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**CDC COVID-19 Vaccine Education**
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 two 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 unapproved products (Pfizer-BioNTech and Moderna’s COVID-19 vaccines) for active immunization to prevent COVID-19 in individuals 16 years of age and older in the United States.

Several other COVID-19 vaccines are in clinical trials but have not been approved. Some of these vaccines 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 can we expect a vaccine to be available?**

The Pfizer vaccine became available in North Dakota starting December 14th. The Moderna vaccine will be available the week of December 21st. Early on, vaccines will be limited to certain priority groups.

For the most up-to-date information, please visit the NDDoH website.

A COVID-19 pipeline tracker is available online.

3) **Why is this 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](https://www.operationwarp-speed.com).

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.

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

According to the Children’s Hospital of Philadelphia’s [Vaccine Education Center](https://www.vaccine.edu), several approaches to COVID-19 vaccines are currently being tested. They include both tried-and-true as well as new approaches.

Here is a brief summary of these different strategies:

- **Inactivated vaccine** — The whole virus is killed with a chemical and used to make the vaccine. This is the same approach that is used to make the inactivated polio (shot), hepatitis A and rabies vaccines.

- **Subunit vaccine** — A piece of the virus that is important for immunity, like the spike protein of COVID-19, is used to make the vaccine. This is the same approach that is used to make the hepatitis B and human papillomavirus vaccines.

- **Weakened, live viral vaccine** — The virus is grown in the lab in cells different from those it infects in people. As the virus gets better at growing in the lab, it becomes less capable of reproducing in people. The weakened virus is then used to make the vaccine. When the weakened virus is given to people, it can reproduce enough to generate an immune response, but not enough to make the person sick. This is the same approach that is used to make the measles, mumps, rubella, chickenpox and one of the rotavirus vaccines.

- **Replicating viral vector vaccine** — In this case, scientists take a virus that doesn’t cause disease in people (called a vector virus) and add a gene that codes for, in this case, the coronavirus spike protein. Genes are blueprints that tell cells how to make proteins. The spike protein of COVID-19 is important because it attaches the virus to cells. When the vaccine is given, the vector virus reproduces in cells and the immune system makes antibodies against its proteins, which now includes the COVID-19 spike protein. As a result, the antibodies directed against the spike protein will prevent COVID-19 from binding to cells, and, therefore, prevent infection. This is the same approach that was used to make the Ebola virus vaccine.

- **Non-replicating viral vector vaccine** — Similar to replicating viral vector vaccines, a gene is inserted into a vector virus, but the vector virus does not reproduce in the vaccine recipient. Although the virus can’t make all of the proteins it needs to reproduce itself, it can make some proteins, including the COVID-19 spike protein. No currently licensed vaccines use this approach.

- **DNA vaccine** — The gene that codes for the COVID-19 spike protein is inserted into a small, circular piece of DNA, called a plasmid. The plasmids are then injected as the vaccine. No currently licensed vaccines use this approach.

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

- The Pfizer and Moderna vaccines are both mRNA vaccines.

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.

At the October Advisory Committee on Immunization Practices (ACIP) meeting, the number of participants in clinical trials and diversity of participants were presented.

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, two of the manufacturers of COVID-19 vaccines in late stage clinical trials, are reporting at least 30% of participants being from diverse backgrounds (Black, Hispanic, Asian, American Indian). At the October ACIP meeting, the number of participants in clinical trials and diversity of participants were presented.

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. It is likely that 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. It is likely that a COVID-19 vaccine will be made available using an EUA.

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

Additional information about EUA is available on FDA's [website](https://www.fda.gov).

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 might the FDA issue an EUA before a BLA for a COVID-19 vaccine?**

- A vaccine for COVID-19 is most likely going to first be 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.
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 in clinical trials?

Pfizer and Moderna have both indicated that their COVID-19 vaccines are safe and effective.

Pfizer’s COVID-19 vaccine showed no serious safety concerns, and there were no serious adverse events reported for Moderna’s COVID-19 vaccine.

Pfizer reported 95% efficacy for those who received two doses, while Moderna reported 94.1% efficacy for those who received two doses.

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

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

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

A COVID-19 vaccine with 95% efficacy means that it has the ability to prevent 19 out of 20 COVID-19 infections in those who are vaccinated. In other words, the vaccinated group experienced 95% fewer COVID-19 cases than they would have if they had not been vaccinated.
15) How does the efficacy of the Pfizer and Moderna vaccines compare to other vaccines?

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

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

16) What is the efficacy of the COVID-19 vaccine if I only receive one dose?

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.

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

According to data released by Pfizer and Moderna, clinical trial participants did pass away during the safety monitoring period following vaccination. 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, 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.

- 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.

18) 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) will also be used. VSD is an active surveillance system that monitors electronic health data for adverse events in various healthcare settings. The Clinical Immunization Safety Assessment Project (CISA) will conduct
clinical research and assess complex vaccine safety issues. A new, additional safety monitoring program, V-SAFE, is also planned to monitor COVID-19 vaccines using smartphones for health surveys. Additional information about safety monitoring is available on CDC’s COVID-19 vaccine website.

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

Recently, Pfizer started to include children in COVID-19 vaccine clinical trials. Moderna has also announced that they will begin enrolling children. The vaccine was not specifically studied in pregnant women. 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 are currently underway and results are expected in the near future. Moderna’s DART studies found no safety concerns in pregnant animals.

20) 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 subgroups. 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.

21) 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.

22) 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.

23) I heard reports of anaphylaxis following receipt of the Pfizer COVID-19 vaccine. 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 Pfizer’s COVID-19 vaccine. The CDC is investigating these reports and will update vaccine recommendations as more information becomes available.

The Pfizer vaccine was studied thoroughly in clinical trials prior to receiving EUA. The phase 3 trial results indicated *that vaccine was 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 the Pfizer vaccine.

Individuals who have a history of anaphylaxis to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) may receive COVID-19 vaccine, 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 CDC has posted guidelines for managing anaphylaxis at vaccination sites [here](#).

24) 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.

Because of reports of anaphylactic reactions in individuals vaccinated outside of clinical trials, additional guidance has been created. 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.

25) 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. **The cases in the vaccine group do not represent a frequency above the rate of Bell’s palsy that is expected in the general population.** Also, there is currently no evidence to conclude a causal relationship between vaccination and Bell’s palsy. The FDA will recommend surveillance for cases of Bell’s palsy as the vaccine is administered to the general population to determine if vaccination is associated with increased risk of Bell’s palsy.

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

26) 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.

27) 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.
28) 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.

29) 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.

30) 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.

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

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

Priority Groups

32) Who has been identified as priority populations?

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

At this time, the ACIP has decided on the following phases:
- Phase 1A: Healthcare workers and long-term care residents
- Phase 1B: Persons aged 75 years of age and older and frontline essential workers
- Phase 1C: Persons 65-74 years of age, persons aged 16-64 with high-risk medical conditions, and other essential workers

The federal Advisory Committee on Immunization Practices (ACIP) will make continued recommendations as to who should be prioritized for COVID-19 vaccine. To view the slides from previous ACIP meetings regarding this topic, please visit their website. Further, the North Dakota COVID-19 Vaccination Ethics Committee is currently developing priorities amongst the likely priority groups, as vaccine will be very limited to start and will need to be prioritized amongst ACIP priorities.
Please visit the NDDoH COVID-19 vaccine [website](#) for the most up-to-date information regarding priority groups.

### 33) How are the priority groups for COVID-19 vaccine allocation and distribution created?

The federal [Advisory Committee on Immunization Practices](#) will ultimately make recommendations regarding priorities for COVID-19 vaccination. It is likely that the state will have to further prioritize amongst these groups due to limited vaccine supplies.

The North Dakota Advisory Committee on COVID-19 Vaccination Ethics has been tasked with providing recommendations to Unified Command for allocating doses of vaccine as they arrive in the state. The Committee is comprised of five voting members: a physician, an ethicist, a local public health representative, a representative of the Department of Human Services and a representative of the Department of Health. The committee is facilitated by a retired medical epidemiologist who is acting as advisor to the Division of Immunization.

The committee unanimously voted to be guided by a set of ethical principles laid out by the National Academies of Science, Engineering and Medicine in a document called Framework for Equitable Allocation of COVID-19 Vaccination. The ethical principles can be summarized as follow:

- Achieving maximum societal benefit by optimally protecting health and socioeconomic well-being
- Ensuring that each human life is treated with equal dignity, worth and value
- Mitigating the disparities in disease impact on different populations
- Ensuring fairness and impartiality
- Acting transparently
- Making decisions based on the best available evidence

For more information on the ACIP’s recommendations, please check out the [ACIPs’ Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine - United States, 2020](#)

### 34) Why was my group not considered in a higher tier in the priority groups?

Great consideration went into determining priority groups. The North Dakota Advisory Committee on COVID-19 Vaccination Ethics considers the following in determining priority:

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

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

The committee recognizes that there is no one “right” answer, but some answers are better than others. **Unfortunately, not everyone can be highest priority for vaccination.**

For more information on priority groups, please visit the CDC [website](https://www.cdc.gov).

**35) How will healthcare providers be notified when subsequent priority groups are able to be vaccinated?**

Healthcare providers will be notified by email, the NDDoH website and social media of who should be prioritized for COVID-19 vaccine. Additionally, webinars will be held to educate providers about priority groups.

**Storage and Handling**

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

**Pfizer**

Pfizer’s COVID-19 vaccine must be stored at -70°C. These temperatures are only maintained in ultra-low temperature freezers. The vaccine is viable at this temperature for up to six months.

If stored in its original shipping container, dry ice must be replenished within 24 hours of receipt (dry ice supplied by the federal government). Dry ice must be replenished at least every five days after that for up to 15 days total. The shipment containers should not be opened more than twice a day for more than one minute each. Specific instructions about how to unpack and manage the Pfizer shipping container are available on the NDDoH [website](https://www.nddoh.gov).

Once the vaccine is thawed and put into a refrigerator, it needs to be used within five days (120 hours).
For more information on storage and handling of the Pfizer COVID-19 vaccine, please see the FDA EUA Pfizer-BioNTech *Fact Sheet for Healthcare Providers Administering Vaccine*.

**Moderna**

Moderna’s COVID-19 vaccine must be stored at -25°C to -15°C. These temperatures can be achieved in a regular freezer. The vaccine is viable at this temperature for up to six months. Once the vaccine is thawed, it can last in the refrigerator for 30 days. It can also be kept at room temperature for up to 12 hours.

**37) 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.

**38) 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.

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

39) 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.

40) Will shipments of COVID-19 vaccine include ancillary supplies?

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

**Pfizer**
Pfizer Ancillary supplies supports administration of 975 doses - designed for use in adults, the kit will contain:
- Needles, 1,029 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 1,024 per kit
- Mixing Needles, 205 per kit
- Mixing Syringes, 204 per kit
- Alcohol prep pads, 2,458 per kit
- Diluent, 200 per kit
- Needle Card, 10 per kit
- 40 surgical masks and 20 face shields for vaccinators, per kit
- Vaccination Card, 1,000 per kit

**Moderna**
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.

**Vaccine Information & Presentation**

41) **When will the COVID-19 vaccine become available?**

The Pfizer vaccine became available in North Dakota starting December 14th. The Moderna vaccine will be available the week of December 21st. Early on, vaccines will be limited to certain priority groups.

For the most up-to-date information, please visit the NDDoH website.

A COVID-19 pipeline tracker is also available online.

42) **How many doses come in each kit?**

*Pfizer*

Pfizer’s COVID-19 vaccine ships in minimum increments of 975 doses.

*Moderna*

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

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

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

There will be multiple presentations of the COVID-19 vaccine which may include single-dose vials, multi-dose vials, or pre-filled syringe. What we know now is:

*Pfizer*

The Pfizer COVID-19 vaccine comes in a 5-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.

**44) 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).

**Vaccine Specifics**

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

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

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

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

**46) 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.

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

No. However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment. 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.
48) Is it necessary to start a COVID-19 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.

49) 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.

50) Are COVID-19 vaccines interchangeable?

No. In order to complete the COVID-19 vaccine series, the ACIP recommends that the second dose of the vaccine be the same brand/manufacturer as the first dose.

51) 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.

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

No. Initial supplies of vaccines should not be held back to ensure persons receive their second dose. The federal government will be holding back a supply of COVID-19 vaccine for second doses. The CDC has indicated that additional allocations will be made available to accommodate the second dose.

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

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

No. COVID-19 viral tests are used to detect current infection. COVID-19 vaccines cannot cause COVID-19 infections.
54) 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) anticipated to be available are not live vaccines. More information will be shared as it becomes available.

Administering COVID-19 Vaccine

55) 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.

56) 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).

57) 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).
58) 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.

59) 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 two coronavirus vaccines as well as administration codes unique to each such vaccine.

91300: Pfizer COVID-19 Vaccine
91301: Moderna 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
Additional information about COVID-19 vaccine administration fees is available at COVID-19 Vaccine Policies & Guidance | CMS.

60) 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.

61) 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. If this interval is not met, revaccination is not recommended.

62) What route is COVID-19 vaccine administered?

The Pfizer and Moderna COVID-19 vaccines are both administered via the intramuscular (IM) route.

63) 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.

64) 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.

65) 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 (i.e., food) should be observed for 30 minutes post-vaccination.

66) If there are remaining doses in the vial, can we draw more than 5 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.

67) How do I track and manage excess vaccine doses (such as a 6th 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.

68) 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.

69) 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.

70) 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.

71) 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 the Pfizer COVID-19 Vaccine
- Pfizer COVID-19 Vaccine Standing Orders
- Pfizer COVID-19 Vaccine Preparation and Administration Summary
- 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](#).

**72) 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 the Moderna COVID-19 Vaccine
- Moderna COVID-19 Vaccine Storage and Handling Recommendations

**73) What are the most common side effects from COVID-19 vaccination?**

Pfizer and Moderna have included preliminary data on side effects reported in Phase III clinical trials.

**Pfizer**

No serious safety concerns observed.

- The only grade 3 (severe and undesirable) adverse events greater than 2% in frequency were:
  - Fatigue - 3.8% of participants
  - Headache - 2.4% of participants

**Moderna**

Local and systemic symptoms followed for 7 days post-vaccination

- Adverse events most commonly associated with vaccination:
  - Pain at the injection site - 92% of participants
  - Fatigue - 70% of participants
  - Headache - 64.7% of participants
  - Myalgia - 61.5% of participants
  - Arthralgia - 46.4% of participants
  - Chills - 45.4% of participants
  - Nausea/vomiting - 23.0% of participants
Axillary swelling/tenderness - 19.8% of participants
Fever - 15.5% of participants
Swelling at the injection site - 14.7% of participants
Erythema at the injection site - 10% of participants

- Solicited local and systemic adverse reactions reported following administration of vaccine had a median duration of 2-3 days
- Reactogenicity symptoms higher after second dose
- No vaccine-related serious adverse events reported

These mild to moderate side effects are signals that the immune system is working.

74) 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 recipients and caregivers can be accessed here.

The FDA's EUA fact sheet for vaccination providers (those giving vaccine) can be accessed here.

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

No. A patient presenting for vaccination is considered consent.

76) 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.

77) 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.

78) 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 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 will NOT receive COVID-19 vaccine before other states.
Additional information about COVID-19 vaccine is available on [CDC’s COVID-19 vaccine website](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html).

### 79) Will people who are vaccinated need to continue to wear PPE, practice social distancing, and observe quarantine recommendations?

Yes. Until a significant proportion of the population is immunized, mitigation strategies, such as mask-wearing and social distancing, will still be required.

### Who Should and Shouldn’t Be Vaccinated

#### 80) 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) to a previous dose or any component of a COVID-19 vaccine.

#### 81) Will people with underlying conditions be recommended to 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.

#### 82) Will people who are immunocompromised be recommended to 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.

#### 83) Will people who have had COVID-19 be recommended to receive the COVID-19 vaccine?

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

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus, persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.
84) **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.

85) **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.

86) **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.

87) **Can pregnant women receive COVID-19 vaccine?**

Yes. Pregnant women may choose to be vaccinated. They should weigh the risk of COVID-19 (i.e. healthcare workers) with the risks of vaccination. Pregnant women should discuss vaccination with their healthcare provider. The American College of Obstetrics and Gynecology has published guidance [here](#).

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

Yes. Women who are breastfeeding may choose to be vaccinated. mRNA 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 vaccines on the breastfed infant or milk production/excretion. The American College of Obstetrics and Gynecology has published guidance [here](#).

89) Can children be vaccinated against COVID-19?

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

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

**Vaccine Reporting**

90) 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](#).

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

**PrepMod**

PrepMod is expected to be fully implemented before mass vaccination is needed and will be available for all North Dakota healthcare providers to use during mass vaccination clinics.

PrepMod will allow 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.

92) **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.

93) **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](https://vaers.hhs.gov). 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](https://vaers.hhs.gov).

For spontaneous adverse events reporting to VAERS for populations served by IHS and Tribal facilities, more information can be found on the IHS [website](https://www.ihs.gov).

**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](https://www.cdc.gov).

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.

94) 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. Additionally, the NDDoH will not be reporting vaccination rates for staff and residents of nursing homes or for places of employment, such as schools.

**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.*

95) “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 vaccine was 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. Further, the FDA has strict guidelines for any vaccine authorized by EUA. They established clear and rigorous recommendations on vaccine performance and safety. Further, expert committees (VRBPAC and ACIP) will analyze the data from clinical trials to affirm vaccine safety and effectiveness prior to an EUA being granted. In addition, the FDA is committed to engaging in continuous monitoring of COVID-19 vaccines to ensure they are safe and effective.

96) “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. 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. Further, the preliminary data from both Pfizer and Moderna have shown their vaccines to be around 95% efficacious, far above the FDA’s goals of 50% efficacy. As Dr. Paul Offit has said,
“The choice not to get a COVID-19 vaccine is the choice to be among the now [290,000] 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.

97) “I want to see long-term safety data before I get the vaccine.”

It is understandable to want to see long-term safety data before getting vaccinated, but this is not something that is currently available. Thousands of people are dying each week, and getting vaccinated is the only way to prevent COVID-19. What we do know is that COVID-19 vaccines appear to be safe and effective.

Although a vaccine was developed quickly, vaccine sponsors and the federal government will continue to monitor the vaccines and assure they are safe and effective. Some steps of development are proceeding at the same time. Manufacturing of the vaccine occurred during the trial period before data on safety was available, while this increased the financial risk, it did not increase the product risk.

Further, Pfizer and Moderna had large Phase III clinical trial sizes ranging from 30,000 to 44,000 participants. The size of these trials helped to establish the validity and safety of the vaccines being tested. Further, the current vaccine safety monitoring system is strong and robust, with the capacity to effectively monitor COVID-19 vaccine safety in almost real-time. And any vaccine authorized for use will be reviewed by expert committees (VRBPAC and ACIP) prior to an EUA being issued in the United States

98) “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 regarding EUA and has been reviewed by both VRBPAC and the ACIP (expert committees that provide recommendations and guidance on immunizations). In the last ten months, we have had over 290,000 deaths associated to COVID-19. While preventive measures like social distancing and masks help to slow the spread, the only truly preventive measure against this virus is to vaccinate.

Preliminary data from Pfizer and Moderna is extremely promising. Phase III trial results on both vaccines indicate an efficacy around 95%, rivalling the effectiveness of some of the best vaccines available to us against other viruses such as MMR (97% effective) and chickenpox (92% effective) vaccines. In addition, efficacy for the Pfizer and Moderna vaccine was consistent across
age, gender, race, and ethnicity demographics. There is no reason to wait for a better vaccine when both the Pfizer and Moderna vaccines efficacy is among the best we have available compared to all recommended vaccines.

99) “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. Since the beginning of the pandemic, there have been over 12 million documented cases of and over 300,000 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.

Further, 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.

100) “Why should I get a COVID-19 vaccine?”

The COVID-19 pandemic has had a significant impact on all of our lives. Although you may not know anyone who has been directly affected by the disease, it is ever-present in our community. Further, more than 1 in a 600 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.
101) “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.

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

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

To encourage expedient development of medical countermeasures during a public health crisis, the PREP Act was created in 2005. The PREP Act authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act Declaration that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. Previous PREP Act declarations have been issued numerous times, including those for the H1N1 pandemic in 2009.

The PREP Act does provide manufacturers of countermeasures (i.e. COVID-19 vaccine) some immunity from liability, but this does not mean COVID-19 vaccine injuries are not covered or compensated for. They are covered under the Countermeasures Injury Compensation Program.
(CICP). The PREP Act authorizes CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under the PREP Act declaration.

Although vaccine manufacturers are not liable for unforeseen adverse events, they would be liable for negligence.

For more information on the PREP Act, please see the Public Health Emergency website.

For more information on CICP, please see the HRSA website.

103) “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.

104) “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.

I have heard there is a new strain of coronavirus circulating in the U.K. Will the COVID-19 vaccines provide protection against it?

It is unlikely the new virus strain (caused by a mutation) will affect the efficacy of a vaccine in the short term. It is possible a variant of the virus may someday make current vaccines ineffective, but chances of this happening are very low. The manufacturers anticipated potential mutation of the virus, as this is common in coronaviruses. Because of this knowledge, both Moderna’s and Pfizer’s vaccines 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 evade our immune systems.

Is the COVID-19 vaccine made with fetal cells?

- The mRNA COVID-19 vaccines produced by Pfizer and Moderna do not require the use of any fetal cell cultures in order to manufacture the vaccine.
- The following organizations assert that the mRNA COVID-19 vaccines 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, the North Dakota Catholic Conference and the Immunization Action Coalition
- For more information on this topic please view the NDDoH handout.

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 800.472.2180.