# COVID-19 Vaccine

## Frequently Asked Questions

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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 12 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 May 12, 2021, anyone 12 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 vaccines, 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:

- 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.
- 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.**
  - 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.
  - 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.

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](https://www.nytimes.com/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 for individuals 16 and older. Pfizer enrolled 2,260 individuals in their adolescent (ages 12-15) 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 efforts 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 include 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.

12) Have any of the COVID-19 vaccine manufacturers applied for full FDA licensure in the U.S. (submitted a BLA)?

Yes. Pfizer, which received EUA for its COVID-19 vaccine in December of 2020, initiated its biological license application (BLA) for full approval of its vaccine for people ages 16 and older on May 7, 2021. Pfizer has requested a priority review, which asks the FDA to take action within six months (compared to the typical 10 month process). Moderna initiated its BLA on June 1, 2021. Moderna has also requested a priority review.

**COVID-19 Vaccine Safety and Efficacy**

13) 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.
Similarly, if a COVID-19 vaccine has been authorized or licensed for use in the U.S. and a potential adverse event is detected through our safety monitoring systems, vaccine administration may be paused so the event can be investigated.

14) 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 were safe and effective in clinical trials. These vaccines continue to be monitored through our safety monitoring systems to assure they are safe.

Millions of people in the United States have received COVID-19 vaccines under the most intensive safety monitoring in our history. To date, the only severe adverse event that has been associated with receiving the Pfizer or Moderna COVID-19 vaccines is a severe allergic reaction (anaphylaxis), which is manageable with treatment.

The FDA and CDC recommended a pause in the administration of Johnson & Johnson’s (Janssen) COVID-19 vaccine on April 13, 2021 to investigate 6 cases of women developing a rare type of blood clot with low platelet counts following vaccination (to read more on this topic, click here). On April 23, 2021, following a thorough safety investigation, the FDA and CDC recommended resuming the administration of Johnson & Johnson COVID-19 vaccine in the U.S. The FDA has stated: “We have concluded that the known and potential benefits of the Janssen COVID-19 vaccine outweigh its known and potential risks in individuals 18 years of age and older. We are confident that this vaccine continues to meet our standards for safety, effectiveness and quality.”

As of May 7, 2021, the CDC and FDA had identified 28 cases of this rare adverse event out of 8.7 million administered doses of Johnson & Johnson COVID-19 vaccine. This adverse event, which is likely related to receipt of the Johnson & Johnson COVID-19 vaccine, is rare and CDC continues to recommend the vaccine for use in the United States.

Pfizer reported 95% efficacy in individuals 16 years of age and older who received two doses and 100% efficacy in adolescents 12 to 15 years of age who received two doses of vaccine, while Moderna reported 94.1% efficacy for those 18 years of age and older who received two doses and 100% efficacy in adolescents 12 to 17 years of age who received two doses of vaccine. 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.
15) 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.

16) 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 vaccines to other routinely recommended vaccines:

- Pfizer novel coronavirus vaccine (2 doses): 95% (adults 16+ years) and 100% (adolescents 12-15 years)
- Moderna novel coronavirus vaccine (2 doses): 94.1% (adults 18+ years) and 96% (adolescents 12-17 years)
- Johnson & Johnson novel coronavirus vaccine (1 dose): 66%
- Influenza vaccine (1 dose): ~44%
- Chickenpox/Varicella vaccine (2 doses): 90%
- Measles (MMR-2 doses): 97%

17) 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 consistently across age, ethnicity and gender 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.
18) 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 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 598,000 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.

19) **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.

Updated 6/10/2021
20) 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.

21) The administration of the Johnson & Johnson COVID-19 vaccine was paused in the United States. What does this mean?
In early April 2021, the government recommended pausing the use of Johnson & Johnson (J&J) COVID-19 vaccine after six women received the vaccine and subsequently developed rare blood clots in combination with low levels of blood platelets (thrombocytopenia). This condition is known as thrombosis-thrombocytopenia syndrome (TTS). All six cases of TTS occurred in women between the ages of 18 and 48, and symptoms occurred 6-13 days after vaccination.

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.) recommended the 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.

Updated 6/10/2021
On April 23, 2021, following a thorough safety investigation, the FDA and CDC recommended resuming the administration of Johnson & Johnson COVID-19 vaccine in the U.S. The FDA has stated: “We have concluded that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks in individuals 18 years of age and older. We are confident that this vaccine continues to meet our standards for safety, effectiveness and quality.”

As of May 7, 2021, the CDC and FDA had identified 28 cases of this rare adverse event out of 8.7 million administered doses of Johnson & Johnson COVID-19 vaccine. This adverse event, which is likely related to receipt of the Johnson & Johnson COVID-19 vaccine, is rare and CDC continues to recommend the vaccine for use in the United States.

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.

22) 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?

The CDC has stated that current evidence suggests a plausible, causal association between thrombosis-thrombocytopenia syndrome (TTS) and the Johnson & Johnson COVID-19 vaccine. This event appears to be extremely rare, with 28 cases identified after 8.7 million doses of the Johnson & Johnson vaccine were administered. Because this event is so rare, it may not be detected in clinical trials that include tens of thousands of people.

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 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.

23) I recently received a Johnson & Johnson COVID-19 vaccine and I am worried about developing this serious side effect (TTS). What should I do?

It is important not to panic, as these events appear to be a very rare side effect. 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.

Updated 6/10/2021
24) 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 Pfizer’s expanded clinical trial to 12-15 year olds, there were no deaths reported. 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.

25) How will the safety of the COVID-19 vaccines 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.
  - Parents and guardians can now enroll adolescents (ages 12 and older) in V-SAFE and complete health check-ins on their behalf after COVID-19 vaccination.
- Additional information about safety monitoring is available on CDC’s COVID-19 vaccine website.

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

Yes. Pfizer has conducted a clinical trial in children ages 12-15 and is now authorized for emergency use in 12 and older in the U.S. Preliminary data indicates that the vaccine demonstrated 100% efficacy and was well tolerated in participants aged 12-15 years old. Pfizer has also started enrolling children 6 months - 11 years in clinical trials.

Moderna has conducted a clinical trial in children ages 12-17, and the vaccine was found to be 96% effective. Moderna has requested authorization of their vaccine for this age group. Moderna is currently enrolling their clinical trial for children ages 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.

27) 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.

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

Fainting, also called syncope, is a common event surrounding vaccination. It is not caused by 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.

29) 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.
30) 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.

31) 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 do not use any latex-containing products (ex. gloves) when administering the vaccine.

32) 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 eggs.

33) Do COVID-19 vaccines contain pork products?

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

34) 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.

35) I heard reports of blood clots following receipt of Johnson & Johnson’s COVID-19 vaccine. Should I be concerned about this adverse reaction from the vaccine?

There is a plausible, causal relationship between receiving a Johnson & Johnson COVID-19 vaccine and a very rare, but serious adverse event - blood clots with low platelets (e.g. thrombosis with thrombocytopenia syndrome, or TTS). However, after reviewing all available safety data, the CDC and the FDA continue to recommend the use of this vaccine in the United States given that the vaccine’s known and potential benefits outweigh the known and potential risks.

The adverse event is very rare, occurring at a rate of 9 out of every million Johnson & Johnson COVID-19 vaccines administered to women between the age of 18 and 49 years old. For women 50 years of age and older and men of all ages, this adverse event is even more rare.

If you have received a Johnson & Johnson COVID-19 vaccine, you should be aware of and watchful for the following symptoms the first three weeks following vaccination:

- Severe/persistent headaches or blurred vision
- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Easy bruising or tiny blood spots under the skin beyond the injection site.

Seek medical care immediately if you develop one or more of these symptoms. For further information on this rare potential adverse event, please visit the CDC website.

36) I heard reports of inflammation of the heart (myocarditis) and of the outer lining of the heart (pericarditis) following receipt of Pfizer and Moderna COVID-19 vaccines. Should I be concerned?

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the U.S. after mRNA COVID-19 vaccination (Pfizer and Moderna), particularly in adolescents and young adults. These
reports are rare, and to date, the CDC has not identified a safety signal in the Vaccine Adverse Events Reporting System (VAERS) or the Vaccine Safety Datalink (VSD). There has not been a similar reporting pattern observed after receipt of Johnson & Johnson COVID-19 vaccine.

In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating these reports of myocarditis and pericarditis following COVID-19 mRNA vaccination.

If you have received a Pfizer or Moderna COVID-19 vaccine, you should be aware of and watchful for the following symptoms in the first week following vaccination:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Seek medical care if you think you or your child have any of these symptoms.

CDC continues to recommend COVID-19 vaccination for everyone 12 years and older given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death. If you or your child has already gotten the first dose of Pfizer or Moderna’s COVID-19 vaccine, it’s important to get the second dose unless a vaccination provider or your doctor tells you not to get it.

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis. Also, most patients with myocarditis and pericarditis who received care responded well to medicine and rest and quickly felt better.

If you have concerns about COVID-19 vaccination, talk with your or your child’s doctor, nurse, or clinic and visit the CDC website for more information.

37) 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

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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.

### 38) If I’m currently using hormonal birth control (hormonal contraception), should I consider avoiding Johnson & Johnson’s COVID-19 vaccine?

People using hormonal birth control can receive any FDA-authorized COVID-19 vaccine. Although the risk of blood clots is increased with some hormonal birth control methods (e.g. birth control pills, patch, and ring), based on available data, experts believe that these factors do not make people more likely to develop thrombosis with thrombocytopenia syndrome (TTS) after receiving the Johnson & Johnson COVID-19 vaccine. TTS is a very rare condition that involves blood clots with low platelets.

All women younger than 50 years old (regardless of birth control use) should be aware of the rare, but increased risk for TTS following vaccination with Johnson & Johnson COVID-19 vaccine. For those who are concerned about developing TTS, other COVID-19 vaccines (Pfizer and Moderna) are available and have not been associated with this rare adverse event.

### 39) 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. 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 occurring.

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40) 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.

41) 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 and the May 12, 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.

42) 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.

Updated 6/10/2021
43) 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.

44) 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.

45) 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.

46) 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.

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**Getting Vaccinated**

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

As of May 12, 2021, COVID-19 vaccination is open to the entire general public 12 years of age and older. You can find providers offering COVID-19 vaccine in your area at [vaccines.gov](https://vaccines.gov).

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

Individuals 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 adults at increased risk for potentially severe and life-threatening outcomes from COVID-19 infection:

- Cancer
- Chronic kidney disease
- Chronic lung disease, including COPD, asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Dementia or other neurological conditions
- Diabetes (type 1 or type 2)
- Down syndrome
- Heart conditions, such as heart failure, coronary artery disease, cardiomyopathies or hypertension
- HIV infection
- Weakened immune system
- Liver disease
- Overweight or obesity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid-organ or blood stem cell transplant
- Stroke or cerebrovascular disease
- Substance use disorder

Current evidence suggests that children with underlying conditions, such as genetic, neurologic, metabolic conditions, or with congenital heart disease can be at increased risk for severe illness from COVID-19. Similar to adults, children with obesity, diabetes, asthma, or chronic lung disease, sickle cell disease, or immunosuppression can also be at increased risk for severe illness from COVID-19.

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To see more information on underlying medical conditions and COVID-19 please see the NDDoH website or the CDC website.

49) 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 12 years of age and older is eligible for COVID-19 vaccine in the state.

Find COVID-19 vaccine in your area by visiting vaccines.gov.

50) 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.

51) 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.

52) 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.

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53) 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.

54) 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.

55) I never received a COVID-19 vaccination card. Can I still get one?

It is possible to get a record of your COVID-19 vaccination, although it may or may not be a vaccination card. Instead, it may be a print-out of your vaccination record.

To obtain proof of vaccination, start by visiting the healthcare provider/vaccination site where you were vaccinated and see if they’ll give you a copy of your immunization record or a vaccination card. Bring an ID and try to recall the date you were vaccinated. If you received two shots at different places, NDDoH recommends returning to the site where you got the second dose (if you received Moderna or Pfizer’s COVID-19 vaccine), which may be able to provide the information needed for a complete card.

When you get vaccinated, your healthcare provider records all of your vaccinations in your electronic medical record that has a link to the state’s vaccination registry. You can always get a copy of your immunization record from the North Dakota Immunization System (NDIIS). To obtain your NDIIS records, please use one of the following methods:

- Call: 701.328.3386 or 800.472.2180
- Web: North Dakota Immunization Information System (NDIIS)
- Link to: Immunization record request
- Contact for immunization records: immrecord@nd.gov
- Email contact for NDIIS: ndiis@nd.gov

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56) What should I do if I lose my immunization record card? Is it possible to receive another one?

First, visit with the healthcare provider/vaccination site where you were vaccinated and see if they’ll give you a replacement. Bring an ID and try to recall the date you were vaccinated. If you received two shots at different places, NDDoH recommends returning to the site where you got the second dose (if you received Moderna or Pfizer’s COVID-19 vaccine), which may be able to provide the information needed for a complete card.

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- Email contact for NDIIS: ndiis@nd.gov

57) 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.

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

To find COVID-19 vaccine, the NDDoH recommends using vaccines.gov.

If you have not received a COVID-19 vaccine, but need help finding and registering for vaccine in your area, 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.

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

vaccines.gov 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

Updated 6/10/2021
60) **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.

61) **Can you 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.

62) **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.

63) **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.

64) **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.

65) **Should people who have had COVID-19 receive the COVID-19 vaccine?**

Yes. The CDC recommends that everyone be vaccinated, regardless of whether or not they already had COVID-19. This is because immunity after COVID is unpredictable; we do not know how long protection from COVID-19 lasts after the initial infection, how well natural infection protects against the variant.

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strains, and we know that reinfection is possible. COVID-19 vaccines provide a stronger and more consistent immune response than natural infection. Getting vaccinated after recovering from COVID-19 acts as a booster for the immune system. This immune system “boost” may offer additional protection against COVID-19 variants and prevent the spread of COVID-19 to others.

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.

66) 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.

67) 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](https://www.cdc.gov) and [NDDoH](https://www.nd.gov/health) recommendations on quarantine following exposure to COVID-19.

68) 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.

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69) Why can’t I just get a COVID-19 antibody test to see if I’m immune instead of getting vaccinated?

It is important to understand that an antibody test cannot give a definitive answer as to whether or not you are immune to COVID-19.

Our immune system, which involves a complex network of cells, organs and tissues, identifies foreign substances in your body and helps fight infections and diseases. Antibodies are a protein that play a role in this complex network and are produced by the immune system in response to an infection. They can attach to foreign invaders like bacteria, viruses, and fungi (referred to as antigens) in our body and mark them for destruction. After infection with the COVID-19 virus, it can take two to three weeks to develop enough antibodies to be detected in an antibody test. After this exposure/infection, antibodies continue to circulate in the blood, providing protection against future exposure to that antigen.

While antibodies are a crucial part of our immune system, a positive antibody test has no bearing on whether these proteins will actually provide enough protection against COVID-19 infection if you are exposed to the virus in a real-world situation OR how long their protection will last. Additionally, it is important to understand that with new variants of the virus spreading both globally and in the U.S., antibodies may not be able to recognize and produce a neutralizing immune response (e.g. an immune response strong enough to protect you from getting sick) to a variant of the virus if you are exposed.

While antibody tests for the coronavirus can help patients determine whether they were once infected, the best way to protect yourself from reinfection and those around you from COVID-19 is to get vaccinated.

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

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

71) 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.
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.

Can people with a history of multisystem inflammatory syndrome (MIS-C or MIS-A) receive a COVID-19 vaccine?

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A). People with a history of MIS-C or MIS-A may choose to be vaccinated.

A conversation between the patient, their guardian(s), and their clinical team or a specialist may assist with decisions about the use of a COVID-19 vaccine, though a conversation with a healthcare provider is not required before vaccination.

Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

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 June 9, 2021, more than 123,000 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.
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.

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.

75) 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.

76) 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.

77) Is there a COVID-19 vaccine that has been authorized for use in children?
Yes. In early May 2021, the FDA and CDC authorized and recommended Pfizer’s COVID-19 vaccine for everyone 12 years of age and older to help protect against COVID-19. The American Academy of Pediatrics (AAP) has stated, “Vaccines are safe and effective in protecting individuals and populations against infectious diseases. New vaccines are evaluated by a long-standing, rigorous, and transparent process through the US FDA and the CDC by which safety and efficacy data are reviewed prior to authorization and recommendation...The AAP recommends COVID-19 vaccination for all children and
adolescents 12 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age.”

Moderna’s COVID-19 vaccine is currently only authorized for individuals 18 years and older. However, the Moderna COVID-19 vaccine has been found to be 96% effective in 12-17-year olds and the company has requested authorization of their product for this age group.

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

78) Why should I vaccinate my child against COVID-19?

We all want our children to get back to the activities they love - whether that is being back in school, participating in extracurricular activities, or hanging out with friends and loved ones without masks. Vaccinating children and adolescents is the best way to restore normalcy to their lives safely.

As of June 3, 2021, over 3.99 million children have tested positive for COVID-19 since the beginning of the pandemic. The virus has also caused over 16,800 hospitalizations and more than 300 deaths among kids in the states and territories that have reported data. While these rates may seem low, COVID-19 has led to higher rates of hospitalization in adolescents compared to any of the last four years of seasonal influenza. Additionally, as more adults get vaccinated against COVID-19, children are making up a greater portion of overall COVID-19 cases in our country.

It is also important to understand that while children, in comparison to adults, tend to fare better from COVID-19 infections and are infected at lower rates - they can still be the source and recipient of outbreaks. Research has shown that transmission of COVID-19 can and does occur in children and adolescents. Additionally, adolescents, compared to younger children, are more likely to be infected and transmit the virus. The best way to protect ourselves, our children, and our community from this virus is for those who are eligible for COVID-19 vaccine to get vaccinated.

If you would like more information on COVID-19 vaccine for children and teens, please check out the following resources:

- CDC Handout - COVID-19 Vaccine for Preteens and Teens
- CDC Handout - What to Expect after Getting a COVID-19 Vaccine
- CDC Frequently Asked Questions about COVID-19 Vaccination

79) 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

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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.

80) 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 vaccines.gov to determine where vaccine is being provided in your area.

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

COVID-19 vaccines and other vaccines may now be administered together. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether potential reactions/side effects from COVID-19 vaccine is increased with coadministration, including with other vaccines known to potentially produce stronger inflammatory response following vaccination, such as adjuvanted vaccines or live vaccines. Consult with your healthcare provider regarding receiving additional vaccines in addition to a COVID-19 vaccine at a single visit.

82) 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.

83) 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.
84) 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.

85) 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.

86) 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.

87) 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.

88) Is there an interval between influenza vaccination and receiving COVID-19 vaccine?
COVID-19 vaccines can be administered at the same time or at any time interval from other vaccines.

89) How much will the coronavirus vaccine cost?
There should be no out-of-pocket costs for COVID-19 vaccine. 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.

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90) 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.

91) 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.

92) 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.

For more information on the benefits of getting a COVID-19 vaccine, please see the CDC website.

93) 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.

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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 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.

94) If I get a COVID-19 vaccine, what are the recommendations for quarantine and masking?

What can I do safely?

As of May 13, 2021, CDC recommendations state that 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]) persons in non-healthcare settings can:

- Resume activities without wearing masks or physically distancing, except where required by federal, state, local, tribal, or territorial laws, rules and regulations, including local business and workplace guidance
- Resume domestic travel and refrain from testing before or after travel or self-quarantine after travel

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● Refrain from testing before leaving the United States for international travel (unless required by the destination) and refrain from self-quarantine after arriving back in the United States

● Refrain from testing following a known exposure, if asymptomatic, with some exceptions for specific settings

● Refrain from quarantine following a known exposure if asymptomatic

● Refrain from routine screening and testing if feasible

Persons who are fully vaccinated should continue to get tested if they are experiencing COVID-19 symptoms and follow CDC and health department travel requirements and recommendations. For greater detail on CDC recommendations, please see their website.

95) Why do we have to continue to wear masks and practice social distancing following a COVID-19 vaccination in some locations?

Before we can completely 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.

● **The herd immunity threshold for COVID-19 is unknown.** It is still uncertain when enough 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.** 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.

● **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

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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.

**96) 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 50-80% 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.

**97) 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.

98) I heard CDC doesn’t investigate vaccine breakthrough cases (where someone tests positive for COVID-19 after they are fully vaccinated) if the cycle threshold (CT) value is greater than 28. Is that true?

No, that is not true. CDC defines breakthrough cases as an individual who is PCR or antigen positive on a respiratory specimen collected ≥14 days after completing a COVID vaccination series. Any case that meets this definition is counted as a breakthrough case regardless of the CT value. Whole genome sequencing can only be performed on these specimens with a CT value of 28 or lower. The ability to perform sequencing does not change their status as a breakthrough case.

99) 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 598,000 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% in adults and adolescents, 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 to prevent the spread of COVID-19.

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100) 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.

101) 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.

102) Will the COVID-19 vaccines provide protection against the COVID-19 variants?

It is unknown whether the new virus strains (caused by mutations) will affect the efficacy of vaccines in the long run. 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. The FDA and CDC continue to monitor this situation. In a recent update, the CDC stated that currently authorized vaccines continue to offer protection against COVID-19 variants.

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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.

103) I heard that there are many reports of people who were vaccinated and then died. Is this true?

A common piece of misinformation is that COVID-19 vaccines have caused thousands of deaths. This claim is misleading. It is important to remember that 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 thousands of COVID-19 vaccines 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.

If a serious adverse event or death is reported to our vaccine safety monitoring systems following a COVID-19 vaccination, they are taken very seriously and thoroughly investigated. The CDC has determined that the vast majority of the deaths reported following COVID-19 vaccination were not caused by the COVID-19 vaccine. (The rare exception is the few cases of TTS leading to death following receipt of the Johnson and Johnson vaccine.)

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. 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 following receipt of the Pfizer and Moderna COVID-19 vaccines, and the risk is extremely rare following receipt of the Johnson & Johnson vaccine.

When confronted with this misinformation, it is important to remember:

- **VAERS is a passive surveillance system** - Anyone can report to VAERS, and any adverse event following a vaccination is encouraged to be reported so it can be investigated. Thus, *anyone* can report *anything* to VAERS. VAERS was established in 1990 as an early warning system to detect vaccine safety problems in the United States. VAERS serves an important function in our vaccine safety monitoring system. But, the system has limitations, and it cannot be used to determine whether a vaccine caused or contributed to a reported death. The system helps to create signals, which are then investigated by scientists and other vaccine surveillance systems. The CDC even states the following disclaimer regarding the system: “The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable.”

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● **These reports do not establish causality** - A report to this system doesn’t prove that the identified vaccine (e.g. COVID-19 vaccine) caused the adverse event described (e.g. death). *No proof* that the event was caused by the vaccine is required in order for VAERS to accept the report. 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).

104) **I heard that if I get a COVID-19 vaccine my life insurance policy would be voided. Is this true?**

This is not true. The North Dakota Insurance Department has stated that receiving a COVID-19 vaccine will not affect your life insurance policy. Insurance companies cannot add such exclusions to existing policies, and no insurance companies have applied to the ND Insurance Department to add such an exclusion to new policies.

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

There will not be a penalty from the state of North Dakota for refusing COVID-19 vaccine. However, some employers may decide not to cover pay from quarantine and/or isolation required from COVID-19 exposure or infection if you refuse to vaccinate. Additionally, some companies may require COVID-19 vaccination as a condition of employment.

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 safe and an effective way to prevent disease. 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](https://www.cdc.gov).

106) **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.

107) **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 requirements 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.

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

The [FDA guidelines](https://www.fda.gov) 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](https://www.redcross.org) and [Vitalant](https://www.vitalant.org) 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](https://www.cdc.gov/vaccines) to their donation appointment.

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

On Jan. 15, the [U.S. Food and Drug Administration](https://www.fda.gov) 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](https://www.redcross.org) or [Vitalant](https://www.vitalant.org). 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.

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

[The Society of Breast Imaging](https://sobi.org) 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.

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

The 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 because patients who 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.

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

COVID-19 vaccine will not be mandated at a state level for all North Dakotans, but it is possible that private business may require vaccination for employment.

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.
113) 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.

114) 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.

115) 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.

116) 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.

117) 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.

118) I do not have access to dependable transportation to get to my COVID-19 vaccine appointment. Are there any resources I can access to schedule a ride?

Contact your local health department or call the NDDoH Hotline at 1.866.207.2880 for assistance. The Hotline can help find potential transportation options for those seeking a ride to receive a COVID-19 vaccine.

Alternatives:
Two ride-sharing companies in the U.S. are offering free rides for COVID-19 vaccine, they can be found here:

- Uber website: Committed to helping (uber.com)
- Lyft website: Helping people get rides to vaccine appointments – Lyft | Vaccine Access

A number of bus systems are offering free rides in North Dakota for COVID-19 vaccine. Check them out here:

- Fargo: MATBUS - News Detail
- Grand Forks: Cities Area Transit (CAT) | City of Grand Forks, ND (grandforksgov.com)

119) I do not have access to dependable child care. Are there any free child care options for me to utilize during my vaccination appointment?

The YMCA is offering free, drop-in child care in support of reducing barriers to vaccine access. As quoted from the YMCA, “The free, drop-in child care is the latest offering by Ys to provide safe and enriching places for children to learn and grow during the COVID-19 pandemic. When schools shut down last March, more than 1,400 YMCA sites offered child care to first responders and essential workers. Expanded child care and day camps provided support to parents over the summer. As children returned to school last fall, more than half of all Ys worked with local school districts to provide some form of virtual learning support, including transforming Y facilities into virtual learning spaces.”

Parents should contact their local YMCA to learn if it is offering free, drop-in child care during vaccination appointments. Visit Find Your Y to find YMCAs in your area.

To read more about this program, please visit the YMCA website.

120) 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, 2020, 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.

Updated 6/10/2021
● 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-19 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.