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

Vaccine Development and Approval

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

Yes. Currently, there are three vaccines available to prevent COVID-19 in the U.S.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unlicensed but authorized products for active immunization to prevent COVID-19 in individuals 18 years of age and older for Moderna and Johnson & Johnson's COVID-19 vaccines in the United States.

On August 23, 2021, the [FDA approved](#) Pfizer's COVID-19 vaccine for the prevention of COVID-19 in individuals 16 years of age and older. Dr. Woodcock (acting FDA commissioner) stated, "The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product." The vaccine will be marketed as Comirnaty. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

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 the viral genome sequence is available.
- Financing – The federal government has provided funding 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, there will be large amounts of vaccine ready. This is not typical because if a 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 distribution
 - 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

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?

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 trials, and approved/authorized for use, please see [The New York Times Coronavirus Vaccine Tracker](#).

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

According to an [article](#) published in *Human Vaccines and Immunotherapeutics* in 2012, phase III clinical trials for vaccines currently being used in the United States included, on average, 29,844 participants.

Ongoing phase III clinical trials for COVID-19 vaccine include or plan to include at least 30,000 participants.

Pfizer enrolled more than 43,000 individuals in their Phase III clinical trial for individuals 16 and older. Pfizer enrolled 2,260 individuals in their adolescent clinical trials (ages 12-15) and 4,500 individuals in their pediatric (6 months - 11 years of age) clinical trials. Moderna enrolled approximately 30,000 people in their adult Phase III clinical trial. Moderna enrolled 3,700 participants aged 12-18 in their adolescent study. Johnson & Johnson also enrolled more than 44,000 people in their adult clinical trial.

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.

The FDA has recently approved Pfizer's COVID-19 vaccine for use in individuals 16 years of age and older (The first COVID-19 vaccine to receive full approval). Pfizer's COVID-19 vaccine for children aged 12-15, a 3rd dose for certain people who are immunocompromised, and boosters for a select group of individuals are still available through EUA.

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, Moderna and Johnson & Johnson COVID-19 vaccines are available under EUA. The FDA has fully approved Pfizer's COVID-19 vaccine for use in individuals 16 years of age and older. Pfizer's COVID-19 vaccine for children ages 12-15, a 3rd dose for certain people who are immunocompromised, and boosters for a select group of individuals are still 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 advice 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 requested a [priority review](#) of its application. On August 23, 2021, the FDA approved Pfizer's

COVID-19 vaccine for the prevention of COVID-19 in individuals 16 years of age and older - making it the first COVID-19 vaccine to receive this distinction. The vaccine will be marketed as Comirnaty.

[Moderna](#) initiated its BLA on June 1, 2021. Moderna has also requested a priority review. On August 25, 2021 Moderna [announced](#) they had completed the rolling submission process for its BLA to the FDA.

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) How do we know the COVID-19 vaccines are safe?

Pfizer, Moderna and Johnson & Johnson have all indicated that their COVID-19 vaccines were safe and effective in clinical trials. Millions of people in the United States have received COVID-19 vaccines under the most intensive safety monitoring in our history. To read more on this topic, please visit the CDC website [here](#).

To date, COVID-19 vaccines have been shown to be safe and effective with mild side effects that typically resolve within 1-2 days. However, COVID-19 vaccines have also been linked to rare, more serious side effects.

Two potential severe adverse events have been associated with receiving the Pfizer or Moderna COVID-19 vaccines:

- Severe allergic reaction (anaphylaxis)
 - Rate: 2-5 per million vaccinated in the U.S. (extremely rare)
 - Symptoms include: skin rash, nausea, vomiting, difficulty breathing and shock
 - Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination and are manageable with treatment
 - To read more on anaphylaxis visit the CDC website [here](#)
- Inflammation of the heart (myocarditis and pericarditis)
 - Rate: 12.6 cases per million doses administered for individuals 12-39 years

- Most cases are in male adolescents and young adults 16 years of age or older
- Myocarditis is more common after the second dose
- Symptoms: chest pain, shortness of breath, fast-beating/fluttering/pounding heart
- Symptoms typically appear several days after COVID-19 vaccination
- Most patients who receive care respond well to treatment and rest and quickly feel better
- To read more on myocarditis and pericarditis visit the CDC website [here](#)

Two potential severe adverse events have been associated with receiving the Johnson & Johnson COVID-19 vaccine:

- A rare type of blood clot with low platelet counts (also known as thrombosis with thrombocytopenia syndrome or TTS).
 - Rate: 7 per million for women 18 to 49 years of age who have been vaccinated, and for both women 50 years of age and older and men the rate is less than 1 per million people vaccinated (extremely rare)
 - Most cases are in women younger than 50 years of age
 - Symptoms: severe headache, shortness of breath, chest pain, leg swelling, gut pain that doesn't go away, and easy bruising or tiny blood spots under the skin
 - Symptoms typically appear 1-2 weeks after vaccination
 - To read more on TTS visit the CDC website [here](#)
- Guillain-Barre Syndrome (GBS)
 - A rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis
 - Rate: 12.8 per million doses administered (extremely rare)
 - Most cases are in men, many 50 years of age and older
 - Symptoms: weakness and tingling in the feet and legs spread to the upper body. Paralysis can occur.
 - Symptoms typically reported about 2 weeks after vaccination
 - To read more on GBS visit the NIH website [here](#)

When deciding if you should be vaccinated, it is important to weigh the risks and benefits of vaccination with the risks of COVID-19. The CDC continues to recommend vaccination for all individuals 12 years of age and older.

15) What is the current *effectiveness* of COVID-19 vaccines authorized for emergency use in the U.S., including against variants like Delta?

In clinical trials, 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. 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 offers complete protection against COVID-19-related hospitalization and death 28 days after vaccination.

It is unknown whether the new virus variants (caused by mutations) will affect the efficacy of vaccines in the long run. [Pfizer](#), [Moderna](#), and [Johnson & Johnson](#) 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 Delta variant, which originated in India, has become the dominant variant in the U.S. and globally. Recent research suggests that Delta is more contagious and spreads faster than previous strains. Delta may also cause more severe outcomes in comparison to previous variants, with increased risks of [hospitalization](#) and [death](#).

COVID-19 vaccines authorized in the U.S. continue to be remarkably effective against severe disease, hospitalization, and death from COVID-19. [Nearly all recent COVID-19 hospitalizations and deaths](#) are occurring among unvaccinated individuals. Vaccinating is the best way to protect yourself, loved ones, and those in your community from COVID-19. Additionally, as more people become vaccinated, the virus will not be able to find a susceptible host to replicate in (and potentially mutate). Therefore, vaccination is an important step to prevent variant strains from emerging.

16) 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 cases 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.

17) 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.

The available data shows that a 2-dose series [provides consistently higher protection](#) compared to a partial (one-dose) series. Additionally, [recent research](#) has shown that a single dose of a two-dose COVID-19 vaccine does not provide adequate protection against the Delta variant (which is now the dominant variant in the U.S.), however, fully vaccinated individuals retain [significant protection](#) against

severe outcomes, hospitalization and death from Delta. ***For best protection, it is recommended that individuals receive two doses.***

18) 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.

19) 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 49, 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*** – In these six events, the event happened very shortly after vaccination. However, 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.

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 September 22, 2021, the CDC and FDA had identified 47 cases of this rare adverse event out of 14.8 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.

20) 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 there is an increased risk of a rare adverse event called thrombosis with thrombocytopenia syndrome (TTS) following receipt of the Johnson & Johnson COVID-19 vaccine. To date, the CDC has identified 47 cases of TTS out of the 14.8 million doses of the Johnson & Johnson vaccine 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 TTS), 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 300,000 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.

21) 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](#).

22) 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.**

23) 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 also 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](#).

24) 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 the vaccine is now authorized for emergency use for everyone 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. On September 28, 2021, Pfizer announced they have [submitted initial data](#) from a phase two/three trial of their vaccine in children 5-11 years of age to the FDA. FDA's [VRBPAC committee will be meeting on October 26, 2021](#) to address Pfizer's request to amend its EUA to allow for the use of their COVID-19 vaccine in children 5-11 years of age. Data on Pfizer's trials in children from 6 months to 4 years of age are also expected in the coming months.

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. Additionally, a recent [study](#) conducted in Israel analyzed data on 15,060 pregnant women and compared COVID-19 related outcomes in the vaccinated and unvaccinated pregnant women. Their findings suggest that Pfizer's COVID-19 vaccines are safe and vaccination was associated with a significantly lower risk of SARS-CoV-2 infection compared to those who were not vaccinated. Additionally, [preliminary findings](#) from safety monitoring systems in the U.S. did not show obvious safety signals among pregnant persons who received mRNA COVID-19 vaccines.

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.

25) 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.

26) 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.

27) 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.

28) Do COVID-19 vaccines cause sudden hearing loss?

No. [Recent research](#) has concluded that vaccination against COVID-19 does not increase one's risk for sudden hearing loss and that these two events are not causally related.

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

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

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

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

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

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

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

32) Do COVID-19 vaccines contain pork products?

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

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

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

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

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

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

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

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

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

It is important to remember that this adverse event is very rare, occurring at a rate of 7 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 (less than 1 per 1 million people vaccinated). The Pfizer and Moderna vaccines have not been associated with blood clots and would be an alternative to those who are concerned about this rare side effect.

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](#).

35) 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 the CDC and its partners are actively monitoring reports of myocarditis and pericarditis after COVID-19 vaccination. 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. [Research](#) has shown that incidence of myocarditis following an mRNA COVID-19 vaccine is rare and that symptoms in a majority of cases resolve following care. CDC and its partners will continue to investigate 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.

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis. 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.

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.

36) I heard reports of Guillain-Barré syndrome (GBS) following receipt of Johnson & Johnson COVID-19 vaccines. Are these events related?

On July 13, 2021, the FDA released a [statement](#) that suggested that there is possible increased risk of GBS following receipt of a J&J COVID-19 vaccine. The FDA has added additional information to the vaccine's FDA [fact sheet](#) on the risk of GBS. The chance of GBS occurring is very low following J&J vaccination. As of September 22, 2021, 210 preliminary reports of GBS have been identified in VAERS out of the more than 14.8 million J&J COVID-19 vaccine doses that have been administered in the U.S. Cases occur mostly in males and have largely been reported approximately two weeks after vaccination. You should seek medical attention right away if you develop any of the following symptoms following receipt of a J&J vaccine: weakness or tingling sensations, difficulty walking, difficulty with facial movement, double vision/inability to move eyes, and/or difficulty with bladder control/bowel function.

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of GBS. Safety monitoring systems will continue to monitor for cases of GBS to determine if vaccination is associated with onset of GBS.

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

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

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

- First, the person who made the claim is not the head of Pfizer research. **The truth:** the individual worked at Pfizer nearly a decade ago in a division that was not directly involved in vaccinology.
- Second, the claim says the COVID-19 mRNA vaccine produces a protein called syncytin-1, which is vital for placental formation. If the body creates an immune response to syncytin-1, the immune system may inadvertently attack the placenta during future pregnancies and lead to infertility. **The truth:** the vaccine works by forming an immune response to the SARS-CoV-2 spike protein. The SARS-CoV-2 spike protein does share a very small genetic sequence with syncytin-1. However, there is little concern about the possibility of the anti-spike protein antibodies attacking the syncytin-1 protein because the immune system recognizes the surface of target proteins, and this is rarely confined to a short genetic sequence (like the genetic sequence shared between the SARS-CoV-2 spike protein and syncytin-1).

- Finally, if this claim was true, those who have had natural infection with COVID-19 would also produce antibodies to the syncytin-1 protein and would experience infertility. Currently, we have no evidence that natural infection is leading to infertility in women.

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

38) I have heard that the COVID-19 vaccine could affect male fertility. Is this true?

No. There is no evidence nor any valid theories to suggest any credible risk of male (or female) infertility following COVID-19 vaccine administration.

What we do know is that research has suggested that COVID-19 may lead to a [6x higher risk](#) of erectile dysfunction compared to those with no history of COVID-19. Additionally, COVID-19 may affect [semen count/quality](#).

39) 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.

40) 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.

41) 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.

42) 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 July 22, 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.

43) 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 July 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 (J&J) COVID-19 vaccine clinical trial. On July 13, 2021, the FDA released a [statement](#) that suggested that there is possible increased risk of GBS following receipt of a J&J COVID-19 vaccine. The FDA has added additional information to the vaccine's FDA [fact sheet](#) on the risk of GBS. The chance of GBS occurring is very low following J&J vaccination. As of September 22, 2021, 210 preliminary reports of GBS have been identified in VAERS out of the more than 14.8 million J&J COVID-19 vaccine doses that have been administered in the U.S. Cases occur mostly in males and have largely been reported approximately two weeks after vaccination. You should seek medical attention right away if you develop

any of the following symptoms following receipt of a J&J vaccine: weakness or tingling sensations, difficulty walking, difficulty with facial movement, double vision/inability to move eyes, and/or difficulty with bladder control/bowel function.

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of GBS. Safety monitoring systems will continue to monitor for cases of GBS to determine if vaccination is associated with onset of GBS.

44) 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.

45) 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.

46) 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. Both Pfizer and Moderna used fetal cells to test the science behind their vaccine platforms.
 - 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.

- Two major Islamic scholars' councils, including the Fiqh Council of North America and the Assembly of Muslim Jurists of America, have studied the vaccine at great length and [have concluded that they are halal or lawful](#).
- Individuals should not delay vaccination because of product preference.
- For more information on this topic please view the [NDDoH handout](#).

47) 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.

48) I have questions about COVID-19 vaccine. Can I schedule an appointment with my provider to talk about COVID-19 vaccination and will insurance cover it?

Yes. You can schedule appointments with your provider to discuss COVID-19 vaccination. Insurance should cover such visits under a standard office visit.

Getting Vaccinated

49) 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 [ndvax.org](#) or [vaccines.gov](#).

The North Dakota Department of Health COVID-19 Vaccine Primary Series Decision Tree can be used to assess an individual's eligibility for COVID-19 vaccine. This document can be accessed [here](#).

50) Can people with underlying conditions receive the vaccine?

Yes. People with underlying conditions are at a higher risk for severe COVID-19. 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.

Individuals with underlying medical conditions may be eligible for a booster dose of COVID-19 vaccine. Please [click here](#) for more information.

51) 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 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:

- 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 and 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.

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

52) 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 ndvax.org or vaccines.gov.

53) 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 [AAP](#) & [CDC recommend](#) implementing mitigating strategies to reduce transmission of SARS-CoV-2 in schools. The CDC has recently updated guidelines, and has stated the following: "Given new evidence on the B.1.617.2 (Delta) variant, CDC has updated the [guidance for fully vaccinated people](#). CDC recommends universal indoor masking for all teachers, staff, students, and visitors to K-12 schools, regardless of vaccination status. Children should return to full-time in-person learning in the fall with layered prevention strategies in place."

Educators and those working in the school setting should weigh the risk and benefits of vaccination with the risk of COVID-19 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.

54) 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.

55) 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.

56) 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.

57) Will I need a booster dose even if I have completed my COVID-19 vaccine series (e.g. a 3rd dose of Pfizer's or Moderna's COVID-19 vaccine or 2nd dose of Johnson & Johnson's COVID-19 vaccine)?

On September 23, 2021, the CDC recommended that certain populations receive a booster shot of Pfizer's COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series.

The CDC has said the follow groups **should** receive a booster shot of Pfizer's COVID-19 vaccine at least 6 months after their original Pfizer primary series:

- Individuals 65 years and older and residents in long-term care settings
- Individuals 50-64 years with [underlying medical conditions](#) should receive a

The CDC has said the following groups **may** receive a booster shot of Pfizer's COVID-19 vaccine at least 6 months after their original Pfizer primary series:

- Individuals 18-49 years who are at high risk for severe COVID-19 due to certain [underlying medical conditions](#)
- Individuals aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting

To read more about the difference between "should" and "may" stated in the above CDC recommendations, please [click here](#). This updated interim guidance from CDC applies to millions of adults in the U.S., and follows the Sept. 22 decision by the U.S. Food and Drug Administration (FDA) in support of this allowance.

At this time, the Pfizer booster authorization only applies to people whose primary series was completed with the Pfizer vaccine. People in the recommended groups who got the Moderna or Johnson & Johnson vaccine will likely need a booster shot. More data on the effectiveness and safety of Moderna and Johnson & Johnson booster shots are expected in the coming weeks. With those data in hand, CDC will keep the public informed with a timely plan for Moderna and Johnson & Johnson booster shots.

For more information, please see the NDDoH handout on boosters [here](#).

58) What occupational or institutional settings qualify an individual for a Pfizer COVID-19 vaccine booster?

On September 23, 2021, the CDC recommended that [certain populations](#) receive a booster shot of Pfizer's COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series. Adults aged 18–64 years who work or reside in certain settings may be at increased risk of being exposed to COVID-19. Occupations at increased risk for COVID-19 exposure and transmission include

front line essential workers and healthcare workers. Some additional examples include (but not limited to):

- First responders (healthcare workers, firefighters, police, congregate care staff)
- Education staff (teachers, support staff, daycare workers)
- Food and agriculture workers
- Manufacturing workers
- Corrections workers
- U.S. Postal Service workers
- Public transit workers
- Grocery store workers

Since that risk can vary across settings and based on how much COVID-19 is spreading in a community, people aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may get a booster shot after considering their individual risks and benefits. This recommendation may change in the future as more data become available.

59) When can I get a COVID-19 vaccine booster if I am NOT in one of the recommended groups?

Additional populations may be recommended to receive a booster shot as more data becomes available. The COVID-19 vaccines approved and authorized in the United States ***continue to be effective at reducing risk of severe disease, hospitalization, and death***. However, the virus that causes COVID-19 constantly evolves. Experts are looking at all available data to understand how well the vaccines are working for different populations. This includes looking at how new variants, like Delta, affect vaccine effectiveness.

60) If we need a booster shot, does that mean that the vaccines aren't working?

No. ***COVID-19 vaccines are working well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant***. However, public health experts are starting to see reduced protection, especially among certain populations, against mild and moderate disease.

61) What should people who received Moderna or Johnson & Johnson's vaccine do?

The Advisory Committee on Immunization Practices (ACIP) and CDC's recommendations are bound by what the FDA authorization allows. At this time, the Pfizer booster authorization only applies to people whose primary series was the Pfizer vaccine. People in the recommended groups who got the Moderna or Johnson & Johnson vaccine will likely need a booster shot at some point in time. More data on the effectiveness and safety of Moderna and Johnson & Johnson booster shots are expected in the coming weeks.

62) What are the risks of getting a booster?

For many who have completed their primary series with the Pfizer vaccine, ***the benefits of getting a booster shot outweigh the known and potential risks***. So far, reactions reported after the third Pfizer

shot were similar to that of the 2-shot primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the 2-shot primary series, serious side effects are rare, but may occur. Additionally, [findings](#) from V-safe (one of the vaccine safety monitoring systems in the U.S.) have found no unexpected patterns of adverse reactions following an additional dose of COVID-19 vaccine. CDC will continue to monitor the safety and effectiveness of COVID-19 vaccines, including booster doses.

63) Does the addition of boosters change the definition of “fully vaccinated” for those eligible for booster shots?

People are still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer or Moderna vaccines, or two weeks after a single-dose vaccine, such as the Johnson & Johnson vaccine. This definition applies to all people, including those who receive an additional dose as recommended for moderate to severely immunocompromised people and those who receive a booster shot.

64) Can you explain the “permissive” recommendations related to people 18 to 49 with underlying medical conditions, and people 18 to 64 who may be exposed due to occupational/institutional setting? How are these different from the other two recommendations?

Adults 18–49 years of age who have underlying medical conditions are at increased risk for severe COVID-19, as are people 18-64 years of age who are in an occupational or institutional setting where the burden of COVID-19 and risk of transmission are high. However, that risk is likely not as high as it would be for adults 50 years and older who have underlying medical conditions, or people who live in long-term care settings. With the lower risk, the data do not support that everyone who falls into this group should get a booster shot. Therefore, CDC’s recommendation is not as strong for these populations, but still allows a booster shot to be available for those who would like to get one. People 18 years of age and older who are at high risk for severe COVID-19 due to underlying medical conditions or their occupation should consider their individual risks and benefits when making the decision of whether to get a booster shot. This recommendation may change in the future as more data becomes available.

65) Will providers accept anyone who says they’re eligible to receive a booster shot? Will people need to show a doctor’s note/prescription or other documentation?

Individuals can self-attest (i.e. self-report that they are eligible) and receive a booster shot wherever vaccines are offered. This will help ensure there are not additional barriers to access for these select populations receiving their booster shot.

It is important to bring your vaccine record card with you when you receive your booster dose so it can be updated with information regarding your third dose of Pfizer vaccine.

66) What's the difference between a booster and an additional dose?

A *booster dose* of vaccine is given when the initial, sufficient immune response to a primary vaccine series is likely to have waned over time. On September 23, 2021, the CDC recommended certain populations receive a booster shot of Pfizer's COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series.

An *additional dose* of vaccine is given when the initial immune response following a primary vaccine series is likely to be insufficient. The CDC recommends moderately to severely immunocompromised people consider receiving an additional (third) dose of an mRNA COVID-19 vaccine. For some immunocompromised individuals, receiving an additional third dose of COVID-19 vaccine helps them to build a better immune response - potentially similar to what most people receive with just two doses.

67) I received a Johnson & Johnson COVID-19 vaccine. Do I need to be revaccinated with an mRNA COVID-19 vaccine (Pfizer or Moderna)?

No. Johnson & Johnson's COVID-19 vaccine has been determined to be both safe and effective and boosters are not recommended at this time. Additionally, [research](#) has suggested that Johnson & Johnson's vaccine works well against the Delta variant, and research has shown that the "Johnson & Johnson single-shot COVID-19 vaccine elicited neutralizing antibody activity against the Delta variant at an even higher level than what was recently observed for the Beta (B.1.351) variant in South Africa where high efficacy against severe/critical disease was demonstrated."

On August 18th, 2021, the U.S. Department of Health and Human Services put out the following statement, "We anticipate booster shots will likely be needed for people who received the Johnson & Johnson (J&J) vaccine. Administration of the J&J vaccine did not begin in the U.S. until March 2021, and we expect more data on J&J in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well."

On September 21, 2021, Johnson & Johnson released initial data on booster doses. Individuals who received a booster shot at six months following their initial dose had a 12-fold increase in antibodies. The [press release](#) stated, "New data also showed that protection against COVID-19 increases when a booster shot of the Johnson & Johnson vaccine is administered. The safety profile of the vaccine remained consistent and was generally well-tolerated when administered as a booster."

To read more about Johnson & Johnson's COVID-19 vaccine, please visit the CDC [website](#).

68) 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.

69) Should immunocompromised individuals who completed their COVID-19 vaccine series receive an additional dose?

The FDA has recommended an additional dose (not considered a booster) of Pfizer or Moderna COVID-19 vaccine for certain immunocompromised individuals. *At this time, there is not enough evidence for Johnson & Johnson COVID-19 recipients to make a recommendation regarding additional doses, thus individuals who have received this vaccine are not authorized for an additional dose.*

A [third dose of Moderna or Pfizer](#) can be administered to those who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. A third dose of Moderna or Pfizer vaccine is recommended 28 days following the first two doses of COVID-19 vaccine and should be the same manufacturer as the primary series.

It is important that immunocompromised individuals, including those who receive a third dose of Moderna or Pfizer, continue to follow prevention measures. These measures include wearing a mask, staying 6 feet apart from others, and avoiding crowds and poorly ventilated indoor spaces. Additionally, close contacts of immunocompromised patients should be strongly encouraged to get vaccinated against COVID-19.

For more information, please see the CDC [website](#).

70) Who is considered eligible for receiving an additional dose of COVID-19 vaccine?

Currently, CDC is recommending that moderately to severely immunocompromised people receive an additional dose. This includes people who have (but NOT limited to):

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

Again, this is a limited list of those eligible for an additional COVID-19 vaccine dose. People should talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them. Please see the [CDC website](#) for greater detail.

71) 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.

72) If I have received an additional dose (third dose of mRNA COVID-19 vaccine), do I need a booster as well?

Immunocompromised people who received an additional dose of COVID-19 vaccine are among those not yet indicated for boosters. An additional dose of mRNA COVID-19 vaccine is recommended for moderately to severely immunocompromised people at least 28 days after the initial two-dose series, in whom the primary series is likely to provide insufficient protection. A booster dose is administered 6 months after the two-dose primary series, when an initial immune response to the vaccine is likely to have waned over time.

The CDC has not issued recommendations for a COVID-19 vaccine booster dose at least 6 months after a primary series for people who have received an additional dose (e.g. third dose of mRNA COVID-19 vaccine).

73) 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 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. Additionally, [recent research](#) out of Kentucky has shown that those who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated.

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.

74) 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.

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

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

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

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

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

76) 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.

77) 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 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.

78) 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.

79) 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.

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

The current CDC recommendations state that anyone who has previously had COVID-19 should complete a COVID-19 vaccine 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. However, at this time, there are no recommendations related to giving a single dose of a two-dose COVID-19 vaccine series to those who have recovered from COVID. Those who are able and qualified for COVID-19 vaccination and have received a first dose of a two-dose series should complete the vaccine series, regardless of a previous 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. Additionally, [recent research](#) out of Kentucky has shown that those who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated.

81) 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.

82) Can pregnant women receive COVID-19 vaccine?

Yes. Because of their increased risk of severe COVID, pregnant women are encouraged to be vaccinated against COVID.

On July 30, 2021, the two leading organizations representing specialists in obstetric care, the American College of Obstetrics and Gynecology (ACOG) and the Society for Maternal-Fetal Medicine (SMFM), put out a [joint statement](#) which stated, "Vaccines are our single most effective tool against preventable viruses or diseases, including COVID-19. ACOG and SMFM encourage pregnant individuals to get vaccinated without delay because widespread uptake of the vaccines is the best chance we have to save lives and end this pandemic." ACOG President, Dr. Tucker, has additionally stated, "[ACOG is recommending vaccination of pregnant individuals](#) because we have evidence of the safe and effective use of the vaccine during pregnancy from many tens of thousands of reporting individuals, because we know that COVID-19 puts pregnant people at increased risk of severe complications, and because it is clear from the current vaccination rates that people need to feel confident in the safety and protective value of the COVID-19 vaccines. Pregnant individuals should feel confident that choosing COVID-19 vaccination not only protects them but also protects their families and communities." To view ACOG published guidance, click [here](#).

On September 29, 2021, the CDC [recommended urgent action](#) to increase COVID-19 vaccination among people who are pregnant, recently pregnant, who are trying to become pregnant now, or who might become pregnant in the future. The highest number of COVID-19 related deaths in pregnant people in a single month of the pandemic was reported in August 2021. Additionally, approximately 97% of pregnant people hospitalized (either from illness or for labor and delivery) with confirmed

COVID-19 were unvaccinated. The CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.

As of September 27, 2021, more than 161,000 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. Additionally, a recent [study](#) conducted in Israel analyzed data on 15,060 pregnant women and compared COVID-19 related outcomes in the vaccinated and unvaccinated pregnant women. Their findings suggest that Pfizer's COVID-19 vaccines are safe and vaccination was associated with a significant lower risk of SARS-CoV-2 infection compared to those who were not vaccinated.

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 unborn child, 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.

For additional information on COVID-19 vaccine and pregnancy, click [here](#).

NDDoH will update this information as more details become available.

83) Can pregnant women receive a COVID-19 vaccine booster?

[ACOG](#) (The American College of Obstetricians and Gynecologists) has provided the following recommendations regarding pregnant women and boosters: "ACOG recommends that pregnant people, including pregnant healthcare workers, receive a booster dose of the Pfizer-BioNTech COVID-19 vaccine at least 6 months following the completion of their initial Pfizer-BioNTech COVID-19 vaccine series."

The CDC recommendations state that individuals 18 and older with underlying medical conditions [may receive a booster dose](#) of Pfizer COVID-19 vaccine at least 6 months after completing their Pfizer primary series, based on their individual benefits and risks. This includes [pregnant and recently pregnant women](#).

Pregnancy is considered an underlying medical condition because pregnant and recently pregnant women are at an increased risk of severe illness from COVID-19. In addition to the risk of severe illness and death for pregnant and recently pregnant people, there is also an increased risk for adverse

pregnancy and neonatal outcomes, including preterm birth and admission of their neonates to an ICU. Lastly, the highest number of COVID-19-related deaths in pregnant people in a single month of the pandemic was reported in August 2021.

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

Yes. COVID-19 vaccination is recommended for people who are breastfeeding. 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 \(ACOG\)](#) strongly recommends that lactating individuals be vaccinated against COVID-19. They have additionally 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](#).

85) 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.

86) Is there a COVID-19 vaccine that has been authorized for use in children?

Yes. In 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.

Vaccines for children under 12 years of age are not yet available but may be available by late 2021 or sometime in 2022.

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

We all want 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 September 23, 2021, over 5.7 million children have tested positive for COVID-19 since the beginning of the pandemic. The virus has also caused over 21,000 hospitalizations and more than 498 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. In August, hospitalizations among children and adolescents [increased 4x](#) more in states with low levels of vaccination compared with states with high levels of vaccination. Additionally, after declining in early summer, child cases have been increasing exponentially. Children now account for 1 out of every 4 cases of COVID-19 in the United States.

It is also important to understand that while children, in comparison to adults, tend to fare better from COVID-19 - 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.

In a [real-world example](#), 47 cases of COVID-19 were linked in Oklahoma to a gymnastic facility in April and May of 2021. Thirty-one of those cases were in individuals under the age of 19. Only 23% who were eligible for COVID-19 vaccine were fully vaccinated. Two adult patients (both unvaccinated) were hospitalized (one led to an ICU admission) for COVID-19. This particular outbreak was linked to the Delta variant. Delta is highly transmissible and has been determined to be as contagious as chickenpox. Delta is now the dominate variant in the U.S., and may lead to increased attack rates. 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. With a new variant like Delta, it is more important than ever to get vaccinated - so we can get back to doing the things we love, like participating and attending kids sporting events, *safely*.

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](#)

88) Why does the CDC and American Academy of Pediatrics (AAP) recommend masking in schools, regardless of vaccination status?

The CDC and AAP recommend the use of masks regardless of vaccination status because:

- **Students under 12 are ineligible for vaccine** - A significant portion of students are not yet eligible for COVID-19 vaccines.
- **Masks reduce transmission** - Masking is proven to reduce transmission of the virus and protect those who are not vaccinated. [Research](#) suggests that requiring masks in K-12 schools limits COVID-19 outbreaks. Schools without mask requirements are 3.5x more likely to have COVID-19 outbreaks compared to schools that started the year with mask requirements.
- **Vaccines are not 100% effective** - While currently available COVID-19 vaccines are highly effective, there are still those who are fully vaccinated that may not be fully protected against the virus.
- **Delta variant** - The Delta variant is highly transmissible and is now the dominant strain of COVID-19 in the U.S.

In a [real-world example](#) from May of 2021, 26 COVID-19 cases occurred among elementary school students and their contacts following exposure to an unvaccinated infected teacher who inconsistently wore a mask in the classroom. None of the students were age-eligible for COVID-19 vaccine. The attack rate among students in the infected teacher's classroom was 50%. Risk correlated with seating proximity to the teacher with an attack rate of 80% among students that sat in the first two rows of desks.

By using all the tools we have available to us to reduce the transmission of COVID-19, we help to protect our children, loved ones, and our community against this virus. Every layer - vaccinating, masking, and social distancing, help students get back to school safely.

To read more on the AAP guidance, please visit their [website](#). To see the CDC guidance for COVID-19 prevention in K-12 schools, see their [website](#).

89) 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.

90) 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

91) 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.

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:

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92) 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.

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

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

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

To see where COVID-19 vaccination is currently being offered in North Dakota, please check out ndvax.org. This free website can help you find when and where COVID-19 vaccine is available in your area. This website also allows for individuals to search by age group seeking a vaccine, vaccine brand name, and date of clinic.

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

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

95) 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. So far, reactions reported after the third Pfizer shot were [similar to that of the 2-shot primary series](#). Side effects usually go away on their own within 24-48 hours of vaccination.

96) 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.

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

The CDC and FDA encourage the public and healthcare providers to report possible side effects (called adverse events) to the [Vaccine Adverse Event Reporting System](#) (VAERS). This national system is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

CDC is also implementing a new smartphone-based tool called V-SAFE to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a V-SAFE information sheet telling you how to enroll in V-SAFE. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

98) 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. 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 [ndvax.org](#) or [vaccines.gov](#) to determine where vaccine is being provided in your area.

99) 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.

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

At this time, we do not know how long immunity following vaccination will last. What we do know is that getting vaccinated is the best way to protect yourself and those around you from this virus.

Both Pfizer and Moderna have recently released data suggesting the length of protection provided by their COVID-19 vaccines:

- Pfizer efficacy at 6 months: 84% (reference [here](#))
- Moderna efficacy at 6 months: 93% (reference [here](#))

Johnson & Johnson has not released any data on efficacy at six months. However, Johnson & Johnson has said that their vaccine provides protection for at least eight months. (See [here](#))

On September 23, 2021, CDC [recommended](#) that certain populations receive a booster shot of Pfizer's COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series. The decision followed a careful examination of the latest data and robust and deliberative discussion around booster shots. This includes:

- Data from a small clinical trial show that a booster dose of Pfizer COVID-19 vaccine increased immune response in those who completed a primary series six months prior
- Among adults 65 years and older, data show vaccines remain effective in preventing hospitalization and severe disease, but recent evidence suggests they are less effective in preventing infection or milder symptomatic illness due to waning over time and the Delta variant
- Emerging evidence shows that among healthcare and other frontline essential workers, vaccine effectiveness is waning against COVID-19.

With the Delta variant surging and cases of COVID-19 increasing significantly across the United States, a booster shot will help provide continued protection against severe disease in these populations who are especially at risk for severe COVID-19. At this time, the FDA's Pfizer booster authorization only applies to these select populations who received the Pfizer vaccine as their primary series. People in the recommended age groups who received the Moderna or Johnson & Johnson vaccine will likely need a booster shot, and more data on the effectiveness and safety of these booster shots are expected in the coming weeks. ACIP will continue to meet to evaluate new data and may recommend booster shots for other populations and vaccine recipients soon.

101) 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.

102) 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.

103) 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.

104) 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.

105) 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.

106) 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.

107) 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.

108) 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.

109) 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.

110) 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 475 North Dakotans have died from COVID-19. While preventative measures like social distancing and masks help to slow the spread, ***the only truly preventive measure against this virus is to vaccinate.***

By vaccinating against COVID-19, you not only protect yourself, but also prevent spread of the disease to your friends, loved ones, and those in your community. COVID-19 can have serious, life-threatening complications and there is no way to know how the virus will affect you. COVID-19 vaccines have been shown to be safe and effective, and they are especially effective at preventing severe disease, hospitalization and death from COVID.

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

111) 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.

On August 23, 2021, the FDA approved Pfizer's COVID-19 vaccine for those 16 and older - making it the first COVID-19 vaccine to be licensed in the U.S. For any vaccine (including COVID vaccines) to receive full approval, the FDA requires six months of follow-up data. The data from clinical trials and post-

authorization safety monitoring systems continue to support that Pfizer's COVID-19 vaccine is safe and effective. Full licensure means that Pfizer's vaccine has now undergone the same rigorous testing and regulatory review as dozens of other licensed vaccines.

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, 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.

**112) If I get a COVID-19 vaccine, what are the recommendations for quarantine and masking?
What can I do safely?**

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:

- You can resume activities that you did prior to the pandemic.

- To reduce the risk of being infected with the Delta variant and possibly spreading it to others, wear a mask indoors in public if you are in an area of [substantial or high transmission](#).
- You might choose to wear a mask regardless of the level of transmission if you have a weakened immune system or if, because of your age or an underlying medical condition, you are at increased risk for severe disease, or if a member of your household has a weakened immune system, is at increased risk for severe disease, or is unvaccinated.
- If you travel in the United States, you do not need to get tested before or after travel or self-quarantine after travel.
- You need to pay close attention to the situation at your international destination before traveling outside the United States.
 - You do NOT need to get tested before leaving the United States unless your destination requires it.
 - You still need to [show a negative test result](#) or documentation of recovery from COVID-19 before boarding an international flight to the United States.
 - You should still get tested 3-5 days after international travel.
 - You do NOT need to self-quarantine after arriving in the United States.
- If you had close contact with someone who has COVID-19, you should get tested 3-5 days after your exposure, even if you don't have symptoms. You should also wear a mask indoors in public for 14 days following exposure or until your test result is negative. You should isolate for 10 days if your test result is positive.

For greater detail on CDC recommendations, please see their [website](#).

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

Those who are vaccinated may become infected with the virus that causes COVID-19, either symptomatically or asymptotically. Further, it is possible that vaccinated individuals may spread the virus to others. Recently published [research](#) suggests that vaccinated individuals can have the same viral load as those who are unvaccinated. However, it is unclear if the virus detected in a vaccinated individual is viable. Additionally, viral loads in vaccinated individuals diminish more quickly than in unvaccinated individuals, meaning those who are vaccinated will likely be infectious for a shorter period of time. This knowledge has prompted the CDC's to change their [recommendations](#) for masking among fully vaccinated individuals. It is important to remember that a majority of transmission, hospitalizations and deaths from COVID-19 are *still among the unvaccinated*. The best way to protect yourself and those around you from this virus is to get vaccinated.

114) If an outbreak occurs and most of the cases were among the vaccinated, doesn't that mean that the vaccine is not effective?

No. It is important to look at the proportion of the population that *is* vaccinated compared to the proportion that remains unvaccinated. The more vaccinated a population, the more we'll hear of the

vaccinated getting infected – but it's important to look at the *rates* of cases among the vaccinated versus the unvaccinated.

Instead of looking solely at the number of cases in the vaccinated and unvaccinated, you must look at the attack rate. The attack rate is the percentage of an at-risk population that contracts the disease during a specified time interval. When a large percent of the population is vaccinated, there may be more cases reported among the vaccinated versus the unvaccinated, but the *rate* of cases is likely to be *significantly lower* among the vaccinated - and that is what is truly important to consider when determining how well a vaccine is working at preventing disease.

Additionally, it is important to keep in mind that the unvaccinated represent the majority of transmission, hospitalization and deaths from COVID-19. Most vaccinated people who are infected with COVID-19 (which is still uncommon) do not have symptoms, and those that do tend to have mild illness. Currently available COVID-19 vaccines are highly effective at preventing severe disease, hospitalizations, and deaths from this virus. The best way to protect yourself and those around you from COVID-19 is to get vaccinated.

115) 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.** 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.** The Delta variant now represents over 99% of cases in the United States. Delta causes more infections, spreads faster, and may be more deadly than early forms of COVID-19. Fully vaccinated people with Delta variant breakthrough infections (although still uncommon) can spread the virus to others. However, vaccinated people appear to spread the virus for a shorter time.
- **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 antigens to a coronavirus closely related to the COVID-19 virus or that the test quality was flawed.

116) 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.

117) If I am fully vaccinated, should I be concerned about breakthrough cases?

A breakthrough case is when a person gets infected with COVID-19 despite being fully vaccinated. Like with other vaccines, COVID-19 vaccine breakthrough cases will occur. It is important to understand that:

- **No vaccine is 100% effective and breakthrough cases are expected.** Breakthrough cases are *uncommon* but they can occur (even before Delta). When they do occur, they typically produce mild symptoms or no symptoms at all (asymptomatic). There will be a small percentage of fully vaccinated people who are hospitalized, and/or die from COVID-19.
- **Variants may affect how effective COVID-19 vaccines are.** Current data suggest that COVID-19 vaccines authorized for use in the U.S. offer protection against most COVID-19 variants circulating in our country and *are highly effective at preventing hospitalization and death from the virus*. However, variants will cause some vaccine breakthrough cases.
- **The situation is rapidly changing.** Delta has quickly become the dominant variant in the United States and is highly transmissible and considered to be as contagious as chicken pox. But, we are still gathering information on how Delta differs from previous strains of the virus and how this impacts vaccine effectiveness.
- **People with breakthrough infections may be able to spread COVID-19 to others.** Data from an [outbreak investigation from Massachusetts](#) found that vaccinated individuals infected with the Delta variant have a similar viral load to the unvaccinated. High viral load suggests an increased risk of transmission. On July 27, 2021, CDC released recommendations that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial to reduce the spread of the virus.
- **Vaccines provide the best protection.** Vaccination is the most important strategy to prevent severe illness and death. The CDC has estimated that unvaccinated people are 8x as likely to get the virus and experience disease symptoms, 25x as likely to be hospitalized, and 24x as likely to die, compared to people who are vaccinated. The best way to protect ourselves and those around us from COVID-19 is to vaccinate.

For more information on breakthrough cases please visit the CDC [website](#).

118) 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 711,000 deaths associated to COVID-19 and it is now a 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.***

The U.S. is extremely fortunate to have three safe and effective COVID-19 vaccines authorized for use in our country. Additionally, data suggests that these vaccines continue to provide strong protection against severe outcomes related to COVID-19 from variants, such as Delta. People who are not vaccinated continue to be at greatest risk from the virus - virtually all COVID-19 hospitalizations and deaths are among those who remain unvaccinated.

It is important for everyone to be vaccinated to prevent the spread of COVID-19.

119) 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](#).

120) Will the COVID-19 vaccines provide protection against the COVID-19 variants (e.g. Delta variant)?

It is unknown whether the new virus variants (caused by mutations) will affect the efficacy of vaccines in the long run. [Pfizer](#), [Moderna](#), and [Johnson & Johnson](#) 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.

The Delta variant, which originated in India, is a highly contagious COVID-19 strain. It has become the dominant variant in the U.S. and globally. [Recent research](#) suggests that Delta causes more infections, spreads faster, and may be more deadly than early forms of COVID-19.

On September 23, 2021, the CDC [recommended](#) that certain populations receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series. In addition, the CDC Director recommended a booster dose for those in high risk occupational and institutional settings. With the Delta variant surging and cases of COVID-19 increasing significantly across the United States, a booster shot will help provide continued protection against severe disease in these populations who are especially at risk for severe COVID-19. For example:

- Because residents in long-term care (LTC) settings live closely together in group settings and are often older adults and/or have underlying medical conditions, they are at increased risk of infection and severe illness from COVID-19.
- The risk of severe illness from COVID-19 increases with age, and can also increase for adults of any age with certain underlying medical conditions. This is why CDC recommends that individuals 50 to 64 with underlying medical conditions receive a Pfizer-BioNTech booster shot. Individuals 18-49 with underlying medical conditions may also receive a booster if they determine the personal benefits outweigh the risks.

While COVID-19 vaccine effectiveness against severe disease remains high for healthcare personnel and other essential workers, those with even mild illness often cannot work. In addition, some individuals may care for or live with at-risk people, such as the immunocompromised, and others may live in a congregate setting such as a homeless shelter or correctional facility where there is higher risk for transmission. For these reasons – as well as continued strain on the U.S. healthcare infrastructure due to the widely circulating Delta variant – CDC recommends that adults at high risk of disease from occupational and institutional exposures to COVID-19 get the Pfizer booster based on their individual benefits and risks.

Data suggests that [virtually all recent COVID-19 hospitalizations and deaths](#) are occurring among unvaccinated individuals. Vaccinating is the best way to protect yourself, loved ones, and those in your community from COVID-19.

For more information on the Delta Variant and COVID-19 vaccine, please click [here](#).

121) 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 and GBS 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."
- **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).

122) 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.

123) 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](#).

124) 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.

125) 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](#).

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

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

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

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

Individuals who have received a COVID-19 vaccine are able to donate convalescent plasma with the [Red Cross](#) or [Vitalant](#). Currently, the Red Cross is working as quickly as possible to evaluate this change—as it may involve complex system updates. Please check with your local plasma donation center to see what their guidelines are regarding convalescent plasma donations and COVID-19 vaccine.

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

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

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

129) 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.

130) 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.'"

Additionally, the Biden administration has developed a [six-pronged national strategy](#) to combat COVID-19. This plan includes the Department of Labor's Occupational Safety and Health Administration (OSHA) developing a rule that will require all employers with 100 or more employees to ensure their workforce is fully vaccinated or require any workers who remain unvaccinated to produce a negative test result on at least a weekly basis before coming to work. OSHA will issue an Emergency Temporary Standard (ETS) to implement this requirement. This requirement will impact over 80 million workers in private sector businesses with 100+ employees. NDDoH advises employers to seek advice from an attorney if there are questions regarding this new guidance.

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

131) 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.

132) 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.

133) 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](#).

134) 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](#).

The NDDoH has worked with MyIR to get an official COVID immunization certificate and a complete immunization certificate built into MyIR Mobile for North Dakota users. The COVID immunization certificate also includes a QR code that can be scanned by venues or businesses that are requiring proof of vaccination.

135) 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 most professions. It is unlikely the NDDoH will be able to provide vaccination rates by priority groups, as this information is not reported through the NDIIS. However, CMS has begun to post COVID-19 vaccination rates for long-term care residents and staff by facility. You can access these rates on the CMS [website](#).

136) 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 \(uber.com\)](https://uber.com)
- Lyft website: [Helping people get rides to vaccine appointments – Lyft | Vaccine Access](https://www.lyft.com/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 \(grandforksgov.com\)](https://www.grandforksgov.com/cities-area-transit-cat)

137) 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](#).

138) 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.
- People offering to sell/ship doses of a vaccine in exchange for a fee.
- Unsolicited emails, phone calls, and/or text messages from someone claiming to be from a medical office, insurance company or COVID-19 vaccine center to determine eligibility that you are unfamiliar with.
- Advertisements for vaccines through online and social media platforms.

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

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