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COVID-19 Vaccine Frequently Asked Questions for Healthcare Professionals

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To read the FAQ for the general public, please visit the North Dakota Department of Health (NDDoH) website.

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

Several other COVID-19 vaccines are in clinical trials but have not been approved. Some of the vaccines in clinical trials are currently being manufactured at the same time that clinical trials are occurring, so if approved for distribution, doses are available. If not approved, manufactured doses will be discarded.

2) When did COVID-19 vaccines become available?

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

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

A COVID-19 pipeline tracker is available online.

3) Why is the COVID-19 vaccine development timeline so condensed compared to when other vaccines are licensed?

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

- Utilizing existing technology – many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.
- Developing vaccines immediately after viral genome sequence is available.
- Financing – The federal government has provided financing for COVID-19 vaccine development.
- Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, they will have

large numbers of doses ready. This is not typical because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.

- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:
    - Developing plans for how to distribute the first, limited quantities that will be available
    - Ensuring adequate supplies for distributing and administering vaccine, like vaccine vials, syringes and other equipment needed to vaccinate
    - Establishing mechanisms for distribution to large subsets of the population

A diagram explaining how the process has been shortened is available from Operation Warp Speed.

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

Operation Warp Speed is a partnership between the United States Department of Health and Human Services, the United States 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 United States are in the process of completing these rigorous studies with no compromises in the process.

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

A summary of Operation Warp Speed's Strategy and Approach is found in the New England Journal of Medicine**.**

5) What types of COVID-19 vaccines are in clinical trials?

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

Here is a brief summary of these different strategies:

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

- mRNA vaccine — In this approach, the vaccine contains messenger RNA, called mRNA. mRNA is taken up in cells and then the cell processes it to make proteins. Once the proteins are produced, the immune system will recognize them and make a response against them to create immunity. In this case, the protein produced is the COVID-19 spike protein. No currently licensed vaccines use this approach.
    - ***The Pfizer and Moderna vaccines are both mRNA vaccines.***

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

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

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

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

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

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

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

Vaccine manufacturers must follow guidance provided by the FDA while developing any COVID-19 vaccine. This includes requirements to share information about how they determined that a vaccine is safe and effective. They will need to provide data for review and information, so the FDA and other scientists can understand how the studies were designed, how many people were evaluated, and how the testing to obtain the data was done. At first, COVID-19 vaccine(s) will not be fully licensed (Biological License Application) but will receive Emergency Use Authorization.

9) What is Emergency Use Authorization?

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

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

Additional information about EUA is available on FDA's website.

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

- An EUA is granted by the FDA and can be completed in a short amount of time (weeks). An EUA allows the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. The FDA must determine, among other things, that the ***known and potential benefits of a product outweigh its known and potential risks***.
- A BLA is also undertaken by the FDA but can take up to a year to complete. A BLA can only be approved if FDA determines there is ***substantial evidence of safety and effectiveness*** from adequate and well-controlled trials.
- Both EUAs and BLAs require data showing the vaccine is safe and effective.
- For both an EUA and a BLA, the FDA receives advisement from the Vaccine and Related Biological Products Advisory Committee (VRBPAC). VRBPAC is an external, expert committee (e.g. scientists, physicians, biostatisticians, and a consumer representative) that reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products.
- Because vaccines are given to millions of ***healthy*** individuals, the requirements for vaccine EUAs are ***much stricter*** than requirements for those drugs that have received EUA thus far during the COVID-19 pandemic for treatment of the ill.

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

- A vaccine for COVID-19 was first approved under EUA to promote more *rapid and widespread* deployment and administration of COVID-19 vaccine.
- A vaccine may be issued under an EUA with the *ultimate goal* of receiving a BLA.

- A vaccine issued under EUA will continue to be monitored and evaluated by multiple agencies in the United States (e.g. the Center for Disease Control and Prevention [CDC] and the FDA), to assure any vaccine authorized under EUA is safe and effective.

COVID-19 Vaccine Safety and Efficacy

12) Is the COVID-19 vaccine safety tested?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recent research conducted among healthcare workers has indicated that currently available COVID-19 vaccines reduce the risk of all SARS-CoV-2 infections, not just symptomatic infections. This is incredibly important because preventing both asymptomatic (no symptoms) and pre-symptomatic infections can help prevent the spread of COVID-19 to others.

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

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

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

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

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

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

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

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

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

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

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

On April 13, the FDA and CDC recommended a pause in the administration of the Johnson & Johnson COVID-19 vaccine.
As of April 13th, there were over 6.8 million doses of the Johnson & Johnson (J&J) vaccine administered and reported in the U.S. The CDC and FDA had received six reports of a rare and severe type of blood clot in individuals who had received the vaccine. (Breakdown: that means the blood clot is extremely rare and currently estimated to occur at a rate of 1 event per 1.13 million doses administered.) The type of blood clot is called a cerebral venous sinus thrombosis (CVST), and it was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred in women between the ages of 18 and 48, and symptoms occurred 6-13 days after vaccination. Of these cases, one died, and one was in critical condition.

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

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

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

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

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

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

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

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

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

22) As a healthcare provider, what actions should we take regarding the pause on administration of Johnson & Johnson's COVID-19 vaccine in the U.S.?

Healthcare providers are recommended to pause the use of the Johnson & Johnson COVID-19 vaccine and to maintain acute clinical awareness of symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine. Symptoms to look out for include:

- Severe Headache
- Backache
- New Neurological Symptoms
- Severe Abdominal Pain
- Shortness of Breath

- Leg Swelling
- Petechiae (tiny red spots on the skin)
- New or Easy Bruising

The CDC also recommends that healthcare providers read the official CDC health alert, Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine, which includes details about how to handle a patient that presents with thrombosis or thrombocytopenia.

Report adverse events to the Vaccine Adverse Event Reporting System.

The NDDoH will provide updates on this developing situation as we know more regarding the Johnson & Johnson COVID-19 vaccine and updates and changes to recommendations and guidelines.

23) How should I counsel patients who have recently received a Johnson & Johnson COVID-19 vaccine?

It is important to tell patients not to panic. These events appear to be a very rare side effect if they are related to vaccination. It is important to counsel patients to monitor for symptoms including: severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, tiny red spots on the skin (petechiae), or new/easy bruising within three weeks of receiving the Johnson & Johnson vaccination. Advise patients to contact their healthcare provider and seek medical care urgently if any of these symptoms occur and inform their provider they have recently received a Johnson & Johnson COVID-19 vaccine. To see the latest updates regarding the Johnson & Johnson vaccine, please see the CDC website.

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

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

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

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

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

COVID-19 vaccine safety will continue to be monitored after a vaccine is made available to the public.

- The Vaccine Adverse Events Reporting System (VAERS) will be used to identify signals that might indicate a safety issue.
- The Vaccine Safety Datalink (VSD) is an active surveillance system that monitors electronic health data for adverse events in various healthcare settings.
- The Clinical Immunization Safety Assessment Project (CISA) will conduct clinical research and assess complex vaccine safety issues.
- A new, additional safety monitoring program, V-SAFE, is being used to monitor COVID-19 vaccines using smartphones for health surveys.
- Additional information about safety monitoring is available on CDC's COVID-19 vaccine website.

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

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

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

Johnson & Johnson has expanded clinical trials to include adolescents 12 and older for their COVID-19 vaccine.

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

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

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

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

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

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

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

To see more information regarding fainting after vaccination, please visit the CDC website.

29) Can individuals with an allergy to latex receive a COVID-19 vaccine?

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 ask patients about any latex allergies so you can ensure that latex containing products (ex. gloves) are not used to care for the patient.

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

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

31) Do COVID-19 vaccines contain pork products?

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

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

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

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

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

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

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

The CDC has posted guidelines for managing anaphylaxis at vaccination sites here.

33) What are the FDA and CDC guidelines regarding allergic reactions and administering COVID-19 vaccine?

The FDA has included a history of severe allergic reactions to a previous dose of COVID-19 vaccine or any COVID-19 vaccine ingredient as a contraindication for the 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.

Because of reports of anaphylactic reactions in individuals vaccinated outside of clinical trials, additional guidance has been created. All individuals should be monitored for 15 minutes post-vaccination. The CDC has recommended persons who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) can receive COVID-19 vaccine, but under the following conditions:

- Individuals must be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefit of vaccination.

- Individuals should be observed after vaccination to monitor for the occurrence of immediate adverse reactions for 30 minutes (versus 15 minutes generally recommended following vaccination).

Individuals with other types of allergies, such as food, latex, pollen or other substances do not have to take special precautions and can receive a COVID-19 vaccine.

To see the American College of Allergy, Asthma, and Immunology's guidance on risk of allergic reaction to COVID-19 vaccine, please click here.

34) A patient reported a delayed-onset local reaction (erythema, induration, pruritus) following a COVID-19 vaccine dose. Is this a contraindication for future COVID-19 vaccines?

No, this is not a contraindication or a precaution. 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.

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

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

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

There were no cases of Guillain-Barré Syndrome (GBS) reported following vaccination in the Pfizer and Moderna COVID-19 vaccine clinical trials. Additionally, the Advisory Committee on

Immunization Practices (ACIP) shared safety data in March 2021; the data showed no association between GBS and COVID-19 vaccination.

There were single reports of GBS in a vaccine recipient and a placebo recipient in the Johnson & Johnson COVID-19 vaccine clinical trial. In FDA's assessment the events are unlikely related to the vaccine but a causal relationship cannot be definitively excluded. Safety monitoring systems will continue to monitor for cases of GBS to determine if vaccination is associated with onset of GBS.

37) Can patients who have previously had Guillain-Barré Syndrome (GBS) receive a COVID-19 vaccine?

Patients 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.

38) 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.

Questions about Enrolling as a COVID-19 Vaccine Provider with NDDoH

39) Which healthcare providers should enroll with the NDDoH to receive COVID-19 vaccine?

Any healthcare provider who is able to vaccinate is encouraged to enroll to receive COVID-19 vaccine through the state. This includes private healthcare providers, local public health, tribal health, pharmacies, and long-term care facilities.

Some facilities are receiving COVID-19 vaccine directly from the federal government; this includes Indian Health Service (IHS), Department of Defense, and Veterans Administration. These facilities should not enroll to receive COVID-19 vaccine from the NDDoH.

40) Can healthcare providers still enroll as COVID-19 vaccine providers with NDDoH? Where can we learn more?

Enrollment for providers to receive COVID-19 vaccine is still open. Providers are encouraged to enroll as soon as possible, as vaccine will likely be available in the near future. Additional information about enrollment is available on the NDDoH COVID-19 vaccine website.

41) If our clinic has several outlying clinics, does each clinic need to enroll to become a COVID-19 vaccine provider?

Yes. Each physical site where COVID-19 vaccine will be located needs to be enrolled separately.

42) Can a vaccine be redistributed among providers within the same healthcare system?

As much as possible, vaccine will be shipped to the healthcare organization location where it will be administered to limit the possibility of storage and handling issues. Limited providers have been selected to redistribute COVID-19 vaccine within their own organizations. This includes large health systems and district local health departments.

43) Can COVID-19 vaccine be transferred to other providers?

COVID-19 vaccine can be transferred to other enrolled COVID-19 vaccine providers in an effort to avoid wastage. Transfers need to be pre-approved by the NDDoH by emailing covidvaccine@nd.gov. COVID-19 vaccine cannot be transferred to providers who have not enrolled with the NDDoH to receive COVID-19 vaccine.

44) Can a healthcare organization choose to order/stock certain COVID-19 vaccines?

No. Allocations will be based upon available COVID-19 vaccines.

Storage and Handling

45) What are the requirements for storage of the COVID-19 vaccine?

Pfizer

Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -80º to -60ºC (-112º to -76ºF).

- Store vaccine vials upright in the tray.
- Protect from light.
- Vaccine may be stored until the expiration date.
    - As the expiration date approaches, contact the manufacturer to determine if it has been extended. Do not discard vaccine without ensuring the expiration date has passed.

Freezer

Before mixing, the vaccine may be stored in the freezer between -25º to -15ºC (-13º to 5ºF) for up to 2 weeks. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks.

- These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter.
- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
- Use CDC's freezer storage temperature log for COVID-19 vaccine to document storage unit temperatures.
- Monitor how long the vaccine has been in the freezer using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
- Store the vaccine in the tray.
- Protect from light.
- Do not use dry ice for freezer storage.
- Vials stored in the freezer may be returned one time to ultracold temperature storage (-80ºC to -60ºC [-112ºF to -76ºF]).
- Once returned to ultra-cold storage, the 2-week time frame is suspended.

Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days). After 120 hours (5 days), contact the manufacturer for guidance. If directed to discard any remaining vials, follow the manufacturer's and your jurisdiction's guidance for proper disposal.

- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
- Store the vaccine in the tray.
- Protect from light.
- Do NOT refreeze thawed vaccine.

For more information on storage and handling of the Pfizer COVID-19 vaccine, please see the CDC's *Storage and Handling Summary* and Pfizer's COVID-19 vaccine website on their recommendations on product storage & dry ice.

Room Temperature

- Keep mixed vaccine between 2°C and 25°C (36°F to 77°F) and administer within 6 hours.
- Discard any unused vaccine after 6 hours.
- Do not return to freezer storage.

Moderna

Freezer

Vaccine may be stored in a freezer between -50°C and -15°C (-13°F and 5°F).

- Note: These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter.
- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
- Store in the original carton and protect from light.
- Do not use dry ice for storage

Refrigerator

- Vaccine vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days before vials are punctured. After 30 days, remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction guidance on proper disposal.
- Thawed vaccine cannot be refrozen.
- Use beyond-use date labels to track how long the vaccine has been in the refrigerator. Monitor the beyond-use date/time.
- Remove the box from frozen storage.
- Complete the information on the storage label and attach it to the box holding the vaccine vials.
- Once labeled, store vaccine in the refrigerator.

Room Temperature

- Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours. Do not refreeze.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 12 hours. Do not refreeze.

For more information on the preparation and administration of the Moderna COVID-19 vaccine, please see the CDC's *Storage and Handling Summary* and Moderna's COVID-19 vaccine website for their information on storage and handling.

Johnson & Johnson

Refrigerator

CDC recommends storing vaccine between 2º to 8ºC (36º to 46ºF):

- Unpunctured vials until the expiration date
    - Unpunctured vials may also be stored between 9ºC and 25ºC (47ºF and 77ºF) for up to 12 hours.
- Punctured vials for up to 6 hours. Note the date and time the vial was first punctured. Discard vaccine not used within this time frame.
    - Alternate option: A punctured vial may be stored at room temperature (9º to 25ºC [47º to 77ºF]) for up to 2 hours.

Room Temperature

- Note the date and time the vial was first punctured.
- Keep the vaccine at room temperature (up to 25°C or 77°F) for up to 2 hours.
- Discard if not used within this time.

Do not freeze.

Protect from light.

As the expiration date approaches, determine if it has been extended using the same methods outlined in the "Deliveries" section. Do not discard vaccine without ensuring the expiration date has passed. Use CDC's expiration date tracking tool to document expiration date changes.

For more information on the preparation and administration of the Johnson & Johnson's COVID-19 vaccine, please see the CDC's *Storage and Handling Summary*.

46) Do I need to purchase a data logger for my refrigerator/freezer?

Facilities are recommended to have a digital data logger (DDL) to continuously monitor the temperature of the vaccine. Listed below are recommendations that should be considered before purchasing one:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door.
- The data logger must have functionality that does not require a computer password to access the temperature display.

- The display must remain active for temperature readings (i.e., must not have sleep mode turned on).
- Alarm for out-of-range temperatures.
- A display that shows the current temperature, as well as minimum and maximum temperatures.
- Low battery indicator.
- Accuracy of +/-1°F (+/-0.5°C).
- Detachable probe in buffered material.
- Memory storage of at least 4,000 readings (device must not rewrite over old data and must stop recording when the memory is full).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

47) Will providers be responsible for purchasing an ultra-cold storage unit?

At this time, the NDDoH ***does not recommend*** that providers purchase a separate ultra-cold storage unit.

If receiving the minimum package quantity of 975 doses, the ultra-frozen vaccine will arrive in a shipping container able to maintain the ultra-cold temperatures for up to 15 days. The Pfizer vaccine is stable at refrigerator temperatures for 5 days and stable at -25°C to -15°C for up to two weeks.

Additionally, the NDDoH warehouse is able to repackage the Pfizer vaccine into smaller quantities that providers can use within 5 days.

48) What happens if the diluent or the cold chain is not maintained?

Providers should call the manufacturer listed on the box for viability determination. If the dose is deemed non-viable, then the doses should be reported in the NDIIS as wasted.

49) What ancillary supplies are included with shipments of COVID-19 vaccine?

COVID-19 vaccine shipments will contain the following ancillary supplies:

Pfizer

Pfizer Ancillary supplies supports administration of 1,170 doses - designed for use in adults, the kit will contain:

- Needles, 1,240 per kit (various sizes for the population served by the ordering vaccination provider)

- Syringes, 1,240 per kit
- Mixing Needles, 205 per kit
- Mixing Syringes, 205 per kit
- Alcohol prep pads, 2,900 per kit
- Diluent, 200 per kit
- Needle Card, 10 per kit
- 50 surgical masks and 25 face shields for vaccinators, per kit
- Vaccination Card, 1,200 per kit

Update 1/20/2021: FDA amended the Emergency Use Authorization to reflect the additional dose and McKesson increased the individual Pfizer ancillary kit contents from a kit that supported 975 doses to a kit supporting 1170 doses (195 vials x 6 doses = 1,170). These supplies have been added to the boxes (and noted in the above list). While the number of syringes in each ancillary box will increase to support six doses, this does not necessarily guarantee that every vial will yield six doses. Only low dead-volume syringes and/or needles will consistently ensure extraction of six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Moderna and Johnson & Johnson

Moderna Ancillary supplies supports administration of 100 doses - designed for use in adults, the kit will contain:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

The NDDoH warehouse is able to repackage both vaccines into smaller quantities. If your facility is receiving less than the federal minimum shipping quantity, your facility will receive adequate ancillary supplies for the amount of vaccine received.

50) Under what conditions may we transport mRNA COVID-19 vaccines? Is transport of a partial vial or predrawn syringe ever permissible?

Although routine transportation of vaccines to different facilities is not generally recommended, there are times when this is necessary. CDC recommends transporting COVID-19 vaccine in vials and always with a continuous temperature monitoring device to ensure adherence to authorized storage times and temperatures.

Because liquid mRNA COVID-19 vaccines should not be shaken vigorously, it is preferred to transport vials in their solid frozen state, if possible, or to initiate transport while they are frozen. Moderna recommends that thawed vials of liquid be cushioned to minimize agitation during transport. Thawed vaccine should never be refrozen.

Johnson & Johnson's COVID-19 vaccine may be transported more than once. Do not use dry ice when transporting vaccine. Both punctured and unpunctured vials may be transported. For more details on transporting Johnson & Johnson's COVID-19 vaccine, please see the CDC handout.

A partially used vial may be transported (e.g., in the process of vaccinating homebound individuals), but cannot be transferred from one provider to another nor can it be transported across state lines. Details are provided in the 2021 CDC Vaccine Storage and Handling Toolkit addendum on mRNA COVID-19 vaccines.

There may be instances when the only option is to transport vaccine in a predrawn syringe. CDC refers to the U.S. Pharmacopeia (USP) guidance for transporting predrawn vaccine in syringes on page 11 of the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners. The complete document provides detailed guidance on mRNA COVID-19 vaccine transport and is available for download from this site.

Vaccine Information & Presentation

51) How many doses come in each kit?

Pfizer
Pfizer's COVID-19 vaccine ships in minimum increments of 1,170 doses.

Moderna
Moderna's COVID-19 vaccine ships in minimum increments of 100 doses.

Johnson & Johnson
Johnson & Johnson's COVID-19 vaccine ships in minimum increments of 100 doses.

The NDDoH warehouse is able to redistribute vaccines into smaller quantities. If your facility is allocated less than the minimum shipping increments, you will receive vaccine from the NDDoH warehouse.

52) Will the COVID-19 vaccines be single-dose or multi-dose vials? Do the vaccines require reconstitution (mixing)?

Pfizer

The Pfizer COVID-19 vaccine comes in a 6-dose multi-dose vial. It requires diluent and on-site mixing.

Moderna

The Moderna COVID-19 vaccine comes in a 10-dose multi-dose vial. It does not have diluent or require on-site mixing.

Johnson & Johnson

The Johnson & Johnson COVID-19 vaccine comes in a 5-dose multi-dose vial. It does not have diluent or require on-site mixing.

53) How soon after reconstitution does the Pfizer COVID-19 vaccine need to be administered?

Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C– 8°C. You must use diluted vaccine within 6 hours (discard any unused diluted vaccine after 6 hours).

54) We received a new allocation of Moderna's COVID-19 vaccine and the vial looks different from previous vials. Is this ok?

Yes, in order to meet the volume demands of the COVID-19 pandemic, Moderna engaged multiple suppliers of vials for their vaccine. Thus far, Moderna's vaccine has been filled and distributed in clear vials. With the addition of new vial suppliers, a portion of the vials recently entering distribution may appear thicker and display a slight green tint as a result of the vial sterilization process during manufacturing. *This tinting is strictly visual and has no impact on the vaccine*. A range of vial colors under various lighting conditions may be encountered in the field and over time, vial tinting may fade naturally, resulting in a faint yellow color.

Please continue to inspect each dose of the Moderna's COVID-19 Vaccine prior to administration in accordance with the Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine.

Vaccine Specifics

55) 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.

If it is not feasible to adhere to the recommended interval, the second dose of Pfizer and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series.

One dose vaccines

The Johnson & Johnson COVID-19 vaccine requires 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. We will update this information as more vaccines become available against COVID-19.

56) What is the COVID-19 vaccine record card included with the vaccine kit?

The purpose of the vaccination record card is to provide documentation for the patient to take with them following vaccination. NDIIS will serve as the permanent medical record and can be used to generate patient specific immunization reports.

57) Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose of Pfizer or Moderna COVID-19 vaccine?

No. However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment. Encourage patients who are vaccinated to take a picture of their immunization record card with their smartphone. Retaining the COVID-19 vaccination record card is important to ensure the second dose of vaccine is the same brand/manufacturer as the first dose received.

58) For COVID-19 vaccines that require a second dose, is it necessary to start a vaccine series over if a patient doesn't come back for a dose at the recommended time?

It is not necessary to restart the vaccine series if the second dose is given beyond the recommended interval. Ideally, Pfizer doses would be given 21 days apart, and Moderna doses would be given 28 days apart. However, if the second dose is not given at the exact interval, that is ok. Ideally, the second dose would be given within 42 days of receiving the first dose. However, it is most important that patients receive the second dose, regardless of the interval.

59) Does the typical 4-day grace period for vaccine administration apply to the COVID-19 vaccine recommendations?

Yes. Doses of COVID-19 vaccine should be given as close to the suggested interval as possible to ensure optimal protection, but the second dose can be given as early as 4 days before the second dose is due. Doses that are inadvertently administered earlier than the grace period *should not be repeated*.

60) Are COVID-19 vaccines interchangeable?

No. For vaccine series that require two doses, the ACIP recommends that the second dose of the vaccine be the same brand/manufacturer as the first dose.

61) For COVID-19 vaccines requiring a second dose, should healthcare providers reserve the second dose?

No. The NDDoH will assure a supply of second doses to healthcare providers who received first doses.

Healthcare providers are encouraged to schedule patients for second doses at the time of the first dose.

62) For COVID-19 vaccines requiring a second dose, 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.

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

The simple answer is no. The vaccine does not contain components nor produce components in the body that would produce a positive result in currently used diagnostic tests.

Two main tests are currently in use to detect COVID-19 in the body. An RT-PCR test, sometimes just called a PCR test, is a molecular test that looks for the genetic material of the virus itself in the nose, throat, or other areas in the respiratory tract. There are many different PCR tests, and they look for *various* genes found in SARS-CoV-2. The currently used vaccines transport just one segment of genetic material (mRNA or DNA which is translated into mRNA) from the virus to our cells – the segment that codes for the spike protein. The PCR tests performed at the NDDoH lab require genetic material other than the spike protein mRNA to be present before they can be deemed positive. This means the COVID-19 vaccine's sole mRNA sequence, coding only for the spike protein, is not able to cause a positive test result via PCR by itself.

The other commonly used test is a rapid antigen test that looks for one or more proteins that make up the SARS-CoV-2 virus to determine if the person has an active infection. In North Dakota, most of the rapid antigen tests are the Abott BinaxNOW tests. These look for the SARS-CoV-2 nucleocapsid protein (NP), which is different than the spike protein that is produced after vaccination. Receipt of the Pfizer, Moderna or Johnson & Johnson COVID-19 vaccine, where your body produces the spike protein, would not cause someone to test positive using a test looking for the NP.

64) Is the COVID-19 vaccine a live vaccine?

There are currently multiple vaccine candidates in various stages of clinical trials, none of which are live vaccines.

The first two COVID-19 vaccines (Pfizer, Moderna) are not live vaccines. They are mRNA vaccines.

The Johnson & Johnson COVID-19 vaccine is a non-replicating viral vector vaccine. This vaccine uses a weakened and altered version of adenovirus 26 (Ad26) which carries genetic instructions to our cells on how to make a harmless protein from the coronavirus which our body will recognize and build immunity to. Ad26 cannot replicate and make people sick.

65) Can patients test positive for COVID-19 after they are fully vaccinated?

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

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

66) If a patient tests positive after receiving a 2nd dose of COVID-19 vaccination (Pfizer or Moderna), is this a breakthrough case? Does it need to be reported to the NDDoH?

The CDC is defining a breakthrough case as an individual who is PCR or antigen positive on a respiratory specimen collected ≥14 days after completing the series of an FDA-authorized COVID-19 vaccine. COVID-19 cases that occur less than 14 days after completion of the series are likely occurring before the individual could mount a full immune response and are not considered breakthrough cases. Regardless of vaccination status, individuals should still isolate themselves following a positive COVID-19 result.

Providers are encouraged to assess vaccination status of individuals being tested for COVID-19. Facilities that suspect breakthrough cases should hold those specimens and the NDDoH will reach out to those facilities to request those specimens for whole genome sequencing.

Administering COVID-19 Vaccine

67) Which healthcare providers can administer COVID-19 vaccine?

The following healthcare providers are able to administer COVID-19 vaccine: physicians, nurse practitioners, physician assistants, pharmacists, pharmacy interns, pharmacy technicians, registered nurses, licensed practical nurses, level 3 CNAs, and nursing students. Some of these healthcare providers such as pharmacists, pharmacy interns and pharmacy technicians may need to have additional documented training in order to administer the vaccine.

68) Do pharmacists need physician standing orders to administer COVID-19 vaccines?

No. Per guidance from the United States Department of Health and Human Services (HHS), pharmacists are able to authorize COVID-19 vaccination on their own. However, they must have completed the practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE).

69) Can pharmacy technicians administer COVID-19 vaccines? What training is required?

Yes. Per guidance on October 20, 2020 from HHS, pharmacy technicians can provide an FDA-authorized or FDA-licensed COVID-19 vaccine. A few requirements must be met:

- The pharmacy technician must be a registered technician with the North Dakota Board of Pharmacy.
- The pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation.
- The pharmacy technician must be acting under the direct supervision of a pharmacist qualified and registered to provide immunizations in North Dakota.

The technician must complete a practical training program approved by the Accreditation Council for Pharmacy Education (ACPE).

70) What training is required for individuals that are considered "vaccinators" under the PREP Act?

As of March 11, 2021, the president has ordered the PREP Act Declaration Amendment to expand COVID-19 vaccinator eligibility to additional medical professionals, including: Dentists, Emergency Medical Technicians (Advanced and Intermediate EMTs), Midwives, Optometrists, Paramedics, Physician Assistants, Podiatrists, Respiratory Therapists, and Veterinarians. To read more about President Biden's expanded efforts to recruit more vaccinators, visit the White House website.

All vaccinators covered by the PREP Act are required to complete the CDC Module Training for the vaccine(s) they will be working with. COVID-19 Vaccine Training Modules (cdc.gov). Anyone who has not provided vaccine in the last 12 months is required to be observed onsite. CDC has this checklist for observers to use - COVID-19 Vaccine: Vaccine Administration Competencies Assessment Form (cdc.gov) (This checklist is not required, just useful). More training and education information can be found here: Training and Education for COVID-19 Vaccination | CDC. Here is the PREP Act amendment that covers all this: https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID-Amendment5.aspx#:~:text=Under the PREP Act, a Declaration may be,and section 319F–4, which creates a compensation program.

71) Does the NDDoH have any guidance for addressing COVID-19 vaccinations in long-term care facilities?

Yes. The NDDoH has developed resources regarding COVID-19 vaccination in long-term care facilities, it can be accessed here.

72) Are providers able to charge a fee for COVID-19 vaccine administration?

Yes, healthcare 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.

The Medicare payment rates will be $28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of two or more doses, the initial dose(s) administration payment rate will be $16.94, and $28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine.

Vaccine doses purchased with United States taxpayer dollars will be given to the American people at no cost. Providers that participate in the CDC COVID-19 Vaccination Program contractually agree to administer a COVID-19 vaccine regardless of an individual's ability to pay and regardless of their coverage status, and also may not seek any reimbursement, including through balance billing, from a vaccine recipient. Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine can

request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund

For more information on COVID-19 vaccine cost and reimbursement please visit the Centers for Medicare and Medicaid Services (CMS) website.

73) What are the billing codes for COVID-19 vaccines?

CPT codes have been created for reporting COVID-19 vaccines. These CPT codes are unique for each of the coronavirus vaccines as well as administration codes unique to each such vaccine.

91300: Pfizer COVID-19 Vaccine
91301: Moderna COVID-19 Vaccine
91303: Johnson & Johnson (Janssen Pharmaceuticals) COVID-19 Vaccine

0001A: Administration of Pfizer COVID-19 vaccine dose #1
0002A: Administration of Pfizer COVID-19 vaccine dose #2
0011A: Administration of Moderna COVID-19 vaccine dose #1
0012A: Administration of Moderna COVID-19 vaccine dose #2
0031A: Administration of Johnson & Johnson (Janssen Pharmaceuticals) COVID-19 vaccine (single dose)

Additional information about COVID-19 vaccine administration fees is available at COVID-19 Vaccine Policies & Guidance | CMS.

74) Can providers bill for an office visit when administering COVID-19 vaccine?

Yes, providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan. However, the federal intent is that patients have no out-of-pocket expenses for COVID-19 vaccine. More information will be provided in the future regarding office visit fees.

75) Can COVID-19 vaccines be administered at the same time as other vaccines?

COVID-19 vaccines should not be administered at the same time as other vaccines. There should be a 14-day interval between COVID-19 vaccine and other vaccines. This does NOT include injectable medications and supplements, which are not considered to be a vaccination.

However, COVID-19 vaccines and other vaccines *may be administered* within a shorter period in situations where benefits of vaccination are deemed to outweigh the potential unknown risks of

vaccine coadministration (e.g. Tdap following a wound within 14 days of COVID-19 vaccination); this should be considered on a case-by-case basis between a healthcare provider and their patient. If the 14-day interval is not met, revaccination is not recommended.

76) What are the recommendations regarding tuberculosis (TB) testing and COVID-19 vaccination?

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:

- Perform TB symptoms screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination.
- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose completion.
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel
- Test for infection should be done before or at the same time as the administration of COVID-19 vaccination. If this is not possible, prioritization of test for TB infection needs to be weighed with the importance of receiving COVID-19 vaccination based on potential COVID-19 exposures and TB risk factors.
    - Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible.
    - Healthcare personnel without high-risk conditions for TB progression should proceed with contact evaluation (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination.
    - All potential recipients of COVID-19 vaccination should weigh the risk and benefit of delaying TST/IGRA with their providers.

For TB Risk Assessment Tools, visit: https://www.health.nd.gov/TB/HealthcareProviders

77) Can patients who have active TB or have an illness that is being evaluated as active TB still receive an mRNA vaccine?

Yes, although the presence of a moderate or severe acute illness is a precaution to administration of all vaccines. Please consult a healthcare provider if patients are presenting with a moderate or severe illness.

78) What route is COVID-19 vaccine administered?

The Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines are all administered via the intramuscular (IM) route. The deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh can also be used.

79) What is the appropriate anatomic site and needle length for COVID-19 vaccines?

For instruction on vaccine administration for intramuscular (IM) injections, please see the CDC's *You Call the Shots Vaccine Administration Intramuscular (IM) Injection Adults 19 years of age and older*.

80) Do we need to wait for the COVID-19 vaccine to reach room temperature before we administer it to a patient?

The vaccine needs to be thawed, but it does not need to be at room temperature.

81) How long should patients be observed after vaccination?

People should be observed for at least 15 minutes post-vaccination. People with a history of any anaphylaxis to other vaccines or injectable therapies should be observed for 30 minutes post-vaccination.

82) How should we address anxiety-related events following COVID-19 vaccine receipt?

Anxiety-related events following COVID-19 vaccination are not uncommon and can be expected. In these events, a patient may experience dizziness, lightheadedness, feeling faint, rapid breathing, and sweating symptoms following receipt of a COVID-19 vaccine. It is important to be prepared for such incidence when conducting vaccination clinics, including but not limited to:

- Identify people through screening with a history of fainting during the vaccination process
- Provide drinks and snacks
- Have a separate, quieter area for those that are feeling lightheaded or faint to sit or lie down and be monitored following vaccination.

83) If there are remaining doses in the vial, can we draw more than 6 doses of the Pfizer vaccine or 10 doses of Moderna vaccine from the multi-dose vial?

At this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable from each vial. However, since these are preservative free vials, it is critical to note that any further remaining liquid that does not constitute a full dose should not be administered or pooled from multiple vials to create a full dose.

84) Can COVID-19 vaccines be pre-drawn for administration?

The NDDoH ***strongly discourages*** pre-drawing vaccine. However, immunization staff may pre-draw a limited amount of vaccine in a mass-immunization clinic setting if the following conditions apply:

- Only a single type of vaccine is administered at the mass-immunization clinic setting
- Vaccine is not drawn up in advance of its arrival at the mass-vaccination clinic location
- Prefilled syringe doses are stored at temperatures appropriate for the vaccine they hold
- No more than one vial or 10 doses (whichever is greater) is drawn into syringes
- Clinic staff monitor patient flow carefully, avoid drawing up unnecessary doses, and promptly administer pre-drawn doses.

At the end of the clinic day, discard any remaining syringes prefilled by staff. Never save these syringes for another day, and never attempt to put the vaccine dose back into a vial.

Vaccine Specific Requirements:
The Pfizer COVID-19 vaccine is only viable for 6 hours following reconstitution/dilution. Please see Pfizer's Vaccine Preparation and Administration Summary for greater detail.

The Moderna COVID-19 vaccine can be stored at room temperature for 12 hours. Please see Moderna's Vaccine Preparation and Administration Summary for greater detail.

The Johnson & Johnson COVID-19 vaccine can be stored at room temperature up to 6 hours after the first puncture of the vial. Please see Johnson & Johnson's Vaccine Preparation and Administration Summary for greater detail.

85) How do I track and manage excess vaccine doses (such as a 6th/7th Pfizer dose from a vial or an 11th Moderna dose from a vial) in NDIIS?

Providers able to use the additional dose(s) will need to make frequent adjustments to their vaccine inventory doses on hand in the NDIIS. The number of doses entered into your NDIIS inventory is based on doses per vial x the number of vials your site received. If your NDIIS

inventory is a lower number of doses on hand than the number of doses you still have because you have been able to get extra doses out of vials, you will need to adjust your inventory based on how many doses are still remaining in your storage unit. The NDDoH Division of Immunization is reporting provider vaccine inventory to Vaccine Finder daily on behalf of all enrolled providers, so it is important that provider vaccine inventory in the NDIIS is correct and current every day. You should not have a negative balance for your inventory.

The NDIIS has a report available to all active users that will show provider-level COVID-19 vaccine inventory on hand. This report can be used to see NDIIS inventory on hand and to know which lot number needs to be adjusted. There are detailed training materials on how to run the COVID-19 Provider Inventory report and how to make inventory adjustments in the NDIIS on the NDIIS training website (https://www.health.nd.gov/immunize/ndiis/trainings).

If you have COVID-19 vaccine questions, you can contact the Division of Immunization via email at covidvaccine@nd.gov or call 701-328-3386 or toll-free 800-472-2180. Questions about the NDIIS can also be emailed to NDIIS@nd.gov.

86) Do gloves need to be used when administering COVID-19 vaccine?

No. Occupational Safety and Health Administration (OSHA) regulations do not require the wearing of gloves when administering COVID-19 vaccinations, unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has an open lesion on their hand. If a healthcare worker chooses to wear gloves, he or she must change them between each patient encounter.

87) What personal protective equipment (PPE) is recommended for immunizers and those being vaccinated?

In order to reduce the risk of exposure to SARS-CoV-2, the virus that causes COVID-19, CDC recommends that all healthcare providers administering vaccines in any setting wear a surgical face mask at all times. The NDDoH also recommends eye protection.

CDC does not recommend the use of N95 respirators when administering vaccinations by any route.

Healthcare providers should implement policies for the use of cloth face coverings by all patients age 2 years and older who can tolerate them.

Additional guidance regarding PPE and immunization is available on the NDDoH COVID-19

vaccine website.

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

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

Preliminary data from Johnson & Johnson's clinical trial suggests the vaccine could be 74% efficacious against asymptomatic COVID following day 29 after vaccination. More data are needed to substantiate these findings. Studies are expected in the coming months that better answer this question. It is important to note that even if the vaccine does not prevent asymptomatic COVID and only prevents symptomatic COVID, it is still extremely valuable.

89) Where can I find current information on how to protect myself and my patients when administering vaccines during the COVID-19 pandemic?

CDC has published guidelines for safe vaccine administration during the COVID-19 pandemic that will be updated as needed. These guidelines focus on reducing the risk of SARS-CoV-2 transmission while in the location where immunizations are being given and during vaccine administration and can be found on the CDC website.

IAC has assembled key resources, handouts and links related to COVID-19 and vaccination on their *Vaccination and COVID-19* page and in their *Ask the Experts section on COVID-19 and Routine Vaccination*.

The NDDoH also has guidance for PPE and COVID-19 vaccination at Vaccine Storage and Handling | Department of Health.

90) Where can I find more information and resources on Pfizer's COVID-19 vaccine?

Pfizer has created an online resource for healthcare professionals on their COVID-19 vaccine. This resource includes videos, guidelines, FAQs and checklists on vaccine. This resource can be found here.

The CDC has a number of resources regarding Pfizer's COVID-19 vaccine, they can be accessed below:

- CDC's Main Page on Pfizer COVID-19 Vaccine
- Interim Clinical Consideration for Use of COVID-19 Vaccine

- Interim Consideration: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination
- Pfizer COVID-19 Vaccine Standing Orders
- Pfizer COVID-19 Vaccine Preparation and Administration Summary
- Pfizer COVID-19 Vaccine Preparation: Mixing Diluent and Vaccine Poster
- Pre-Vaccination Screening Checklist

The CDC has a self-paced web-based module titled: *Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know*. This learning module is estimated to take around 30 minutes and reviews a variety of important topics regarding Pfizer's COVID-19 vaccine. It can be accessed here.

For a comparison of the currently available COVID-19 vaccines feel free to see the NDDoH *Moderna Vs Pfizer Vs Johnson & Johnson Fact Sheet* or the IAC *COVID-19 mRNA Vaccines: What Clinic Personnel Need to Know Handout*.

91) Where can I find more information and resources on Moderna's COVID-19 vaccine?

Moderna has created an online resource for healthcare professionals on their COVID-19 vaccine. This resource provides additional information, guidelines, FAQs, and resources in multiple languages. The Moderna COVID-19 vaccine website can be accessed here.

The CDC has a number of resources regarding Moderna's COVID-19 vaccine, they can be accessed below:

- CDC's Main Page on Moderna COVID-19 Vaccine
- Interim Clinical Consideration for Use of COVID-19 Vaccine
- Interim Consideration: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination
- Moderna COVID-19 Vaccine Standing Orders
- Moderna COVID-19 Vaccine Storage and Handling Recommendations
- Pre-Vaccination Screening Checklist

The CDC has a self-paced web-based module titled: *Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know*. This learning module is estimated to take around 30 minutes and reviews a variety of important topics regarding Moderna's COVID-19 vaccine. It can be accessed here.

For a comparison of the currently available COVID-19 vaccines feel free to see the NDDoH *Moderna Vs Pfizer Vs Johnson & Johnson Fact Sheet* or the IAC *COVID-19 mRNA Vaccines: What Clinic Personnel Need to Know Handout*.

92) Where can I find more information and resources on Johnson & Johnson's COVID-19 vaccine?

Johnson & Johnson has created an online resource for healthcare professionals on their COVID-19 vaccine. This resource provides additional information, guidelines, FAQs, and videos on their vaccine. The Johnson & Johnson COVID-19 vaccine website can be accessed here.

The CDC has a number of resources regarding Johnson & Johnson's (J&J) COVID-19 vaccine, they can be accessed below:

- CDC Main Page on J&J COVID-19 Vaccine
- Interim Clinical Consideration for Use of COVID-19 Vaccine
- J&J Storage and Handling Summary
- J&J Storage and Handling Labels
- J&J COVID-19 Vaccine Standing Orders
- J&J Transporting Vaccine for Vaccination Clinic Held at Satellite, Temporary or Off-Site Location
- Transport Temperature Log
- J&J COVID-19 Vaccine FAQ

The CDC has a self-paced web-based module titled: *Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know*. This learning module is estimated to take around 30 minutes and reviews a variety of important topics regarding Johnson & Johnson's COVID-19 vaccine. It can be accessed here.

For a comparison of the currently available COVID-19 vaccines feel free to see the NDDoH *Moderna Vs Pfizer Vs Johnson & Johnson Fact Sheet*.

93) What are the most common side effects from COVID-19 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. Side effects are more common after the second dose for mRNA COVID-19 vaccines.

94) What do we tell patients regarding medicines (e.g. acetaminophen or a non-steroidal anti-inflammatory) to manage the side effects of COVID-19 vaccination?

The CDC has stated that you can take pain medication (e.g. non-steroidal anti-inflammatory or acetaminophen) *after* vaccination *if* a patient feels 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 advised for patients to take pain medication in anticipation of potential side effects prior to your vaccine. If a patient has to take pain medication to alleviate side effects, advise them take it *after* they have been vaccinated.

95) Are there educational materials, like a vaccine information statement (VIS), that needs to be given to patients prior to vaccination?

In order for patients to make an informed decision regarding COVID-19 vaccination, an EUA fact sheet will be required to be given to each patient.

The FDA's EUA fact sheet for Pfizer recipients and caregivers can be accessed here.
The FDA's EUA fact sheet for Moderna recipients and caregivers can be accessed here.
The FDA's EUA fact sheet for Johnson & Johnson recipients and caregivers can be accessed here.

The FDA's Pfizer EUA fact sheet for vaccination providers can be accessed here.
The FDA's Moderna EUA fact sheet for vaccination providers can be accessed here.
The FDA's Johnson & Johnson EUA fact sheet for vaccination providers can be accessed here.

96) Are there additional tools and resources we can provide to patients following their COVID-19 vaccination?

VaxText
The CDC has developed VaxText COVID-19 Vaccination Second-Dose Reminder, a free text messaging platform that providers can offer to their patients. Patients can opt in to conveniently receive text message reminders to get their second dose of COVID-19 vaccine. VaxText offers the added benefit of reminding patients to sign up for v-safe. Simply ask vaccine recipients to text ENROLL to 1-833-VaxText (829-8398) to start getting their weekly second dose reminders.

V-SAFE
V-SAFE is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine. Through v-safe, a patient

can quickly tell CDC if they are experiencing any side effects after getting the COVID-19 vaccine. Patients can register by going to vsafe.cdc.gov.

Educational Resources and Handouts

- CDC's *Prevaccination Checklist for COVID-19 Vaccines Handout*
- CDC's *What to Expect Handout*
- CDC's *Continuing the Journey of a COVID-19 Vaccine Handout*
- CDC's *COVID-19 Vaccine Fact Sheet Handout*
- CDC's *V-SAFE Information Sheet Handout*
- CDC's *What to Expect after Getting a COVID-19 Vaccine Handout*

97) What are strategies we can use to ensure that patients receive their second dose of COVID-19 vaccine of a two-dose series?

Strategies to help ensure that patients receive the second dose with the appropriate product and interval between doses include:

- Providing COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card to their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card on their phone).
- Encouraging vaccine recipients to enroll in VaxText, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- Recording each recipient's vaccination in the immunization information system (IIS).
- Recording vaccine administration information in the patient's medical record.
- Making an appointment for the second dose before the vaccine recipient leaves, to increase the likelihood that patients will present at the same vaccination site for the second dose.

98) Is written consent required for COVID-19 vaccination?

No. A patient presenting for vaccination is considered consent.

99) Can COVID-19 vaccine be mandated under Emergency Use Authorization?

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

The Equal Employment Opportunity Commission (EEOC) has stated that employers have the legal right to mandate employees to get a COVID-19 vaccine. Specifically, employers are entitled

and required to ensure a safe workplace in which "an individual shall not pose a direct threat to the health or safety of individuals in the workplace." Requiring a COVID-19 vaccine will not violate the American Disabilities Act (ADA).

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

For more information on EEOC guidelines, please see their website.

100) Where can I find information on mandating COVID-19 vaccine under EUA written in law?

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

(e)Conditions of authorization

(1)Unapproved product

(A)Required conditions

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

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

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

Additional information about COVID-19 vaccine is available on CDC's COVID-19 vaccine website.

101) 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.

102) How should we advise fully vaccinated patients regarding attending indoor gatherings?

If a patient is fully vaccinated (e.g. 2 weeks after 2nd dose of 2-dose series OR 2 weeks after single-dose vaccine) CDC recommends:

- They can gather indoors with fully vaccinated people without wearing a mask.
- They can gather indoors with unvaccinated people from another household without masks, unless any of those people or anyone they live with has an increased risk for severe illness from COVID-19.

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

103) How should we advise fully vaccinated patients regarding travel?

If a patient is fully vaccinated (e.g. 2 weeks after 2nd dose of 2-dose series OR 2 weeks after single-dose vaccine), the CDC has recommended individuals can:

- Travel domestically without a pre- or post-travel test
- Travel domestically without quarantining after travel
- Travel internationally without a pre-travel test depending on destination
- Travel internationally without quarantine after travel

However, it is still recommended to continue to mask and socially distance in public. Additionally, each patient's circumstance is unique and a provider should decide what is best for their patients on a case-by-case basis. For greater detail on CDC recommendations, please see their website.

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

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

- ***Vaccination does not provide immediate immunity***. Both the Pfizer and Moderna vaccines require two doses, weeks apart. The Johnson & Johnson vaccine only requires one dose. It takes time for your body to build protection after any vaccination. It typically takes a week or two following completion of the series (either after 1 dose for Johnson & Johnson or 2 doses for Moderna and Pfizer) to build immunity. During this time, it is still possible to contract an infection and fall ill.
- ***We don't know how well vaccines prevent transmission of COVID-19.*** The Moderna, Pfizer, and Johnson & Johnson vaccines have shown to prevent symptomatic and severe COVID-19 infections remarkably well, but we still do not have enough data to make conclusions regarding their effectiveness at preventing asymptomatic infections. Preliminary data is promising for COVID-19 vaccines, showing they prevent asymptomatic and symptomatic COVID-19.
- ***We don't know how much protection COVID-19 vaccines will provide under real-life conditions.*** While the Moderna, Pfizer, and Johnson & Johnson vaccines have been shown to be efficacious in clinical trial, we have yet to determine how effective the vaccines will be in real-life. Under the controlled and ideal setting of the clinical trial, these vaccines were found to be highly effective at preventing severe disease, hospitalization, and death associated with COVID-19, but real-world factors (e.g. how vaccine is stored, transported, administered) doesn't mimic a controlled clinical trial. New data has shown promising results that vaccines are maintaining effectiveness in real-world settings.
- ***The herd immunity threshold for COVID-19 is unknown.*** It is still uncertain when enough of Americans will be vaccinated to reach a threshold of protection, also known as herd immunity. The more transmissible a pathogen is, the more people must become immune in order to stop it. It is also important to understand that as cases caused by variants emerge and persist that are more easily and quickly spread, it is of even more importance that we vaccinate. The percentage of the population requiring immunization to acquire herd immunity against COVID-19 is not entirely known, but is estimated to be between 70-90%.

- ***It will be impossible to know who is and isn't vaccinated in your community.*** Vaccine is being allocated in a phased approach, and although you may want to get vaccinated, your priority group may not be able to get vaccinated right away. It is going to take time for vaccine to be distributed and enough of the population to be vaccinated to reach potential herd immunity.
- ***We don't know the duration of vaccine protection.*** Information regarding the length of protection from Pfizer, Moderna, and Johnson & Johnson vaccines are still being studied.

COVID-19 Vaccine Administration Errors

COVID-19 vaccination providers are required to report all vaccine administration errors, even those not associated with an adverse event or that may not require revaccination, to the Vaccine Adverse Event Reporting System (VAERS). To file an electronic report, please see the VAERS website. Please complete a VAERS report as soon as possible.

105) If a patient receives an invalid dose of COVID-19 vaccine, when can they receive their next dose?

If an invalid dose of COVID-19 vaccine is administered, revaccination can occur as soon as possible.

106) If a COVID-19 vaccine was administered at an incorrect site (ex. the gluteal muscle instead of the deltoid), should the dose be readministered?

At this time, the CDC does not recommend that doses given at the incorrect anatomical site be readministered. The vaccine recipient may receive the second dose (at the appropriate injection site) per the recommended vaccine schedule.

107) If a vaccine recipient moved during administration and did not receive an entire dose, is there a waiting period before the dose can be repeated or can it be given immediately?

When the vaccine recipient moves and a partial dose is administered, it is up to the professional judgement of the person administering the vaccine whether or not to readminister that dose.

- If they think most of the dose was not administered, then revaccination would be warranted and revaccination can occur *as soon as possible*; the initial dose would be considered an invalid dose.
- If they think most of the dose was given then that dose can be considered a valid dose.

The final dose (i.e., the second valid dose) should be spaced from the first VALID dose by the recommended interval.

108) For COVID-19 vaccines requiring a second dose, what if a patient inadvertently completed their COVID-19 vaccines series with two different mRNA vaccine products? (i.e. Pfizer for dose one and Moderna for dose two)

No additional doses of either vaccine are recommended at this time.

109) If some of the vaccine leaked out of the injection site, do we need to revaccinate the patient?

If it appears that only some of the vaccine was administered and some of it leaked out of the injection site, it is up to the professional judgement of the person administering the vaccine whether or not to readminister that dose.

- If they think most of the dose leaked out of the injection site, then revaccination would be warranted and revaccination can occur as soon as possible; the initial dose would be considered an invalid dose.
- If they think most of the dose remained in the injection site then that dose can be considered a valid dose.

To reduce the potential for vaccine leakage from the use of VanishPoint Syringes, please view the following video on YouTube: VanishPoint Syringe

110) Our clinic accidentally vaccinated a 17-year-old with Moderna's COVID-19 vaccine. Should the patient receive their second dose?

A 17-year old individual who inadvertently received the Moderna COVID-19 vaccine may receive the second dose if clinical decision making determines that the risk-benefit ratio favors administration of the second Moderna COVID-19 dose 28 days or more following the first Moderna COVID-19 vaccine dose.

111) Our clinic vaccinated a 15-year old with Pfizer's COVID-19 vaccine within 4 days of their 16th birthday. Is the dose valid?

Yes. The dose was given within the 4-day grace period and it is considered valid. The patient should receive the second dose 21 days following the first Pfizer COVID-19 vaccine dose.

112) If a patient has, unknowingly to vaccination clinic staff, received a first dose of COVID-19 vaccine at another location, and has inadvertently received a second dose of COVID-19 vaccine that is an incorrect vaccine (mixed series) and given in less than the designated interval of time between doses, should the dose be repeated?

No, the dose should not be repeated. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time. Recommendations may be updated when further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.

Persons should not be scheduled to receive the second dose earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 4 weeks [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period should not be repeated.

It is important to screen patients that present a COVID-19 vaccination clinic to make sure they are receiving the correct vaccine at the correct interval. Some individuals may be on a number of COVID-19 vaccine waitlists, thus they may be offered vaccine from multiple locations. To see strategies on how to reduce error such as this, click here.

Who Should and Shouldn't Be Vaccinated

113) What are the contraindications for the COVID-19 vaccines?

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

114) Can people with underlying conditions receive the vaccine?

Yes. People with underlying conditions are at a higher risk for severe COVID-19 disease. Vaccine may be administered to these individuals who have no contraindications to vaccination. 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.

115) 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.

Individuals should be counseled about: 1) unknown vaccine safety and efficacy profiles in immunocompromised persons, 2) potential for reduced immune responses, and 3) need to continue to follow all current guidance to protect themselves against COVID-19.

116) Can individuals with an acute illness be vaccinated? (e.g. common cold, shingles)

The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines. The NDDoH recommends that individuals consult with their healthcare provider if they are experiencing an acute illness and would like to be vaccinated. In these situations, healthcare providers should consider the risks and benefits of vaccination.

The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition. The safety and efficacy of vaccinating persons who have mild illnesses have been documented. Vaccination should be deferred for persons with a moderate or severe acute illness. After they are screened for contraindications, persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.

Additionally, individuals with shingles should not receive the vaccine at an anatomical site where there is an active rash.

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

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

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection. Thus, **while vaccine supply remains limited**, persons with recent, documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired.

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

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing for prior infection for the purpose of vaccine decision-making *is not recommended*.

118) Should patients get a COVID-19 vaccine even if they 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, patients should be vaccinated regardless whether they 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.

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

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

120) Should people who currently have active infection with SARS-CoV-2 be vaccinated?

Vaccination should be deferred until the person has recovered from acute illness and criteria have been met to discontinue 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.

121) 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.

Congregate settings, including long-term care settings, homeless shelters, and correctional facilities should consider vaccination even if residents/staff are in quarantine.

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

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

123) A patient recently tested positive for SARS-CoV-2. Should healthcare providers recommend monoclonal antibody treatment to help prevent severe disease? If recommended, the patient will not be able to be vaccinated for at least 90 days. Is that ok?

Patients at an increased risk for severe disease should be recommended to receive monoclonal antibody treatment. **It may save a patient's life**. These patients will need to wait 90 days to receive the vaccine, but until that interval is met, it is very unlikely that they will become reinfected with the virus.

124) A patient has tested positive for SARS-CoV-2 after they have received their first dose of COVID-19 vaccine of a two-dose series. Should they be given monoclonal antibody treatment to help prevent severe disease?

Yes, this treatment can be given at the provider's discretion. The CDC recommendations state that for vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decision or timing of such treatment. There is no waiting period required for administering monoclonal antibody treatment following a COVID-19 vaccine. Administering this treatment more than 10-14 days after vaccination may have limited benefit but it is still recommended.

125) A patient previously tested positive for SARS-CoV-2. This patient has received the first dose of their COVID-19 vaccine that requires two doses, and has now tested positive again. This patient is a candidate for antibody treatment. If they receive antibody treatment, when should they get their second dose of COVID-19 vaccine?

The second dose should be deferred for at least 90 days following receipt of antibody therapy.

126) Does antibody treatment impact vaccine efficacy? Does a patient who has received antibody therapy need to restart the COVID-19 vaccine series?

At this time, it is unknown how antibody treatments will impact COVID-19 vaccine efficacy.

Patients who have received one dose of COVID-19 vaccine, followed by monoclonal antibody therapy, do not need to restart the vaccine series which requires 2 doses to complete the series.

These patients should receive their second dose of the vaccine once the 90-day interval has been met.

127) Can pregnant women receive COVID-19 vaccine?

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

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

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

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

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

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

Yes. Women who are breastfeeding may choose to be vaccinated. mRNA and non-replicating viral vector vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. However, there are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA and non-replicating viral vector vaccines on the breastfed infant or milk production/excretion.

The American College of Obstetrics and Gynecology (ACOG) has stated "Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine." Recent research has demonstrated that mRNA COVID-19 vaccines can confer protective immunity from vaccinated mothers to newborns through breast milk and the placenta. The American College of Obstetrics and Gynecology has published guidance here.

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

American Society for Reproductive Medicine has stated, "Patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria. Since the vaccine is not a live virus, there is no reason to delay pregnancy attempts because of vaccination administration or to defer treatment until the second dose has been administered." However, fertility patients who are scheduled for procedures like egg retrieval, embryo transfer or intrauterine insemination are advised to avoid getting a COVID-19 vaccine within three days before and three days after the procedure according to the American Society for Reproductive Medicine. This recommendation is made due to the fact that patients are undergoing surgical procedures could develop vaccine-related side effects like fever or chills that might make it difficult for doctors to know if a post-surgical infection is occurring. Practices should notify and encourage their patients to communicate with their surgeons and fertility programs when they become eligible for COVID vaccination. This will help coordinate planned surgical procedures, fertility testing and treatment, and will decrease the chance of inadvertent procedure cancellation.

130) If a patient is eligible for COVID-19 vaccination but also has other vaccinations due, which vaccines should we give first?

Patients and providers should weigh the risks and benefits of different vaccines on a case-by-case basis. (e.g. If a patient has had COVID-19 in the last 90 days, it might be best to defer COVID vaccination and administer other vaccines to the patient.) Providers and patients should determine which vaccines are recommended for the patient and what the patient's current risk of contracting each disease is. If a patient has impending international travel which will put them at risk for diseases which are vaccine-preventable, they may want to consider receiving travel vaccines. Similarly, if a patient is a healthcare worker but also due for their annual influenza vaccine, COVID-19 may present a more significant risk and they may want to consider receiving the COVID-19 vaccine first.

131) 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.

132) Can children be vaccinated against COVID-19?

Pfizer's COVID-19 vaccine has been authorized for adolescents 16 and 17 years of age. Emergency Use Authorization of the Pfizer vaccine does not include use in individuals younger than 16 years of age. However, Pfizer requested expansion of the Emergency Use Authorization (EUA) of their COVID-19 vaccine to this age group in the United States on April 9, 2021. The NDDoH will update data accordingly when we know more.

Moderna's and Johnson & Johnson's COVID-19 vaccines are only approved for individuals 18 years and older.

133) If a patient is from another state, can they receive a COVID-19 vaccine in North Dakota?

Yes. COVID-19 vaccination is open to everyone eligible under the FDA's Emergency Use Authorizations (e.g. 16 and older for Pfizer and 18 and older for Moderna and Johnson & Johnson). Vaccine should be given to all who are eligible and desire a COVID-19 vaccine, regardless of their state or country of residence.

134) How should our health system address staff members that refuse COVID-19 vaccination?

If a staff member refuses to vaccinate, it is important to provide them with information regarding the risks associated with COVID-19 infections and the risks and benefits of COVID-19 vaccination. Additionally, consider asking them what concerns or questions they have about the vaccine and respectfully address each concern/question. There are patient concerns below that may arise regarding the COVID-19 vaccine with suggested responses.

If a staff member still refuses after their concerns and questions have been addressed, the NDDoH has created a Declination of COVID-19 Vaccination for your use. Feel free to use this optional form. Facilities may change and/or add your own logo.

135) How should we address patients' questions regarding seasonal travel and COVID-19 vaccine?

Recommendations for travelers prior to first dose of COVID-19 vaccine:
If your patient is a seasonal traveler or "snowbird", advise the patient they may be able to be vaccinated in the location they are residing. However, it is important to note that the state of their winter residence may have different availability for COVID-19 vaccination than North Dakota, and their ability to be vaccinated may not be the same in the state of their destination. The NDDoH encourages providers to suggest that their patients check with local health departments for COVID-19 vaccine priority groups/instructions.

Recommendations for travelers after their first dose but before their second dose of COVID-19 vaccine:
Ideally, individuals should receive their second doses from the same healthcare provider who administered the first dose. If a patient has received their first dose of COVID-19 vaccine in North Dakota and has traveled south prior to receiving their second dose of vaccine, advise them that they *may be able* to receive their second dose in that state. However, it is important to note that the state of their winter residence may have different availability for COVID-19 vaccination than North Dakota, and their ability to be vaccinated may not be the same in the state of their destination. If they have traveled to a winter home between doses, the NDDoH encourages providers to advise patients to check with local health departments for instructions. Further, it is important to advise patients to keep their vaccination record card with them. The vaccination record card will include important information on a patient's first dose of COVID-19 vaccine including which vaccine they received, when they received it, and where they received it.

136) If a patient has received their first dose of COVID-19 vaccine in a state of their winter residence and is now home (e.g. back in North Dakota) and requesting their second dose, should we provide it?

Yes. Patients that have received their first dose in a different state and are now back in North Dakota prior to receiving their second dose should be provided COVID-19 vaccine. NDDoH suggests using allocated "first doses" you receive for patients that classify under this group and to plan accordingly.

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

At this time, there are no universal requirements for proof of vaccination (e.g. vaccine passport) to travel. If you are traveling by air, each airline has its own unique requirement and recommendations. The NDDoH recommends that you check with the airline you are travelling through for their specific requirements. Additionally, certain destinations may have their own vaccine requirements. It's best to check with the destination to see if there are any travel-related

requirements. The NDDoH Travel page can also provide you with greater detail regarding traveling during the pandemic. You can visit their website here.

Vaccine Reporting

138) What are the reporting requirements?

All doses of COVID-19 vaccine will need to be reported to the North Dakota Immunization Information System (NDIIS) within 24 hours of administration. This includes doses that are entered via manual data entry into NDIIS, those that are electronically sent through an Electronic Health Record (EHR) system or through another mechanism. For more information on NDIIS, please see the NDDoH website.

139) Where do I report COVID-19 administration data?

PrepMod

PrepMod is available for all North Dakota healthcare providers to use during mass vaccination clinics.

PrepMod allows for members of the public to preregister for COVID-19 vaccine online. This will include electronic registration, consent to vaccination, consent to receive immunization reminders via text message, review the Vaccine Information Statement (VIS) or other fact sheet, report their high risk/priority group and to find the vaccination clinic nearest to them. Healthcare providers using PrepMod will be able to set up clinics and control the appointment times and number of patients per appointment to allow for social distancing. PrepMod will also document all required fields for vaccine administration then report to the NDIIS in real-time. This system will allow for a paperless vaccination clinic and no waiting in the clinic to complete forms. PrepMod will be made available to any healthcare provider in ND who would like to use it for vaccination clinics, not just COVID vaccination.

EHR

With the adoption of electronic health records (EHRs) by many health systems, data from the EHR can automatically document the vaccine record in NDIIS in real time.

140) How quickly does COVID-19 vaccine administration data need to be reported to NDIIS?

The NDDoH requires that vaccination providers enrolled in COVID-19 Vaccination Program report each dose administered within 24 hours of administration to the NDIIS.

141) Where do we report adverse reactions/effects from the COVID-19 vaccine?

NDDoH strongly encourages physicians and other providers to report all moderate and severe vaccine adverse reactions to the Vaccine Adverse Event Reporting System. Any serious adverse reaction should be reported to the NDDoH Immunization Program immediately, which would notify CDC.

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the FDA and the CDC. The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of vaccines in the United States. Reports can be made by healthcare professionals, vaccine manufacturers, and the public. More information on VAERS can be found on the HHS website.

For spontaneous adverse events reporting to VAERS for populations served by IHS and Tribal facilities, more information can be found on the IHS website.

V-SAFE (Vaccine safety assessment for essential workers)

V-SAFE is a new smartphone-based, after-vaccination health checker for people who received COVID-19 vaccines. The system will also provide telephone follow up to anyone who reports medically significant adverse events. A VAERS report will be taken during telephone follow-up if appropriate.

More information on registering for and step-by-step instructions on using V-SAFE please visit the CDC website.

Need help with V-SAFE?
Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348
Open 24 hours, 7 days a week

National Healthcare Safety Network (NHSN)

An acute-care and long-term care facility monitoring system that will promote reporting the VAERS. See more information on NHSN on the CDC website.

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

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

143) What is required of COVID-19 enrolled vaccine providers regarding VaccineFinder?

Only providers administering COVID vaccine to their patients and/or the general public will be turned on for public display in VaccineFinder. If an enrolled provider needs to be turned on for public display in VaccineFinder, they must notify the North Dakota Department of Health (NDDoH) Division of Immunizations via email at covidvaccine@nd.gov. Providers turned on for public display must have their organization contact registered for the VaccineFinder COVID Locating Health provider portal. The organization contact can choose to manage the public display information for their provider site or delegate that responsibility to the primary and back-up contacts as identified on your COVID provider enrollment. Once registered, check your public display details to make sure the information is accurate. Any changes to your public display information must be made through the COVID Locating Health provider portal. Changes to email contacts, provider name or provider address must be sent to the NDDoH at covidvaccine@nd.gov.

The NDDoH Division of Immunizations will continue to report COVID vaccine inventory on behalf of our enrolled providers. The NDDoH submits vaccine inventory from the North Dakota Immunization Information System (NDIIS) seven days a week. Providers should not report any of their own COVID vaccine inventory to VaccineFinder as it will be overwritten the next day when the NDDoH submits inventory on your behalf. Please continue to make sure your COVID vaccine inventory in the NDIIS is up to date.

144) What documents are required for entering COVID-19 vaccine doses administered out-of-state or at facilities, like the VA, that don't report to NDIIS?

Patients must provide a reliable source of documentation for proof of COVID-19 vaccination. Reliable sources include (but are not limited to) the vaccine record card they received at the time of vaccination, a vaccination record from a provider office, or an official certificate of immunization from another jurisdiction immunization information system. The record provided must include, at a minimum, the vaccination date and brand of vaccine administered. Providers should not accept a patient's verbal report of vaccination.

145) 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.

Addressing patient concerns about COVID-19 vaccine

As healthcare professionals, you are a patient's most trusted source for vaccine information. You will play a critical role in helping to build confidence in COVID-19 vaccination. Below are some questions and potential responses to patient concerns about COVID-19 vaccine.

146) "Should I be worried about it being a new vaccine?"

It is understandable to have questions about a new vaccine. COVID-19 vaccine development is unlike any vaccine development process in the past. Although the vaccines were created faster than any vaccine before, safety and effectiveness was paramount every step of the way. The timeline for vaccine development was shortened because certain steps in a typical vaccine development and manufacturing process occurred at the same time. The FDA has strict guidelines for ***any vaccine*** authorized by EUA. They established clear and rigorous recommendations on vaccine performance and safety. Expert committees (VRBPAC and ACIP) will analyze the data from clinical trials to affirm vaccine safety and effectiveness prior to any EUA being granted. We have seen this process in action for the authorization of the Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines. In addition, the FDA is committed to engaging in continuous monitoring of COVID-19 vaccines to ensure they are ***safe*** and ***effective***.

147) "I want the vaccine, but I just don't want to be the first to get it."

Tens of thousands of people participated in COVID-19 vaccine clinical trials to help determine the safety and efficacy of the vaccines. Additionally, over 212 million doses have been administered since December 2020 in the U.S. under the most intensive safety monitoring network in our country's history. Getting vaccinated against COVID-19 not only protects you, but also protects your loved ones and those in your community most vulnerable to the virus. The clinical trial data from both Pfizer and Moderna have shown their vaccines to be around 95% efficacious. Johnson & Johnson's vaccine clinical trial indicated their vaccine was 85% effective at preventing severe disease and 100% effective at preventing hospitalizations and deaths from COVID-19. As Dr. Paul Offit has said, "The choice not to get a COVID-19 vaccine is the choice to be among the now [567,000] people who have died from this virus". Not getting vaccinated is the radical choice. ***The benefits of vaccinating against COVID-19 far outweigh***

the risks. We will rely on everyone to get the vaccine to reach herd immunity and end this pandemic.

148) "I want to see long-term safety data before I get the vaccine."

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

Theoretically, side effects from vaccination could show up at any time, but again, history tells us they almost never happen after six weeks. This makes sense. We would expect any vaccine side effects to occur close to vaccination – as this is when the immune response is most active and working hard to build protection. Once your body has built that protection, the only thing that remains is your body's own ability to provide protection should you ever encounter the virus in the future.

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

Finally, COVID-19 vaccines are much safer than getting COVID-19. COVID has had lasting impacts on many people, and we may just be scratching the surface of what the disease can do and what its long-term impacts are. Thousands of people are dying each week from COVID-19. COVID impacts our lungs, heart, kidneys, and nervous system, just to name a few. Recent studies indicate that 10% of COVID-19 patients may become "long-haulers" and have symptoms of the disease for months. Recent research has suggested that one-third of COVID-19 vaccine survivors

were diagnosed with a neurological or mental health condition within 6 months of their COVID-19 diagnoses. To put this into perspective, these conditions were 44% higher after COVID-19 than after the flu.

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

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

Any COVID-19 vaccine that is authorized for use in the United States has met the FDA's rigorous guidelines for EUA and has been reviewed by both VRBPAC and the ACIP (expert committees that provide recommendations and guidance on immunizations). In the last year, we have had approximately 567,000 deaths associated to COVID-19 in the United States. While preventive measures like social distancing and masks help to slow the spread, ***the only truly preventive measure against this virus is to vaccinate.***

Both the Pfizer and Moderna COVID-19 vaccines have reported efficacy ***around 95%***, rivalling the effectiveness of some of the best vaccines available to us against other viruses such as MMR (97% effective) and chickenpox (92% effective) vaccines.

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

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

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

Clinical trial data for both Pfizer and Moderna showed strong vaccine efficacy for older populations. Elderly individuals should not delay vaccination because of product preference. Any vaccine that has been approved for use in the United States has met FDA standards for safety

and efficacy. Further, vaccine supply is extremely limited and people may not be able to choose which vaccine they would like to receive.

151) "I don't need a COVID-19 vaccine, the disease isn't that serious and we should just let it spread through the community."

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 and now the leading cause of death in our country. Since the beginning of the pandemic, there have been over 30 million documented cases of and over 567,000 deaths attributed to COVID-19 in the United States. Getting vaccinated not only protects you but protects others you care about. By vaccinating you help to prevent the spread of disease to your friends, loved ones, and those in your community.

It is not clear whether those who have cleared infection with COVID-19 virus are immune to future infection. Even if infection created long-lasting immunity, over 70% of the population (over 200 million people) would have to recover from COVID-19 to halt the epidemic. This would create a burden on our healthcare system and lead to many serious complications and millions of deaths.

152) "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. More than 1 in 500 North Dakotans have died from COVID-19. While preventative measures like social distancing and masks help to slow the spread, *the only truly preventive measure against this virus is to vaccinate*.

By vaccinating against COVID-19, you not only protect yourself, but also prevent spread of the disease to your friends, loved ones, and those in your community. COVID-19 can have serious, life threatening complications and there is no way to know how the virus will affect you. COVID-19 vaccines are being carefully evaluated and will be authorized only if they are found to be safe and make it substantially less likely you'll get COVID-19.

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

153) "The new COVID-19 mRNA vaccine will literally alter your DNA, so you essentially become a genetically modified human being."

This is false. While the mRNA vaccines are the first of their kind, ***they cannot alter DNA***. The mRNA vaccines work by introducing a messenger RNA molecule into your body, which causes cells to produce a protein that resembles one of the viral proteins that make up SARS-CoV-2. Your immune system recognizes the viral protein and generates an immune response against it.

The mRNA vaccines are unable to change your genetic makeup because the mRNA injected into the tissue to stimulate an immune response ***do not integrate into the cell nucleus of its recipients, thus genetic modification is not possible***. It only presents the body with the instruction 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.

The CDC has produced a handout on mRNA vaccines for healthcare professionals, this resources provides useful information on mRNA vaccines and discusses how to talk to patients with questions about this vaccine platform. The *Learn More about the New mRNA COVID-19 Vaccines* handout can be found here.

154) "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 H1H1 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.

155) "I have 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.

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

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

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

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

to a short genetic sequence (like the genetic sequence shared between the SARS-CoV-2 spike protein and syncytin-1).

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

For more information, feel free to check out the NDDoH handout and video created to address this topic.

157) "I have heard that getting the COVID-19 vaccine affects a woman's menstrual cycle. Is this true?"

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

It is also not possible for the vaccination of one woman to affect the menstrual cycle of another woman. Additionally, the menstrual cycle of one woman cannot affect the menstrual cycle of another. This concept came from a study conducted in 1971 and is referred to as the McClintock Effect - which suggested that pheromones or other factors can influence and shift periods for women who live together or are in close proximity to one another. Recent research does not support this finding and further suggest that menstrual cycles don't align reliably and it is just coincidence when a woman's period happens to occur at the same time. It does not have anything to do with close proximity, pheromones, or moon phases - let alone COVID-19 vaccination. Things that do affect menstrual cycles include birth control pills, extreme stress, chronic illness, and anorexia/bulimia.

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

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

It is unknown whether the new virus strains (caused by mutations) will affect the efficacy of vaccines in the long run. While COVID-19 variants have been detected and confirmed in North Dakota, both Pfizer and Moderna have reported that their vaccines produce immune responses that recognize and neutralize variant strains, although there was a reduction in antibodies that neutralize some variants. We also know that the Johnson & Johnson vaccine provides some protection against more contagious and potentially deadlier variants of COVID-19. In Brazil and

South Africa, where variant strains have been detected and spreading widely, the Johnson & Johnson vaccine still provided complete protection against hospitalization and death, and 64% (South Africa) and 68.1% (Brazil) efficacy against moderate to severe disease from COVID-19 28 days following vaccination in clinical trial.

It is possible a variant of the virus may someday make current vaccines ineffective. The manufacturers anticipated potential mutation of the virus, as this is common in coronaviruses. Because of this knowledge, vaccines have been designed to target the entire spike protein on the surface of SARS-CoV-2. Vaccinated individuals produce antibodies that recognize many different parts of the spike protein, so even if one portion of the protein changes or mutates, there will be antibodies to other parts of the protein, which makes it harder for the virus to completely evade our immune systems. Further, both Moderna and Pfizer are testing booster vaccines which are designed to target emerging variants of the coronavirus. But it is of great importance that we *vaccinate*, because vaccinating helps to slow the spread of virus, prevent people from getting sick and dying, and decrease the likelihood of other potentially dangerous variants emerging. Vaccinating against COVID-19 *saves lives*.

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

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

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

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

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

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

161) "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.

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

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

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

163) "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.

164) Are any of the COVID-19 vaccines made with fetal cells?

- The mRNA COVID-19 vaccines produced by Pfizer and Moderna **do not require the use of any fetal cell cultures in order to *manufacture* the vaccine.**
    - The following organizations assert that the mRNA COVID-19 vaccines as 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 (USCCB), and the North Dakota Catholic Conference.
- The non-replicating viral vector COVID-19 vaccine made by Johnson & Johnson did require the use of fetal cell cultures to develop and manufacture the vaccine.
    - The Catholic Church and the Southern Baptist Ethics & Religious Liberty Commission have both stated that receiving a COVID-19 vaccine that required fetal cell lines for production or manufacture is morally acceptable.
    - Individuals should not delay vaccination because of product preference.
- For more information on this topic please view the NDDoH handout.

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

No. The Pfizer and Moderna COVID-19 vaccines contain *poly*ethylene 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.

CDC COVID-19 Vaccine Education

The CDC is offering a new, web-on-demand, self-paced module for healthcare providers who will be administering COVID-19 vaccine. The module will cover:

- Information about COVID-19 vaccine Emergency Use Authorization and safety
- General information about vaccine storage, handling, administration, and reporting

For more information on this education see the CDC website.

To access the module, check out the CDC COVID-19 Vaccine Training Module.

Please feel free to contact the NDDoH Immunization Program with any questions or concerns at covidvaccine@nd.gov or 701.328.3386 or toll-free at 800.472.218