoring systems following a COVID-19 vaccination they are taken very seriously and thoroughly investigated. Just because a death occurred following vaccination, it does not mean the vaccine caused the event. There are an average of 8,000 deaths every day in the U.S., and with over a million doses of COVID-19 vaccine being administered to the public *daily* in our country, the likelihood of a death occurring in those who have received a vaccine is not unexpected. That does not mean that the death was caused by getting vaccinated against COVID-19. There has been no increase in the rate of death in the vaccinated population in comparison to those who have not received a COVID-19 vaccine. Further, the CDC has not identified a single case in which the vaccine caused a person's death.

96) What if I refuse a COVID-19 vaccine? Will there be a penalty?

There will be no penalty for refusing a COVID-19 vaccine. ***Yet, vaccinating is the only way to end the pandemic and begin the process of returning to normal life.*** It is important to note that some employers may decide to not cover pay from quarantine and/or isolation required from COVID-19 exposure or infection if you refuse to vaccinate. Further, both the Pfizer and Moderna vaccines preliminary data indicate an efficacy around 95%, which places them among the best vaccines we have available compared to all recommended vaccines. Additionally, Johnson & Johnson clinical trial data indicated their vaccine is 85% effective at preventing severe disease and 100% effective at preventing hospitalization and death from COVID-19 28 days following vaccination.

It is also important to consider the true risk of choosing not to vaccinate. By not vaccinating, you put yourself and those around you at risk of getting sick from COVID-19. This virus 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. The best way to protect yourself and prevent spread of the disease to your friends, loved ones, and those in your community is to ***vaccinate against COVID-19.***

For more information on the benefits of getting a COVID-19 vaccine, please see the CDC [website](#).

97) If I have received my first dose of COVID-19 vaccine of a two-dose series in a state of my winter residence and I am now home (e.g. back in North Dakota), can I receive my second dose of vaccine in North Dakota?

Yes. If you have received your first dose in a different state and are now back in North Dakota prior to receiving your second dose, you should be provided your second dose of COVID-19 vaccine in North Dakota. It is important to keep your Vaccination Record Card with you when you travel home. The Vaccination Record Card will include important information on your first dose of COVID-19 vaccine including which vaccine you received, when you received it, and where you received it.

98) Can I still donate blood if I have received a COVID-19 vaccine?

The [FDA guidelines](#) state that individuals that have received an mRNA COVID-19 vaccine (Pfizer & Moderna vaccine) or a nonreplicating COVID-19 vaccine (Johnson & Johnson vaccine) can donate blood without a waiting period between receiving a COVID-19 vaccine and donating blood. The [Red Cross](#) and [Vitalant](#) have stated that if you have been vaccinated against COVID-19 you can still donate blood. Be prepared to provide the manufacturer name of the COVID-19 vaccine you received when you come to donate blood. Individuals should also consider bringing their [Vaccination Record Card](#) to their donation appointment.

99) What are the requirements if I do travel during the pandemic? Will I be required to provide proof of vaccination (e.g. vaccine passport)?

At this time, there are no universal requirements for proof of vaccination (e.g. vaccine passport) to travel. If you are traveling by air, each airline has its own unique requirement and recommendations. The NDDoH recommends that you check with the airline you are travelling through for their specific requirements. Additionally, certain destinations may have their own vaccine requirements. It's best to check with the destination to see if there are any travel-related requirements. The NDDoH Travel page can also provide you with greater detail regarding traveling during the pandemic. You can visit their website [here](#).

100) Can I still donate convalescent plasma if I have received a COVID-19 vaccine?

On Jan. 15, the [U.S. Food and Drug Administration](#) updated its guidance regarding convalescent plasma donor eligibility for those who receive a COVID-19 vaccine. The new guidance states that individuals who had COVID-19 symptoms and received a confirmed COVID-19 diagnostic test prior to vaccination, have fully recovered from symptoms of the virus within the last six months and meet other donation eligibility criteria may be able to donate convalescent plasma. This is to ensure that COVID-19 convalescent plasma collected from donors contains sufficient antibodies directly related to their immune response to COVID-19 infection.

However, at this time individuals who have received a COVID-19 vaccine are not able to donate convalescent plasma with the [Red Cross](#) or [Vitalant](#). Currently, the Red Cross is working as quickly as possible to evaluate this change—as it may involve complex system updates. Please check with your local plasma donation center to see what their guidelines are regarding convalescent plasma donations and COVID-19 vaccine.

101) I have heard that patients are encouraged to delay mammogram screening after a COVID-19 vaccination. Is this true?

[The Society of Breast Imaging](#) does not recommend or encourage patients to reschedule screenings, but does say patients should consider scheduling screening exams *before the first dose or 4-6 weeks after the second dose as long as that does not excessively delay their mammograms*. When patients do go in for their screening mammogram, please tell the technologist performing your exam if you have recently had the COVID-19 vaccine. Patients are encouraged to be body aware, and should notify their

doctor and undergo appropriate imaging if they feel a new or growing lump in their breast or armpit, *regardless of whether they received a COVID-19 vaccine recently.*

While we are still learning about the side effects that patients experience following their vaccination, many patients experience side effects typical of other vaccines (e.g. muscle ache, headache, arm soreness and fever). However, in a few cases, some patients have reported swelling of the lymph nodes in one armpit (11% of patients after the first dose, 16% after the second dose) that could potentially lead to false-positive readings. This symptom typically appears 2-4 days after vaccination on the side that the patient received the vaccine and usually resolves within two weeks. The swelling of lymph nodes is not uncommon following vaccines and has been reported as a side effect of the influenza vaccine. Side effects mean your body is building immunity and protection from the virus.

102) Should fertility patients coordinate the timing of their COVID-19 vaccine with fertility treatment?

[American Society for Reproductive Medicine](#) has stated, "COVID-19 vaccination is recommended for women who are contemplating pregnancy or who are pregnant in order to minimize risks to themselves and their pregnancy." However, fertility patients who are scheduled for procedures like egg retrieval, embryo transfer or intrauterine insemination are advised to avoid getting a COVID-19 vaccine within three days before and three days after the procedure according to the [American Society for Reproductive Medicine](#). This recommendation is made due to the fact that patients are undergoing surgical procedures could develop vaccine-related side effects like fever or chills that might make it difficult for doctors to know if a post-surgical infection is occurring. It is important to note that each patient should contact their healthcare provider to make the best decision regarding timing of fertility treatment and COVID-19 vaccination.

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

COVID-19 vaccine will not be mandated for all North Dakotans. The unique nature of COVID-19 vaccine being available under EUA (rather than full FDA licensure) when it will first be available is unprecedented.

The Equal Employment Opportunity Commission (EEOC) has stated that employers have the legal right to mandate employees to get a COVID-19 vaccine. Specifically, employers are entitled and required to ensure a safe workplace in which "an individual shall not pose a direct threat to the health or safety of individuals in the workplace." Requiring a COVID-19 vaccine will not violate the American Disabilities Act (ADA).

Further the EEOC has stated that "Simply requesting proof of receipt of a COVID-19 vaccination is not likely to elicit information about a disability and, therefore, is not a disability-related inquiry. However, subsequent employer questions, such as asking why an individual did not receive a vaccination, may elicit information about a disability and would be subject to the pertinent ADA standard that they be 'job-related and consistent with business necessity.'"

For more information on EEOC guidelines, please see their [website](#).

104) Where does it say that vaccines under EUA cannot be required?

It is stated in the provision section [360bbb-3 \(e\)\(1\)\(A\)\(ii\)\(III\) of the Food and Cosmetic Act – 21 U.S.C. 564](#), "Authorization for medical products for use in emergencies," which says:

(e)Conditions of authorization

(1)Unapproved product

(A)Required conditions

With respect to the [emergency use](#) of an [unapproved product](#), the Secretary, to the extent practicably given the applicable circumstances described in subsection (b)(1), shall for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(ii)Appropriate conditions designed to ensure that individuals to whom the product is administered are informed -

(III)of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risk.

105) Will personal information of those vaccinated in North Dakota be shared with the federal government?

No. North Dakota refused to submit identifiable data to the federal government regarding who is vaccinated with COVID-19 vaccine. The NDDoH will only be sharing de-identified data with the federal government.

106) 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 vaccine 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 did **NOT** receive COVID-19 vaccine before other states.

107) Where can I see how many doses of COVID-19 vaccine have been administered in North Dakota?

The NDDoH COVID-19 Vaccine Dashboard provides updated information on COVID-19 vaccine doses administered, doses received, and coverage rates. This dashboard can be accessed [here](#).

108) How can I access my immunization records?

Current and former North Dakota residents can view their own immunization records through [MyIR](#). MyIR is a secure online application that provides direct access to your immunization record. It takes just a few minutes to create an account and access your immunization record from NDIIS. For more information on immunization record requests, please visit the NDDoH [website](#).

109) Will vaccination rates be posted by priority groups? (ex. Vaccination rates for healthcare workers, long-term care residents, or teachers)

No. Vaccination rates are not available by priority group or profession. It is unlikely the NDDoH will be able to provide vaccination rates by priority groups, as this information is not reported through the NDIIS.

110) How can I avoid COVID-19 vaccine scams?

Online scammers are taking advantage of this health emergency by luring victims with false claims that they can deliver COVID-19 vaccination within days for a fee. The U.S. Department of Health and Human Services (HHS) issued a fraud alert on December 3 aimed at Americans eager to get vaccinated against COVID-19, saying: "You will not be asked for money to enhance your ranking for vaccine eligibility." Because doses of vaccine were purchased with U.S. taxpayer dollars, it will be provided to patients at no costs. Providers may charge an administration fee and have the fee reimbursed by private and public insurance companies. It is important to turn to trusted sources when looking for guidance on COVID-19 vaccine, this includes your local public health department, pharmacy, and/or healthcare provider.

The [FBI](#) has warned the public to be extremely wary of the following potential fraudulent activities:

- Advertisements/offers for early access to a vaccine with payment.
- Requests asking an individual *to pay out of pocket* to obtain a vaccine or to put their name on a COVID-19 vaccine waiting list.
- Offers for additional medical testing when obtaining a vaccine.
- People offering to sell/ship doses of a vaccine in exchange for a fee.
- Unsolicited emails, phone calls, and/or text messages from someone claiming to be from a medical office, insurance company or COVID-19 vaccine center to determine eligibility that you are unfamiliar with.
- Advertisements for vaccines through online and social media platforms.

To get more information on COVID-9 vaccine scams, please visit the AARP [website](#) and check out the HHS [Protect Yourself Avoid COVID-19 Vaccine Scams Handout](#).

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