# COVID-19 Vaccine
## Frequently Asked Questions
for Healthcare Professionals

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Vaccine Development and Approval

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

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

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

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

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

2) When did COVID-19 vaccines become available?

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

As of May 12, 2021, anyone 12 years of age and older is now eligible for COVID-19 vaccine in North Dakota.

A COVID-19 pipeline tracker is available online.
3) Why is the COVID-19 vaccine development timeline so condensed compared to when other vaccines are licensed?

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

- Utilizing existing technology – many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.
- Developing vaccines immediately after the viral genome sequence is available.
- Financing – The federal government has provided funding for COVID-19 vaccine development.
- Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, there will be large amounts of vaccine ready. This is not typical because if a vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.
- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:
  - Developing plans for distribution
  - Ensuring adequate supplies for distributing and administering vaccines, like vaccine vials, syringes and other equipment needed to vaccinate
  - Establishing mechanisms for distribution to large subsets of the population

4) The development and production of a COVID-19 vaccine has been called “Operation Warp Speed”. Does this mean shortcuts have been taken?

Operation Warp Speed is a partnership between the 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?

Several approaches to COVID-19 vaccines are currently being tested. They include both tried-and-true as well as new approaches.

Here is a brief summary of these different strategies:

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

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

For more information on the most recent updates on COVID-19 vaccines being developed, undergoing clinical trials, and approved/authorized for use, please see [The New York Times Coronavirus Vaccine Tracker](https://www.nytimes.com/interactive/2020/02/19/us/coronavirus-vaccine-tracker.html).

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

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

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

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

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

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

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

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

9) What is Emergency Use Authorization?

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. The FDA has fully approved Pfizer’s COVID-19 vaccine for use in individuals 16 years of age and older. Pfizer’s COVID-19 vaccine for children ages 12-15, a 3rd dose for certain people who are immunocompromised, and boosters for a select group of individuals are still available through EUA.

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

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

10) Can you explain the difference between 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.

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

Yes. Pfizer, which received EUA for its COVID-19 vaccine in December of 2020, initiated its biological license application (BLA) for full approval of its vaccine for people ages 16 and older on May 7, 2021. Pfizer requested a priority review of its application. On August 23, 2021, the FDA approved Pfizer’s COVID-19 vaccine for the prevention of COVID-19 in individuals 16 years of age and older - making it the first COVID-19 vaccine to receive this distinction. The vaccine will be marketed as Comirnaty.

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

13) What does FDA’s full licensure of Pfizer’s COVID-19 vaccine (Comirnaty) mean for my clinic?

On August 23, 2021, FDA approved the BLA (Biological License Application) for Pfizer’s COVID-19 vaccine for individuals aged 16 years and older; its trade name is Comirnaty. The vaccine remains authorized for emergency use for children 12 to 15 years old and for administration of an additional dose in immunocompromised people and a booster dose for eligible individuals.

No changes have been made to the storage, handling, or vaccine ordering requirements as a result of licensure. Clinicians should continue to administer this vaccine in accordance with current ACIP recommendations and CDC guidelines.
The FDA issued an updated Fact Sheet that reflects the new trade name and combines information for individuals receiving the vaccine in accordance with its licensed indication with information for those receiving the product under the terms of its emergency use authorization (EUA).

Updated resources can be found below:

- All clinics providing Comirnaty should use the updated [Fact Sheet for all recipients and caregivers](#).
- The Fact Sheet for healthcare providers can be found [here](#).
- The link to the prescribing information (PI) for Comirnaty is [here](#).
- For all FDA related resources for Comirnaty please see the FDA [website](#).

**COVID-19 Vaccine Safety and Efficacy**

14) **Is the COVID-19 vaccine safety tested?**

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

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

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

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

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

To date, COVID-19 vaccines have been shown to be safe and effective with mild side effects that typically resolve within 1-2 days. However, COVID-19 vaccines have also been linked to rare, more serious side effects.
Two potential severe adverse events have been associated with receiving the Pfizer or Moderna COVID-19 vaccines:

- **Severe allergic reaction (anaphylaxis)**
  - Rate: 2-5 per million vaccinated in the U.S. (extremely rare)
  - Symptoms include: skin rash, nausea, vomiting, difficulty breathing and shock
  - Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination and are manageable with treatment
  - To read more on anaphylaxis visit the CDC website [here](#)

- **Inflammation of the heart (myocarditis and pericarditis)**
  - Rate: 12.6 cases per million doses administered for individuals 12-39 years
  - Most cases are in male adolescents and young adults 16 years of age or older
  - Myocarditis is more common after the second dose
  - Symptoms: chest pain, shortness of breath, fast-beating/fluttering/pounding heart
  - Symptoms typically appear several days after COVID-19 vaccination
  - Most patients who receive care respond well to treatment and rest and quickly feel better
  - To read more on myocarditis and pericarditis visit the CDC website [here](#)

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

- **A rare type of blood clot with low platelet counts (also known as thrombosis with thrombocytopenia syndrome or TTS).**
  - Rate: 7 per million for women 18 to 49 years of age who have been vaccinated, and for both women 50 years of age and older and men the rate is less than 1 per million people vaccinated (extremely rare)
  - Most cases are in women younger than 50 years of age
  - Symptoms: severe headache, shortness of breath, chest pain, leg swelling, gut pain that doesn’t go away, and easy bruising or tiny blood spots under the skin
  - Symptoms typically appear 1-2 weeks after vaccination
  - To read more on TTS visit the CDC website [here](#)

- **Guillain-Barre syndrome (GBS)**
  - A rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis
  - Rate: 12.8 per million doses administered (extremely rare)
  - Most cases are in men, many 50 years of age and older
  - Symptoms: weakness and tingling in the feet and legs spread to the upper body. Paralysis can occur.
  - Symptoms typically reported about 2 weeks after vaccination
  - To read more on GBS visit the NIH website [here](#)
When deciding if you should be vaccinated, it is important to weigh the risks and benefits of vaccination with the risks of COVID-19. The CDC continues to recommend vaccination for all individuals 12 years of age and older.

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

In clinical trials, Pfizer reported 95% efficacy in individuals 16 years of age and older who received two doses and 100% efficacy in adolescents 12 to 15 years of age who received two doses of vaccine. Moderna reported 94.1% efficacy for those 18 years of age and older who received two doses and 100% efficacy in adolescents 12 to 17 years of age who received two doses of vaccine. The COVID-19 vaccine made by Johnson & Johnson requires one dose, and was 66% effective at preventing moderate to severe COVID-19 in clinical trial participants worldwide. This vaccine is also 85% effective at preventing severe disease and it offered complete protection against COVID-19-related hospitalization and death 28 days after vaccination.

It is unknown whether the new virus variants (caused by mutations) will affect the efficacy of vaccines in the long run. Pfizer, Moderna, and Johnson & Johnson have reported that their vaccines produce immune responses that recognize and neutralize variant strains, although there was a reduction in antibodies that neutralize some variants.

The Delta variant, which originated in India, is a highly contagious COVID-19 strain. It has become the dominant variant in the U.S. and globally. Recent research suggests that Delta has a faster replication rate, a reduced incubation period, and greater viral shedding - all factors that contribute to Delta being more infectious (1000x higher viral load compared to original strain) and more transmissible (as contagious as chicken pox). Delta may also cause more severe outcomes in comparison to previous variants, with increased risks of hospitalization and death.

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

Additional Resources:

- [NDDoH COVID-19 Delta Variant Fact Sheet](#)
- [CDC Website - Delta Variant: What We Know About the Science](#)
- [CDC Website - Who Is Eligible for a COVID-19 Vaccine Booster Shot?](#)
17) **What is efficacy? Is there a difference between vaccine efficacy and effectiveness?**

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

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

18) **How are COVID-19 breakthrough infections tracked and monitored?**

While COVID-19 vaccines are highly effective, no vaccine is 100% effective at preventing COVID-19. With millions of people getting vaccinated against the virus, some people who are fully vaccinated will still get COVID-19. These cases are called breakthrough cases.

In North Dakota, the [NDDoH COVID-19 dashboard](#) includes information on breakthrough cases, hospitalizations, and deaths in the state. The data presented in this dashboard is updated daily.

The CDC investigates breakthrough infections in a number of ways, including national surveillance and through information obtained from vaccine effectiveness studies.

National surveillance involves the CDC working with both state and local health departments to investigate COVID-19 breakthrough cases. You can read more on this system on the CDC [website](#). The goal of this surveillance is to identify any unusual patterns, such as trends in age or sex, the vaccines involved, underlying health conditions, or which of the SARS-CoV-2 variants made these people sick. On May 1, 2021, CDC transitioned the national breakthrough case investigation and reporting system from monitoring all reported breakthrough cases to identifying and investigating only breakthrough cases in patients who were hospitalized or died, which maximizes the quality of data collected on cases of greatest clinical and public health importance.

Vaccine effectiveness studies are conducted by the CDC and include information on breakthrough infections in patients with asymptomatic and milder illness (which is no longer included in national surveillance reports provided online). These studies use existing CDC systems and new systems developed specifically for COVID-19 vaccine to evaluate how well the vaccines work. You can see more about COVID-19 vaccine effectiveness research on the CDC [website](#).
Additionally, CDC is leveraging existing programs, with multiple sites to evaluate COVID-19 vaccine effectiveness among healthcare workers across 26 states. To read more about breakthrough cases, please check out the following resources:

- CDC's What You Should Know About the Possibility of COVID-19 Illness After Vaccination
- CDC’s COVID-19 Vaccine Breakthrough Case Investigation and Reporting

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

There is very limited data on the efficacy of Pfizer’s and Moderna’s COVID-19 vaccines when only one dose is given. Pfizer has indicated that the efficacy of their COVID-19 vaccine after one dose is at least 52%. Moderna has noted 80.2% efficacy after one dose.

The available data shows that a 2-dose series provides consistently higher protection compared to a partial (one-dose) series. Additionally, recent research has shown that a single dose of a two-dose COVID-19 vaccine does not provide adequate protection against the Delta variant (which is now the dominant variant in the U.S.), however, fully vaccinated individuals retain significant protection against severe outcomes, hospitalization and death from Delta. For best protection, it is recommended that individuals receive two doses.

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

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

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

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

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

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

- **Determine if these events are causally related to the vaccine** – In these six events, the event happened very shortly after vaccination. However, correlation is not causation. Causality will be assessed by vaccine and medical experts.

- **Alert healthcare providers to assure proper diagnosis and treatment** – This type of blood clot should not be treated with the usual treatment for blood clots (heparin), so the CDC and FDA needed to get the information out to clinicians ASAP so they could properly detect, PROPERLY TREAT, and properly report the adverse event to CDC and FDA for further investigation.

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

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

As of September 22, 2021, the CDC and FDA had identified 47 cases of this rare adverse event out of 14.8 million administered doses of Johnson & Johnson COVID-19 vaccine. This adverse event, which is likely related to receipt of the Johnson & Johnson COVID-19 vaccine, is rare and CDC continues to recommend the vaccine for use in the United States.

It is important to understand that this pause on J&J’s vaccine administration in the U.S. shows that our vaccine monitoring systems are working. The CDC and FDA are committed to transparency throughout this process and the safety and efficacy of COVID-19 vaccines.

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

The CDC has stated that there is an increased risk of a rare adverse event called thrombosis with thrombocytopenia syndrome (TTS) following receipt of the Johnson & Johnson COVID-19 vaccine. To date, the CDC has identified 47 cases of TTS out of the 14.8 million doses of the
Johnson & Johnson vaccine administered. Because this event is so rare, it may not be detected in clinical trials that include tens of thousands of people.

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

It would be extremely unlikely that an event that occurs at a rate of 1 in 300,000 doses administered to be picked up in a clinical trial of 44,000 people. An event so rare would likely only be picked up once the vaccine is administered to enough people. This is why we continue to monitor vaccines for safety, even after they get authorized or approved by the FDA.

23) As a healthcare provider, what actions should I take regarding recommending Johnson & Johnson’s COVID-19 vaccine to patients?

Effective April 23, 2021, the CDC and FDA recommend that administration of the Johnson & Johnson COVID-19 vaccine resume in the United States. The available data shows that the vaccine’s known and potential benefits outweigh its known and potential risk. You can offer Johnson & Johnson COVID-19 vaccine to people 18 years and older who want to get vaccinated against COVID-19.

As a healthcare provider, your strong recommendation can help a patient make an informed and confident decision about getting vaccinated against COVID-19. If patients have questions about the safety of the Johnson & Johnson COVID-19 vaccine, the CDC recommends the following talking points:

- Discuss the possibility of a rare but increased risk of blood clots with low platelets seen after receipt of the Johnson & Johnson COVID-19 vaccine.
  - To date, most of these reports have been in adult women younger than 50 years old, but there have been reports in men and older women.
  - The reporting rate for this event in women 18 to 49 years old is about 7 per 1 million women vaccinated, so this event is rare.
  - The reporting rate for both women 50 years and older and men is less than 1 per 1 million people vaccinated.

- Discuss the possibility of a rare but increased risk of Guillain-Barre syndrome (GBS) after receipt of the Johnson & Johnson COVID-19 vaccine.
  - As of September 22, 2021, 210 cases have been reported out of the 14.8 million doses of Johnson & Johnson administered in the U.S. - this event appears to be extremely rare
  - Of the original 100 cases reported - 95 of the 100 reported cases required hospitalization and one person has died.
○ Cases appear to be mostly in males 50 years of age and older and cases have largely been reported approximately two weeks after vaccination.

If a patient is hesitant about Johnson & Johnson COVID-19 vaccine, it is important to explain that there are other alternative COVID-19 vaccines available for which this specific risk has not been seen. Consider and discuss if the patient is able and willing to complete a two-dose mRNA vaccine series.

The CDC has created *Talking to Patients about Safety of the Janssen COVID-19 Vaccine* as a resource for healthcare providers.

**24) As a healthcare provider, what should I be aware of regarding the diagnosis and treatment of suspected cases of thrombosis with thrombocytopenia syndrome (TTS) among Johnson & Johnson COVID-19 vaccine recipients?**

Healthcare providers are recommended 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 review the following resources regarding Johnson & Johnson COVID-19 vaccine and diagnosis and treatment of TTS:

- [HAN Notification: Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine](#)
- [Guidance from the American Society of Hematology: Diagnosis and Treatment of Suspected Cases of Thrombosis with Thrombocytopenia Syndrome](#)
- [Revised Janssen COVID-19 Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [CDC Clinical management of suspected VITT after COVID-19 vaccination webinar](#)
- [Talking to Patients about J&J/Janssen COVID-19 Vaccine Handout](#)

Report any suspected adverse events to the [Vaccine Adverse Event Reporting System](#).
25) As a healthcare provider, what should I be aware of regarding the diagnosis and treatment of suspected cases of Guillain-Barre syndrome (GBS) among Johnson & Johnson COVID-19 vaccine recipients?

Healthcare providers are recommended to maintain acute clinical awareness of symptoms that might represent Guillain-Barre syndrome in patients who have recently received the J&J COVID-19 vaccine. Symptoms to look out for include:

- Difficulty with eye muscles or vision
- Difficulty swallowing, speaking, or chewing
- Pricking or pins/needles sensations in the hands and feet
- Pain that can be severe, particularly at night
- Coordination problems and unsteadiness
- Abnormal heart beat/rate of blood pressure
- Problems with digestion and/or bladder control

Report any suspected adverse events to the [Vaccine Adverse Event Reporting System](https://www.vaers.hhs.gov).

26) How should I counsel patients who are concerned about TTS or GBS following receipt of the Johnson & Johnson COVID-19 vaccine?

It is important to tell patients not to panic. These events appear to be a very rare side effect. It is important for patients to monitor for symptoms:

- TTS symptoms include: 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.
- GBS symptoms include: weakness or tingling sensations, difficulty walking, difficulty with facial movement, double vision/inability to move eyes, and/or difficulty with bladder control/bowel function approximately two weeks after 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](https://www.cdc.gov).

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

According to data released by COVID-19 vaccine manufacturers, clinical trial participants did pass away during the safety monitoring period following vaccination. Deaths occurred in participants in the vaccinated and the unvaccinated groups. However, it is important to note that the deaths that occurred in the vaccinated group were not caused by the vaccination.
In the Pfizer briefing document for Emergency Use Authorization (EUA), six deaths were noted in the study population; 2 in the vaccine group and 4 in the placebo group (placebo group = those who did not get the vaccine). In Pfizer’s expanded clinical trial to 12-15 year olds, there were no deaths reported. In the Moderna briefing document for EUA, 13 deaths were noted; 6 in the vaccine group and 7 in the placebo group. In the Johnson & Johnson briefing document for EUA, 25 deaths were noted; 5 in the vaccine group and 20 in the placebo group.

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

28) How will the safety of the COVID-19 vaccines be monitored?

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

- The Vaccine Adverse Events Reporting System (VAERS) will be used to identify signals that might indicate a safety issue.
- The Vaccine Safety Datalink (VSD) is an active surveillance system that monitors electronic health data for adverse events in various healthcare settings.
- The Clinical Immunization Safety Assessment Project (CISA) will conduct clinical research and assess complex vaccine safety issues.
- A new, additional safety monitoring program, V-SAFE, is being used to monitor COVID-19 vaccines using smartphones for health surveys.
  - Parents and guardians can also enroll adolescents (ages 12 and older) in V-SAFE and complete health check-ins on their behalf after COVID-19 vaccination.
- Additional information about safety monitoring is available on CDC’s COVID-19 vaccine website.

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

Yes. Pfizer has conducted a clinical trial in children ages 12-15 and the vaccine is now authorized for emergency use for everyone 12 and older in the U.S. Preliminary data indicates that the vaccine demonstrated 100% efficacy and was well tolerated in participants aged 12-15 years old. On September 28, 2021, Pfizer announced they have submitted initial data from a phase two/three trial of their vaccine in children 5-11 years of age to the FDA. FDA’s VRBPAC committee will be meeting on October 26, 2021 to address Pfizer’s request to amend its EUA to allow for the use of their COVID-19 vaccine in children 5-11 years of age. Data on Pfizer’s trials in children from 6 months to 4 years of age are also expected in the coming months.

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

Moderna is currently enrolling their clinical trial for children ages 6 months - 11 years.
Johnson & Johnson has expanded clinical trials to include adolescents 12 and older for their COVID-19 vaccine.

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

The Moderna and Johnson & Johnson COVID-19 vaccines have not been formally studied in pregnant women yet. Before vaccines are studied in pregnant women, developmental and reproductive toxicity (DART) studies, which use animal models, are conducted to ensure safety of vaccines in pregnant women. Pfizer DART studies have been reported in Europe and there were no safety signals generated. Moderna and Johnson & Johnson’s DART studies found no safety concerns in pregnant animals.

Pregnant women who opt to receive the vaccine should report their pregnancy in V-SAFE to be followed for safety monitoring and pregnancy outcomes.

30) 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.

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

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

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

To see more information regarding fainting after vaccination, please visit the CDC website.
32) 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.

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

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

34) Do COVID-19 vaccines contain pork products?

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

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

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

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

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

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

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

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

36) 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.

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

It is important to remember that this adverse event is very rare, occurring at a rate of 7 out of every million Johnson & Johnson COVID-19 vaccines administered to women between the age of 18 and 49 years old. For women 50 years of age and older and men of all ages, this adverse event is even more rare (less than 1 per 1 million people vaccinated). The Pfizer and Moderna vaccines have not been associated with blood clots and would be an alternative to those who are concerned about this rare side effect.
Patients who have received a Johnson & Johnson COVID-19 vaccine should be instructed to seek immediate medical attention if they develop:

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

Healthcare providers should consider TTS in an evaluation of blood clots after vaccination and report all cases to VAERS.

For further information on how to talk to patient’s regarding Johnson & Johnson’s COVID-19 vaccine see the CDC’s Talking to Patients about Safety of the Janssen COVID-19 Vaccine.

38) I heard reports of inflammation of the heart (myocarditis) and of the outer lining of the heart (pericarditis) following receipt of Pfizer and Moderna COVID-19 vaccines. Are these events related?

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the U.S. after mRNA COVID-19 vaccination (Pfizer and Moderna), particularly in adolescents and young adults. These reports are rare, and the CDC and its partners are actively monitoring reports of myocarditis and pericarditis after COVID-19 vaccination. There has not been a similar reporting pattern observed after receipt of Johnson & Johnson COVID-19 vaccine.

In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. Research has shown that incidence of myocarditis following an mRNA COVID-19 vaccine is rare and that symptoms in a majority of cases resolve following care. CDC and its partners will continue to investigate these reports of myocarditis and pericarditis following COVID-19 mRNA vaccination.

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis. CDC continues to recommend COVID-19 vaccination for everyone 12 years and older given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death.

For more information, please see these additional CDC resources:
Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

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

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

The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of GBS. Safety monitoring system

40) 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.

41) Do COVID-19 vaccines cause Bell’s palsy?

At this time, Bell’s palsy does not appear to be associated with COVID-19 vaccination. In the Pfizer clinical trial data, four cases of Bell’s palsy were noted in the vaccine group while zero cases were noted in the placebo group. In the Moderna clinical trial data, three cases were noted in the vaccine group and one case was noted in the placebo group. In the Johnson & Johnson trial data, two cases were noted in the vaccine group and two cases were noted in the placebo group. In these instances, the cases in the vaccine group did not represent a frequency above the rate of Bell’s palsy that is expected in the general population. This was further substantiated regarding Moderna and Pfizer’s vaccines with data presented at the July 22, 2021 ACIP meeting. Data from the Vaccine Safety Datalink showed no increased risk of Bell’s palsy in vaccinated
individuals. Surveillance for cases of Bell’s palsy will continue as the vaccine is administered to the general population to determine if vaccination is associated with increased risk of Bell’s palsy.

42) Do COVID-19 vaccines cause Guillain-Barre syndrome (GBS)?

There were no cases of Guillain-Barre 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. On July 13, 2021, the FDA released a statement that suggested that there is possible increased risk of GBS following receipt of a J&J COVID-19 vaccine. The FDA has added additional information to the vaccine’s FDA fact sheet on the risk of GBS. The chance of GBS occurring is very low following J&J vaccination. As of September 22, 2021, 210 preliminary reports of GBS have been identified in VAERS out of the more than 14.8 million J&J COVID-19 vaccine doses that have been administered in the U.S. Cases occur mostly in males and have largely been reported approximately two weeks after vaccination. You should seek medical attention right away if you develop any of the following symptoms following receipt of a J&J vaccine: weakness or tingling sensations, difficulty walking, difficulty with facial movement, double vision/inability to move eyes, and/or difficulty with bladder control/bowel function.

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

43) Can patients who have previously had Guillain-Barre 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.

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

ITP is a disorder that can lead to easy or excessive bruising and bleeding. The bleeding results from unusually low levels of platelets — the cells that help blood clot. Thus far, there have been some reports of ITP following vaccination. However, we must remember that association is not causation.
According to the FDA, 1 in 35,000 people in the U.S. present with ITP each year. As millions of COVID-19 vaccines are administered across the country, inevitably some of the vaccinated will be diagnosed with ITP within days of receiving the vaccine. It is human nature to draw a connection between events, especially when they happen close together, but it doesn’t mean vaccination caused ITP. The United States has the most comprehensive vaccine safety monitoring program in the world to detect adverse events following vaccination and investigate any adverse events that follow vaccination to determine if a vaccine could have caused a particular outcome. Thus far, there is no evidence to suggest that COVID-19 vaccination is associated with an increased risk of ITP.

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

45) **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, Veterans Administration, some Federally Qualified Health Centers, and the Federal Retail Pharmacy Program. These facilities do not need to enroll to receive COVID-19 vaccine from the NDDoH.

46) **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. Additional information about enrollment is available on the NDDoH COVID-19 vaccine [website](#).

47) **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.

48) **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.

49) 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.

50) Can COVID-19 vaccine be transferred or donated outside of the United States?

As a COVID-19 provider participating in the CDC COVID-19 Vaccination Program, you cannot transfer or donate COVID-19 vaccines allocated to you directly or from your jurisdiction outside of the United States. Any international transfer or donation of COVID-19 vaccines must be undertaken by the federal government.

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

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

52) We are concerned about ordering/stocking more COVID-19 vaccine due to potential wastage. What should we do?

The CDC and NDDoH are aware that vaccine wastage may increase as more providers receive vaccine, vial sizes increase, and vials are punctured without every dose being used. We want to make sure we take every opportunity to vaccinate individuals who present for vaccination, even if that means some doses will be wasted. Best practices for reducing wastage include:

- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to utilize each dose. Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
- Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
- Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
- It is also important not to puncture more vials than are needed to avoid wastage. Once punctured, multidose vials must be used within:
  - 12 hours (Moderna)
For greater details on best practices, please visit the CDC website. As a contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a waitlist or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.

**Storage and Handling**

53) **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 one month (31 days).* After one month, 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.

Total storage time for Pfizer in the freezer and refrigerator should not exceed 45 total days.

**Update 8/23/21:** The FDA has approved an amendment to the EUA for Pfizer extending the expiration dates of COVID-19 vaccine from six to nine months. Cartons and vials of Pfizer COVID-19 vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed data as long as authorized storage conditions between 90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra-cold temperature range has been broadened to include -90°C (-130°F). Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for extension.

It is highly recommended to use CDC’s [COVID-19 Vaccine and Beyond-Use Dates (BUDs) tracking labels for vaccine during refrigerator storage.](https://www.cdc.gov/vaccines/vpd/covid-19/extension-of-expiration-dates.html)

For more information on storage and handling of the Pfizer COVID-19 vaccine, please see the CDC’s [Storage and Handling Summary](https://www.cdc.gov/vaccines/hcp/professional/product-storage/dry-ice.html) and Pfizer’s COVID-19 vaccine [website](https://www.pfizer.com/covid) 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.

*Total storage time for Pfizer in the freezer and refrigerator should not exceed 45 days.*
**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.

It is highly recommended to use CDC’s [COVID-19 Vaccine and Beyond-Use Dates (BUDs) tracking labels for vaccine during refrigerator storage](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/preparation.html).

For more information on the preparation and administration of the Moderna COVID-19 vaccine, please see the CDC’s [Storage and Handling Summary](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/administering.html) and Moderna’s COVID-19 vaccine [website](https://www.modernatx.com/covid-19) for their information on storage and handling.

**Johnson & Johnson**

**Refrigerator**

CDC recommends storing vaccine between 2° to 8°C (36° to 46°F):
● 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 25ºC or 77ºF) for up to 2 hours.
● Discard if not used within this time.

Do not freeze.

Protect from light.

Update 7/29/21: The Food & Drug Administration authorized an extension of the shelf life for the Johnson & Johnson’s COVID-19 vaccine from 4.5 months to 6 months (an additional 45 days). The decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 6 months when refrigerated at temperatures of 36 – 46 degrees Fahrenheit (2 – 8 degrees Celsius). Vaccine providers should visit https://vaxcheck.jnj/ to confirm the latest expiration dates of vaccine, including those currently available for administration throughout the U.S. This extension applies to refrigerated vials of J&J/Janssen COVID-19 vaccine that have been held in accordance with the manufacturer’s storage conditions.

Best practices for storage and handling COVID-19 vaccine
As the expiration date approaches, determine if it has been extended using the same methods outlined in the “Deliveries” section. Do not discard the 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.

54) Should I be checking expiration dates on vials prior to preparing and administering vaccine?
Yes. The expiration date should be checked prior to preparing or administering vaccine. Expired vaccine or diluent should NEVER be used. As additional stability data become available,
the expiration dates for some products may change. CDC’s [COVID-19 Vaccine Expiration Date Tracking Tool](https://www.cdc.gov/vaccines/COVID-19/expiration-dates) can help providers keep track of the expiration date by lot number.

For COVID-19 vaccines that do not have a final expiration date, CDC has set up an expiration date of 12/31/2069 to serve as a placeholder date. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer’s website.

**Moderna COVID-19 vaccine**: To determine the expiration date, providers can scan the QR code located on the vial or carton or access the manufacturer’s website directly, enter the lot number and the expiration date will be displayed.

**Pfizer COVID-19 vaccine**: This vaccine product has an expiration date located on the vaccine vial. As of August 23, 2021, the FDA approved an amendment to the EUA for Pfizer extending the expiration dates of COVID-19 vaccine from six to nine months. The extended expiration date is effective immediately for all currently available batches that have not yet expired. NOTE: Expiration dates extension does NOT apply to vials dated July 2021 and earlier.

**Johnson & Johnson COVID-19 vaccine**: The expiration date can be obtained by entering the lot number from the carton or vial using the website [www.vaxcheck.jnj](http://www.vaxcheck.jnj) or by phone using an automated response system at 1-800-565-4008. This critical process should take less than one minute to complete. You can read more about checking Johnson & Johnson COVID-19 expiration dates on their website.

Providers may also check expiration dates in NDIIS. Expired doses should not be administered to patients. Vaccine with earliest expiration dates should be used first.

55) **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.

56) 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.

57) 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.

58) 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.

**Update 5/25/2021:** Pediatric ancillary kits include 1” needles only. Pediatric kits are only available in the 450-dose configuration.

**Moderna and Johnson & Johnson**
Modern AAncillary 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.

**59) Why are needles for vaccine administration in the ancillary supply kit different lengths? Why aren’t they all 1” needles?**

COVID-19 vaccines are administered by intramuscular injection. For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue. Ensuring the vaccine is given in the muscle is important to optimize immunogenicity and minimize adverse reactions at the injection site. If vaccine is given
subcutaneously with the incorrect needle length, patients may experience more pain, irritation, and redness at the injection site.

The appropriate needle length depends on age and body mass. CDC’s needle gauge and length chart, included in the ancillary kits, outlines the Advisory Committee on Immunization Practices’ recommendations for needle length. Other vaccine administration and injection resources can be found in CDC’s Vaccine Administration Resource Library.

60) Under what conditions may we transport mRNA COVID-19 vaccines? Is transport of a partial vial or pre-drawn 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 pre-drawn syringe. CDC refers to the U.S. Pharmacopeia (USP) guidance for transporting pre-drawn 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

61) How many doses come in each kit?

  Pfizer
  Pfizer’s COVID-19 vaccine ships in increments of 1,170 doses and 450 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.

62) 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 two vial presentations: a maximum 11-dose or a maximum 15-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.

63) 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).
64) 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

65) 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.
66) **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.

67) **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.

68) **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.

69) **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.

70) **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.

   In exceptional situations in which the mRNA vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA
COVID-19 vaccination series. In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the second dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product. 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. Such persons are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose of an mRNA vaccine.

71) **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.

72) **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.

73) **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 Abbott 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.

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

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

75) 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.

mRNA COVID-19 vaccines (Pfizer, Moderna) are not live vaccines. Instead, they work by teaching our cells to make a harmless piece of a “spike protein,” which is found on the surface of the virus that causes COVID-19. After making the protein piece, cells display it on their surface. Our immune system then recognizes that it does not belong there and responds to get rid of it. When an immune response begins, antibodies are produced, creating the same response that happens in a natural infection.

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.

76) 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.

• **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 across the world. The Delta variant is now the predominant variant in the U.S., and while the vaccines appear to still provide protection, it may not be as effective at preventing infection from these variant strains.

• **The vaccine has been shown to be highly effective at preventing severe COVID-19.** The clinical trials only looked at whether the vaccine prevents disease, not infection, so a vaccinated person could still become infected and/or potentially spread the virus to others. Currently available COVID-19 vaccines are highly effective at preventing hospitalization and death from the virus, even against variants like Delta.

• **Vaccines don’t provide immediate protection.** It takes a few days to a few weeks for vaccines to provide protection. Our body needs time to build an immune response to the vaccine. If someone is exposed to the virus during this time, it is possible they still may become sick from the virus.

• **The test may be a false positive.** False-positive test results can occur. It may be that the test detected antigens to a coronavirus closely related to the COVID-19 virus or that the test quality was flawed.

77) **How should we counsel fully vaccinated patients who are concerned about breakthrough cases?**

It is important to provide patients with the best information we currently have available to us regarding COVID-19 vaccines and breakthrough cases. What we do know is:

• **No vaccine is 100% effective and breakthrough cases are expected.** Breakthrough cases are uncommon but they can occur (even before Delta). When they do occur, they typically produce mild symptoms or no symptoms at all (asymptomatic). There will be a small percentage of fully vaccinated people who are hospitalized and/or die from COVID-19.

• **Variants may affect how effective COVID-19 vaccines are.** Current data suggest that COVID-19 vaccines authorized for use in the U.S. offer protection against most COVID-19 variants circulating in our country and are highly effective at preventing hospitalization and death from the virus. However, variants will cause some breakthrough cases.

• **The situation is rapidly changing.** Delta has quickly become the dominant variant in the United States and is highly transmissible and considered to be as contagious as chicken pox. But, we are still gathering information on how Delta differs from previous strains of the virus and how this impacts vaccine effectiveness.

• **People with breakthrough infections may be able to spread COVID-19 to others.** Data from an [outbreak investigation from Massachusetts](https://www.mass.gov/) found that vaccinated
individuals infected with the Delta variant have a similar viral load to the unvaccinated. High viral load suggests an increased risk of transmission. On July 27, 2021, CDC released recommendations that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial to reduce the spread of the virus.

- **Vaccines provide the best protection.** Vaccination is the most important strategy to prevent severe illness and death. Additionally, recent research suggests that vaccinations lower the odds of long COVID-19 by reducing the risk of any symptoms by 8- to 10-fold and by halving the chances of those symptoms lingering. The CDC has estimated that unvaccinated people are 8x as likely to get the virus and experience disease symptoms, 25x as likely to be hospitalized, and 24x as likely to die, compared to people who are vaccinated. The best way to protect ourselves and those around us from COVID-19 is to vaccinate.

- The best way to protect yourself from COVID-19 is to be vaccinated and practice mitigation strategies, such as wearing a mask, social distancing, and avoiding crowded indoor venues with poor ventilation.

For more information on breakthrough cases please visit the CDC [website](http://www.cdc.gov).

**78) 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**

**79) 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.

80) 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).

81) 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).

82) 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,section 319F–4, which creates a compensation program.

83) 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.

84) 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.
85) Are providers able to charge Canadians for COVID-19 vaccine administration?

Per guidance received from the CDC, healthcare providers may bill Canadians (or those from other countries) for the administration fee for COVID-19 vaccine. The vaccine is supplied by the federal government, so individuals must not be charged for the cost of the vaccine.

86) 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.

87) 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.

88) Can patients schedule a visit just to discuss COVID-19 vaccine with their provider, and can providers bill/get reimbursed for this consult session?

Yes. Patients can schedule visits to discuss vaccination. Typically, providers visiting with patients about vaccines can be billed as a standard office visit.
89) If we administered a COVID-19 vaccine to an adolescent in the time between the FDA EUA authorization and the CDC ACIP recommendations, are we eligible for reimbursement for the administration costs?

No. Vaccine given to adolescents between the EUA authorization and CDC recommendations are not eligible for reimbursement for any administration costs. As is the case with all vaccines used in the United States, even if it is authorized for use, costs cannot be reimbursed prior to when the ACIP meets and CDC officially accepts their recommendation (e.g. May 12, 2021 for Pfizer’s COVID-19 vaccine - view here).

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

COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA. Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to coadminister other vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

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

On December 31, 2020, the North Dakota Department of Health (NDDoH) had sent out an Interim guidance about the timing of COVID-19 mRNA vaccinations and the immune-based tests for M. tuberculosis infection, that is, the tuberculin skin test (TST) and interferon gamma release assays (IGRAs). TSTs and IGRAs were previously recommended to be administered > 4 weeks after completion of COVID-19 vaccination to minimize potential interference between vaccination and TB testing. This was out of an abundance of caution during a period when these vaccines were new.

As of August 31, 2021, the CDC has issued new guidance about COVID-19 vaccination and the timing of immune-based tests for tuberculosis infection, such as the TST and IGRA. Of what is known about the immunologic response to COVID-19 mRNA vaccination, nothing would be expected to change TST or IGRA results. As a result, NDDoH is rescinding its interim guidance on Tuberculosis Testing and COVID-19 Vaccine. COVID-19 vaccination should not be delayed because of testing for TB infection. Testing for TB infection with one of the immune-based methods, either the TST or IGRA, can be done before, after, or during the same encounter as COVID-19 vaccination.


92) 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.

93) 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.
94) 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 Children 7 through 18 Years of Age Handout or Intramuscular (IM) Injection: Supplies (Children Birth through 18 Years of Age Video
- You Call the Shots Vaccine Administration Intramuscular (IM) Injection Adults 19 Years of Age and Older Handout or Intramuscular (IM) Injection: Supplies (Adults 19 Years of Age and Older) Video

95) 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.

96) 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.

97) 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.

98) If there are remaining doses in the vial, can we draw more than 6 doses of the Pfizer vaccine or 10 (or 15) 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.
99) 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.

100) How do I track and manage excess vaccine doses (such as a 6th/7th Pfizer dose from a vial or an 11th or 16th 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.

101) **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.

102) **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 aged 2 years and older who can tolerate them.

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

103) **Can vaccinated individuals asymptomatically transmit SARS-CoV-2?**

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

104) **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.

105) **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 (Updated 9/28/21 with booster information)
- Pfizer COVID-19 Vaccine Preparation and Administration Summary
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*.

**106) 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](#) (Go [here](#) for document in multiple languages)
- [Moderna COVID-19 Vaccine FAQ](#)

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*. 

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- [Pfizer COVID-19 Vaccine Preparation Infographic](#)
- [Pre-Vaccination Screening Checklist](#) (Go [here](#) for document in multiple languages)
- [Pfizer COVID-19 Vaccine FAQ](#)
- [CDC Statement on ACIP Booster Recommendations | CDC Online Newsroom | CDC](#)
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
- CDC/FDA Statement on Lifting Pause of Administering J&J COVID-19 in U.S.
- J&J COVID-19 Vaccine Standing Orders
- Preparation and Administration Summary
- Pre-Vaccination Screening Form (Go here for document in multiple languages)
- 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.

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. Individuals who’ve received a third dose of COVID-19 vaccine are reporting side effects similar to those after the second dose. Side effects usually go away on their own with 24-48 hours of vaccination.
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.

Are there educational materials, like a vaccine information statement (VIS), that need 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 fact sheet for Pfizer's (Comirnaty) COVID-19 vaccine has been updated with full FDA approval information.

The FDA's fact sheet for Pfizer (Comirnaty) recipients and caregivers can be accessed here.
- Translations of this fact sheet can be found here.

The FDA’s EUA fact sheet for Moderna recipients and caregivers can be accessed here.
- Translations of this fact sheet can be found here.

The FDA’s EUA fact sheet for Johnson & Johnson recipients and caregivers can be accessed here.
- Translations of this fact sheet can be found here.

The FDA's Pfizer (Comirnaty) 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.

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. Parents and guardians can now enroll adolescents (age 12 and older) in V-SAFE and complete health check-ins on their behalf after COVID-19 vaccination. Patients and caregivers can register by going to vsafe.cdc.gov.

**Educational Resources and Handouts**

- CDC’s Pre-Vaccination 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 How Vaccines Work Handouts
- CDC’s COVID-19 Vaccine Fact Sheet Handout
- CDC’s COVID-19 Vaccine for Preteens and Teens Handout
- CDC’s V-SAFE Information Sheet Handout
- CDC’s What to Expect after Getting a COVID-19 Vaccine Handout
- CDC’s What do I need to know about Johnson & Johnson COVID-19 Vaccine Now?
- CDC’s: Who is Eligible for a COVID-19 Vaccine Booster Shot?

112) **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.
What are some strategies we can use to minimize the number of unused expired doses?

Monitor expiration dates weekly, rotate stock as needed, and follow a “first in, first out” strategy to manage inventory. If doses are nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots. Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff opportunity to administer expired vaccine.

If an expired vaccine is inadvertently administered, it is considered a vaccine administration error and requires remediation including a VAERS report, contacting the recipient to inform them of the error, and may or may not require revaccination based on the manufacturers’ guidance. Guidance on vaccine administration errors can be found in Appendix A of the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.

Check your vaccine stock using the CDC’s Vaccine Lot Number and Expiration Date webpage. Request access to a new COVID-19 Vaccine Lot Number report via CDC’s Vaccine Code Set Management Service (VCSMS). This report includes COVID-19 vaccine lot numbers and expiration dates provided to CDC by the vaccine manufacturers. This report is updated daily and can be used to support vaccine administration, inventory management, and jurisdiction IISs. Complete the registration form on CDC’s Vaccine Lot Number and Expiration Date webpage to request access to the report.

Additional useful resources, include:

- CDC Vaccine Storage and Handling Toolkit
- CDC U.S. COVID-19 Vaccine Product information

How should we manage expired doses of COVID-19 vaccine?

Any expired, open vials with vaccine not administered or doses of COVID-19 vaccine that have been drawn up into syringes and are not administered at the end of provider clinics need to be entered into NDIIS as provider wastage. The NDDoH does need to track all doses that are not being administered. If providers need education on how to enter a wastage there are training documents on the NDDoH website.

Keep in mind there are no negative consequences for reporting waste. The CDC and NDDoH recognize that unused expired vaccine is a normal part of any vaccination program, especially one of this scope and size.
Vaccine disposal: dispose of the vaccine vial (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. **Do NOT return vaccine in the thermal shipping container.**

For more information, please see the following resources:

- [Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage](#)
- [CDC’s Vaccine Lot Number and Expiration Date Webpage](#)
- [NDDoH NDIIS Training Page](#)

115) **Is written consent required for COVID-19 vaccination?**

No. A patient presenting for vaccination is considered consent.

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

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

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

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

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

In regards to the potential future of COVID-19 mandates in the healthcare field, eight leading organizations representing medical professionals working in infectious diseases, infection prevention, pharmacy, pediatrics, and long-term care are all in consensus that hospitals and other healthcare facilities should require employees to be vaccinated against COVID-19. This statement can be viewed [here](#). Large health systems in our state have begun mandating COVID-19 vaccines including Sanford Health, Altru, CHI St. Alexius Health, and Essentia Health.
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.

How should we advise fully vaccinated patients regarding quarantine and masking? What can they do safely?

CDC recommendations state that fully vaccinated (i.e. In general, ≥2 weeks following receipt of the second dose in a 2-dose series [Pfizer or Moderna COVID-19 vaccines], or ≥2 weeks following receipt of one dose of a single-dose vaccine [Johnson & Johnson COVID-19 vaccine]) persons in non-healthcare settings can:

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

For greater detail on CDC recommendations, please see their website.

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

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

A patient can travel in the United States without getting tested before or after travel or self-quarantine after travel.

If a patient is travelling internationally, it is important that they assess the situation at their international destination before traveling outside the United States.

- A patient does NOT need to get tested before leaving the United States unless their destination requires it.
- They still need to show a negative test result or documentation of recovery from COVID-19 before boarding an international flight to the United States.
- They should still get tested 3-5 days after international travel.
- They do NOT need to self-quarantine after arriving in the United States.

The CDC has stated that fully vaccinated travelers are less likely to get and spread COVID-19. However, it is important to advise fully vaccinated patients who are traveling that they will still need to follow CDC’s safe travel recommendation, including:

- Wearing a mask
- Staying 6 feet from others and avoiding crowds
- Washing hands often and using hand sanitizer

But it is important to note that 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 for the fully vaccinated click here, for their travel recommendations click here.

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

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.

- **The herd immunity threshold for COVID-19 is unknown.** It is still uncertain when enough Americans will be vaccinated to reach a threshold of protection, also known as herd immunity. The more transmissible a pathogen is, the more people must become immune in order to stop it. It is also important to understand that as cases caused by variants emerge and persist that are more easily and quickly spread, it is of even more importance that we vaccinate. The percentage of the population requiring immunization to acquire herd immunity against COVID-19 is not entirely known, but is estimated to be between 70-90%.

- **It will be impossible to know who is and isn’t vaccinated in your community.** It is going to take time for vaccine to be distributed and enough of the population to be vaccinated to reach potential herd immunity.

- **We don’t know the duration of vaccine protection.** Information regarding the length of protection from Pfizer, Moderna, and Johnson & Johnson vaccines are still being studied.

- **We don’t know how well vaccines prevent transmission of COVID-19.** The Moderna, Pfizer, and Johnson & Johnson vaccines have shown to prevent severe disease from the virus that causes COVID-19 remarkably well. However, fully vaccinated people with Delta variant breakthrough infections can spread the virus to others. BUT vaccinated people appear to spread the virus for a shorter time and breakthrough infections remain uncommon.

- **Current vaccines may not be as effective against new strains of the virus.** Delta, which has become the dominant variant in the United States, is highly contagious and causes more severe illness than previous variants in unvaccinated people.

**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.*
121) 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.

122) 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.

123) 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.

124) 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.

125) 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

126) **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.

127) **Our clinic vaccinated a 11-year old with Pfizer’s COVID-19 vaccine within 4 days of their 12th 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.

128) **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.

129) If an individual received a COVID-19 vaccine dose or series not authorized for use in the United States, can they also receive an FDA-authorized vaccine?

Some people may have received a COVID-19 vaccine that is not currently authorized in the United States. No data are available on the safety or efficacy of receiving a COVID-19 vaccine currently authorized in the U.S. after receipt of a non-FDA-authorized COVID-19 vaccine. However, in some circumstances, people who received a COVID-19 vaccine not currently authorized in the U.S. may be offered revaccination with an FDA-authorized vaccine:

- COVID-19 vaccines not authorized by FDA but approved for use by WHO (to see a list of COVID-19 vaccines approved for use by the World Health Organization please click here)
  - People who completed a COVID-19 vaccination series with a vaccine that has been authorized for use by the World Health Organization (WHO) do not need any additional doses with an FDA-authorized COVID-19 vaccine.
  - People who are partially vaccinated with a COVID-19 vaccine series authorized for use by WHO may be offered an FDA-authorized COVID-19 vaccine series.
- COVID-19 vaccines not authorized by FDA or not authorized for emergency use by WHO
  - People who completed or partially completed a COVID-19 vaccine series with a vaccine that is not authorized by FDA or not authorized for use by WHO may be offered an FDA-authorized COVID-19 vaccine series.

The minimum interval between the last dose of a non-FDA authorized vaccine and an FDA-authorized COVID-19 vaccine is 28 days.

Recommendations may be updated when more information becomes available or when additional vaccines are authorized.

130) If an individual received an expired dose of COVID-19 vaccine, is the dose valid?

Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.

Who Should and Shouldn’t Be Vaccinated

North Dakota Department of Health COVID-19 Vaccine Primary Series Decision Tree can be accessed here.
131) **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.

132) **Can people with underlying conditions receive the vaccine?**

Yes. People with underlying conditions are at a higher risk for severe COVID-19. Vaccine may be administered to these individuals 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.

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

133) **Will a patient need a booster dose even if they have completed their COVID-19 vaccine series (e.g. a 3rd dose of Pfizer’s or Moderna’s COVID-19 vaccine or 2nd dose of Johnson & Johnson’s COVID-19 vaccine)?**

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

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

- Individuals 65 years and older and residents in long-term care settings
- Individuals 50-64 years with **underlying medical conditions** should receive a

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

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

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

It’s important to note that ACIP and CDC’s recommendations are bound by what FDA’s authorization allows. **At this time, the FDA’s Pfizer booster authorization only applies to these select populations who received the Pfizer vaccine as their primary series.** People in
the recommended age groups who received the Moderna or Johnson & Johnson vaccine will likely need a booster shot, and more data on the effectiveness and safety of these booster shots are expected in the coming weeks.

Currently, the FDA and CDC have recently recommended a third dose (not considered booster) for moderate to severely immunocompromised individuals. To read more on this recommendation, please click here.

Evidence indicates that COVID-19 vaccines continue to provide strong protection against severe disease, hospitalization, and death. It is of utmost importance for those who have not been vaccinated to receive a COVID-19 vaccine - getting vaccinated is the best way to protect yourself and those around you from this virus.

For more information, please see the NDDoH handout on boosters here.

134) What occupational or institutional settings qualify a patient for a Pfizer COVID-19 vaccine booster?

On September 23, 2021, the CDC recommended that certain populations receive a booster shot of Pfizer’s COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series. This includes adults aged 18–64 years who work or reside in certain settings that may be at increased risk of being exposed to COVID-19.

Occupations and institutional settings at increased risk for COVID-19 exposure and transmission include front line essential workers and healthcare workers. Some additional examples include (but not limited to):

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

Since risk can vary across settings and is based on how much COVID-19 is spreading in a community, people aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may get a booster shot after considering their individual risks and benefits. This recommendation may change in the future as more data become available.
135) When can a patient get a COVID-19 vaccine booster if they are NOT in one of the recommended groups?

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

136) If a patient needs a booster shot, does that mean that the vaccines aren’t working?

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

137) What should patients who received Moderna or Johnson & Johnson’s Janssen vaccine do?

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

138) What are the risks of getting a booster?

For many who have completed their primary series with Pfizer vaccine, **the benefits of getting a booster shot outweigh the known and potential risks.** So far, reactions reported after the third Pfizer-BioNTech shot were similar to that of the 2-shot primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the 2-shot primary series, serious side effects are rare, but may occur. Additionally, **findings** from V-safe (one of the vaccine safety monitoring systems in the U.S.) have found no unexpected patterns of adverse reactions following an additional dose of COVID-19 vaccine. CDC will continue to monitor the safety and effectiveness of COVID-19 vaccines, including booster doses.

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

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

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

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

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

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

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

**142) What’s the difference between a booster and an additional dose?**

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

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

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

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

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

To read more about Johnson & Johnson’s COVID-19 vaccine, please visit the CDC website.

144) 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.

145) Should immunocompromised individuals who completed their COVID-19 vaccine series receive an additional dose (e.g. a third dose)?

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

A third dose of Moderna or Pfizer can be administered to people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. A third dose of Moderna or Pfizer vaccine is recommended 28 days following the first two doses of COVID-19 vaccine and should be the same manufacturer as the primary series, but heterologous additional dose is permitted if this is not feasible.

Due to insufficient data, the EUA amendment for an additional dose does not apply to Johnson & Johnson COVID-19 vaccine or individuals who received Johnson & Johnson COVID-19 vaccine as a primary series.

Immunocompromised individuals who are recommended to receive an additional dose of mRNA vaccine will self-attest their immunocompromised status in order to reduce barriers to vaccination. Note that “fully vaccinated” status is still considered to be 2 weeks after two doses (primary series) of mRNA COVID-19 vaccine, or 2 weeks after one dose on Janssen COVID-19 vaccine, even for immunocompromised individuals.

The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., as part of need assessment for an additional dose) has not been established. Serologic testing or cellular immune testing outside of the context of research studies is not recommended at this time.

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

Additional resources on this topic:
- CDC’s Talking with Patients Who are Immunocompromised can be accessed here.
- CDC’s Interim Considerations can be accessed here.
- IDSA’s Statement on FDA Authorization of Supplemental Vaccine Dose for Immunocompromised Patients can be seen here.
- ACIP’s Altered Immunocompetence General Best Practice Guidelines can be accessed here.
- The NEJM has information for clinicians on this topic, which can be viewed here.
What immunocompromised groups are considered eligible for receiving an additional dose of COVID-19 vaccine?

An additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment. Recommendation do not apply to people with other chronic conditions.

Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.

It is important to reiterate that the immunocompromised conditions/states eligible for an additional dose of vaccine listed above are limited. It is important to have a conversation with each immunocompromised patient and a provider should determine on a case-by-case basis whether or not they should receive an additional COVID-19 vaccine.
If I have received an additional dose of COVID-19 vaccine (e.g. third dose of mRNA COVID-19 vaccine), do I need a booster as well?

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

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

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.

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

Yes. The CDC recommends that everyone be vaccinated, regardless of whether or not they already had COVID-19. This is because immunity after COVID is unpredictable; we do not know how long protection from COVID-19 lasts after the initial infection, how well natural infection protects against the variant strains, and we know that reinfection is possible. COVID-19 vaccines provide a stronger and more consistent immune response than natural infection. Getting vaccinated after recovering from COVID-19 acts as a booster for the immune system. This immune system “boost” may offer additional protection against COVID-19 variants and prevent the spread of COVID-19 to others. Additionally, recent research out of Kentucky has shown that
those who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated.

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

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.

150) 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.

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

The current CDC recommendations state that anyone who has previously had COVID-19 should complete a COVID-19 vaccine series. A recent study has shown that the antibody response to the first vaccine dose in individuals with pre-existing immunity is equal to or even exceeds the titers found in naive individuals after the second dose. However, at this time, there are no recommendations related to giving a single dose of a two-dose COVID-19 vaccine series to those who have recovered from COVID. Those who are able and qualified for COVID-19 vaccination and have received a first dose of a two-dose series should complete the vaccine series, regardless of a previous infection.

Getting vaccinated after recovering from COVID-19 acts as a booster for the immune system. This immune system “boost” may offer additional protection against COVID-19 variants and
prevent the spread of COVID-19 to others. Additionally, recent research out of Kentucky has shown that those who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated.

152) **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.

153) **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.

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

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

155) **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.
156) 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.

157) 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.

158) 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 as part of COVID-19 treatment, 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.

For people receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

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

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A). The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune
response (e.g. a breakdown/maladaptive change in molecular control of immune system processes) when individuals are infected with the virus that causes COVID-19. It is unclear if people with a history of MIS-C or MIS-A are at risk of recurrence of the same dysregulated immune response following reinfection with COVID-19 or in response to vaccination.

These theoretical concerns should be weighed against the known risks of COVID-19 from reinfection and the benefits of protection from a COVID-19 vaccine. Children with MIS-C have higher antibody titers to COVID-19; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.

People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include:

- Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Level of COVID-19 community transmission and personal risk of reinfection
- Lack of safety data of COVID-19 vaccines following these illnesses
- Timing of any immunomodulatory therapies (ACIP's general best practice guidelines for immunization can be consulted for more information)

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

Current evidence suggests that the risk of COVID-19 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

For people who develop MIS-C or MIS-A that is associated with a confirmed SARS-CoV-2 infection but occurs after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax. In addition, information about these cases should be reported to VAERS.
Can pregnant women receive COVID-19 vaccine?

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

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

On September 29, 2021, the CDC recommended urgent action to increase COVID-19 vaccination among people who are pregnant, recently pregnant, who are trying to become pregnant now, or who might become pregnant in the future. The highest number of COVID-19 related deaths in pregnant people in a single month of the pandemic was reported in August 2021. Additionally, approximately 97% of pregnant people hospitalized (either from illness or for labor and delivery) with confirmed COVID-19 were unvaccinated. The CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.

As of September 27, 2021, more than 161,000 pregnant women have received a COVID-19 vaccine and enrolled in V-SAFE (a COVID-19 vaccine safety monitoring system). No pregnancy-related safety concerns have been detected via vaccine safety monitoring systems. Additionally, a recent study conducted in Israel analyzed data on 15,060 pregnant women and compared COVID-19 related outcomes in the vaccinated and unvaccinated pregnant women. Their findings suggest that Pfizer’s COVID-19 vaccines are safe and vaccination was associated with a significant lower risk of SARS-CoV-2 infection compared to those who were not vaccinated.

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

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

For additional information on COVID-19 vaccine and pregnancy, click here.

For additional information on COVID-19 vaccine and pregnancy, please check out the following resources:

- CDC Health Alert Network - COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes for COVID-19
- ACOG - COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care
- CDC - COVID-19 Vaccines While Pregnant or Breastfeeding
- NDDoH - COVID-19 Vaccine & Pregnancy

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

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

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

Pregnancy is considered an underlying medical condition because pregnant and recently pregnant women are at an increased risk of severe illness from COVID-19. In addition to the risk of severe illness and death for pregnant and recently pregnant people, there is also an increased risk for adverse pregnancy and neonatal outcomes, including preterm birth and admission of their neonates to an ICU. Lastly, the highest number of COVID-19-related deaths in pregnant people in a single month of the pandemic was reported in August 2021.
162) **Can women who are breastfeeding receive COVID-19 vaccine?**

Yes. COVID-19 vaccination is recommended for people who are breastfeeding. mRNA and non-replicating viral vector vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. 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)](https://www.acog.org) strongly recommends that lactating individuals be vaccinated against COVID-19. They have additionally stated, “Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine.” [Recent research](https://www.healthywoman.org) 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](https://www.acog.org).

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

[American Society for Reproductive Medicine](https://www.asrm.org) 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](https://www.asrm.org). This recommendation is made due to the fact that patients 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.

164) **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.

165) Can children be vaccinated against COVID-19?

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

Modernar’s COVID-19 vaccine is currently only authorized for individuals 18 years and older. But in a recent statement, the company has stated their plans to apply for authorization of their COVID-19 vaccine in adolescents, 12-17 years of age in June.

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

166) Can we administer COVID-19 vaccine off-label to children under the age of 12?

While the Food and Drug Administration (FDA) granted full licensure to the Pfizer COVID-19 vaccine, the AAP and FDA are discouraging clinicians from administering the vaccine in an off-label use to children under 12 years.

Clinicians who administer COVID-19 vaccines off-label to children under 12 years would be violating their provider agreement, risking liability for adverse events and potentially forfeiting payment.

To read more on this topic, please see the AAP website.

167) 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. 12 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.
168) 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 an infection with the virus that causes COVID-19 and the risks and benefits of COVID-19 vaccination. Consider having one-on-one conversations between supervisors and vaccine decliners. Additionally, ask them what concerns or questions they have about the vaccine and respectfully address each concern/question. Being compassionate and an active listener when addressing individuals' concerns is extremely important. For additional information on how to address specific COVID-19 vaccine concerns, please see the section titled “Addressing Patient COVID-19 Concerns” below.

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.

169) How should we address patients’ who request an exemption from COVID-19 vaccine?

Many businesses and organizations have begun to require/mandate COVID-19 vaccination for their workforce. As a healthcare provider, you are considered to be the number one trusted source of vaccine information for patients. You need to be prepared to answer patients' questions about COVID-19 vaccines and be ready to address patients that request exemptions from COVID-19 vaccine. COVID-19 vaccines are the safest and most effective way to protect ourselves and those around us from this virus. Medical accommodations should only be given to those that have a true contraindication to a COVID-19 vaccine.

Contraindication for COVID-19 vaccine include:

- Severe allergic reaction (e.g. anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

Examples of conditions that should NOT be considered for a medical exemption include:

- History of severe allergic reaction to foods (like eggs or gelatin), oral medication, latex, rubber, pets, insects, and environmental triggers
- History of immunocompromising conditions where the vaccine may be less effective
- Fear of needles
- A history of vaccine side effects or general avoidance of vaccines.
Be knowledgeable of the precautions and contraindications for COVID-19 vaccine. The Interim Clinical Considerations for COVID-19 vaccine are available on the [CDC website](https://www.cdc.gov).

170) **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.

171) **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.
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**

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.

Update 9/22/21: Importance of Updating COVID-19 Vaccine Inventories

Starting the week of September 19, 2021, the CDC will be assessing each state’s reported COVID-19 vaccine inventory and weekly doses administered. States will then be given a weekly allocation of COVID-19 vaccine based on those numbers. *It is imperative that providers maintain the most accurate inventory as possible in the North Dakota Immunization Information System (NDIIS).* NDIIS inventory is reported on your behalf to the federal government. If NDIIS inventories are not accurate it is possible that North Dakota will not receive enough COVID-19 vaccine to fill provider orders.

COVID-enrolled providers should run the NDIIS COVID-19 Provider Inventory report weekly, at a minimum, to make sure your NDIIS vaccine inventory matches the vaccine you have on hand at your facility.

Instructions on how to run the COVID-19 Provider Inventory report can be found here. Instructions on how to adjust NDIIS vaccine inventory can be found here.
174) **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.

175) **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.

176) **Can COVID-19 vaccine providers enter vaccine lot numbers into NDIIS?**
No. All COVID-19 vaccine in the U.S. is publicly funded at this time. For providers enrolled in the COVID-19 vaccine program with the North Dakota Department of Health Immunization Division, all public (i.e. state) COVID-19 vaccine will be entered into your North Dakota Immunization Information System (NDIIS) vaccine inventory by the NDDoH COVID vaccine team. NDIIS provider users are not able to enter a public vaccine lot in your NDIIS inventory. Any vaccine lot entered into a facility’s NDIIS vaccine inventory by a non-NDDoH NDIIS user will save as privately purchased vaccine. If you have received a lot number at your facility that is not in your NDIIS vaccine inventory, please contact a member of the NDDoH COVID vaccine team immediately by emailing covidvaccine@nd.gov and the lot will get added to your inventory.
177) **Can COVID-19 vaccine providers alter expiration dates in NDIIS?**

No. It is important that providers do not change expiration dates in NDIIS. Providers may check expiration dates in NDIIS. If you have questions regarding your expiration dates in NDIIS, please email covidvaccine@nd.gov.

178) **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://www.vaers.org/).

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.cdc.gov/vaccines/).

**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/vaccines/vacinfo/v-safe.html).

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](https://www.cdc.gov/nhsn/).
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 for all priority groups, as this information is not reported through the NDIIS. However, CMS has begun to post COVID-19 vaccination rates for long-term care residents and staff by facility. You can access these rates on the CMS website.

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.

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.
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.

“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 under 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.

“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 392 million doses have been administered in the U.S. since December 2020 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. Additionally, currently available evidence suggests that all three available COVID-19 vaccines continue to provide strong protection against severe outcomes, such as hospitalization and death, from widely circulating variants (including Delta). As Dr. Paul Offit has said, “The choice not to get a COVID-19 vaccine is the choice to be among the now [711,000+] 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.
“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.

On August 23, 2021, the FDA approved Pfizer’s COVID-19 vaccine for those 16 and older - making it the first COVID-19 vaccine to be licensed in the U.S. For any vaccine (including COVID vaccines) to receive full approval, the FDA requires six months of follow-up data. The data from clinical trials and post-authorization safety monitoring systems continue to support that Pfizer’s COVID-19 vaccine is safe and effective. Full licensure means that Pfizer’s vaccine has now undergone the same rigorous testing and regulatory review as dozens of other licensed vaccines.

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

Should a question about vaccine safety arise down the road, the United States has powerful vaccine safety monitoring systems to help us detect adverse events and assess whether they are associated with vaccination. So far, data from our safety monitoring systems is reassuring and tells us that COVID-19 vaccines are safe. The safety of these vaccines will continue to be monitored for years to come.
Finally, COVID-19 vaccines are much safer than getting COVID-19. COVID has had lasting impacts on many people, and we may just be scratching the surface of what the disease can do and what its long-term impacts are. Thousands of people are dying each week from COVID-19. COVID impacts our lungs, heart, kidneys, and nervous system, just to name a few. Recent studies indicate that 10% of COVID-19 patients may become “long-haulers” and have symptoms of the disease for months. Recent research has suggested that one-third of COVID-19 survivors were diagnosed with a neurological or mental health condition within 6 months of their COVID-19 diagnoses. To put this into perspective, these conditions were 44% higher after COVID-19 than after the flu.

Without a vaccine, we would all likely get COVID at some point, and you don’t know how it will affect you. Any theoretical long-term risk of the vaccine is still to be determined, and while it’s understandable to want to see long-term safety data, getting vaccinated is the only way to prevent COVID-19. To the best of our knowledge, 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.

186) “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 or BLA and has been reviewed by both VRBPAC and ACIP (expert committees that provide recommendations and guidance on immunizations). Since the beginning of the pandemic, we have had over 711,000 deaths associated to COVID-19 in the United States. While preventive measures like social distancing and masks help to slow the spread, the only way to prevent infection with this virus is to vaccinate.

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

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

187) “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.

188) “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 43 million documented cases of and over 711,000 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. When healthcare systems are overwhelmed, this affects the entire community. This means if you have a healthcare emergency, for example a broken bone or car accident, the access to healthcare services may be limited. It is important everyone in a community is vaccinated against COVID so that we can ensure healthcare services are available for everyone for unpreventable healthcare emergencies.

It is also important to consider that virtually all recent COVID-19 hospitalizations and deaths are occurring among unvaccinated individuals. Additionally, with a new dominant variant of COVID-19 circulating in the U.S. (Delta), which is more contagious and transmissible than previous strains of the virus, it is more important than ever that we get vaccinated to protect ourselves, loved ones, and those in our community from COVID-19.

189) “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 475 North Dakotans have died from COVID-19. While preventative measures like social distancing and masks help to slow the spread, the only way to prevent infection with 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. This is of more importance than ever with variants of the virus now widely circulating in the U.S. Delta, which originated in India, now represents a majority of new cases of COVID-19 in our country and is highly contagious and likely linked to more severe outcomes from infection. COVID-19 can have serious, life-threatening complications and there is no way to know how the virus will affect you.

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

190) “Why should I vaccinate my child against COVID-19?”

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

As of September 23, 2021, over 5.7 million children have tested positive for COVID-19 since the beginning of the pandemic. The virus has also caused over 21,000 hospitalizations and more than 498 deaths among kids in the states and territories that have reported data. While these rates may seem low, COVID-19 has led to higher rates of hospitalization in adolescents compared to any of the last four years of seasonal influenza. In August, hospitalizations among children and adolescents increased 4x more in states with low levels of vaccination compared with states with high levels of vaccination. Additionally, after declining in early summer, child cases have been increasing exponentially. Children now account for 1 out of every 4 cases of COVID-19 in the United States.

It is also important to understand that while children, in comparison to adults, tend to fare better from COVID-19 - they can still be the source and recipient of outbreaks. Research has shown that transmission of COVID-19 can and does occur in children and adolescents. Additionally, adolescents, compared to younger children, are more likely to be infected and transmit the virus.

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

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

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

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

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

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

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

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

To read more on the AAP guidance, please visit their website. To see the CDC guidance for COVID-19 prevention in K-12 schools, see their website.
192) If an outbreak occurs and most of the cases were among the vaccinated, doesn’t that mean that the vaccine is not effective?

No. It is important to look at the proportion of the population that are vaccinated compared to the proportion that remain unvaccinated. The more vaccinated a population is, the more we’ll hear of the vaccinated getting infected – but it’s important to look at the rates of cases among the vaccinated versus the unvaccinated.

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

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

193) “The new COVID-19 mRNA vaccine can alter your DNA.”

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 resource 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.
“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 (includes COVID vaccines that are being used under EUA and those with full licensure). 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.

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

It is important to understand that an antibody test cannot give a definitive answer as to whether or not you are immune to COVID-19.
Our immune system, which involves a complex network of cells, organs and tissues, identifies foreign substances in your body and helps fight infections and diseases. Antibodies are a protein that play a role in this complex network and are produced by the immune system in response to an infection. They can attach to foreign invaders like bacteria, viruses, and fungi (referred to as antigens) in our body and mark them for destruction. After infection with the COVID-19 virus, it can take two to three weeks to develop enough antibodies to be detected in an antibody test. After this exposure/infection, antibodies continue to circulate in the blood, providing protection against future exposure to that antigen.

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

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

196) "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.

197) "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.

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

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

What we do know is that research has suggested that infection with the virus that causes COVID-19 may lead to a *6x higher risk* of erectile dysfunction compared to those with no history of COVID-19. Additionally, infection with the virus that causes COVID-19 may affect semen count/quality.

199) “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. Things that do affect menstrual cycles include birth control pills, extreme stress, chronic illness, and anorexia/bulimia.

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

200) “I have heard there are new variants of coronavirus (like Delta) 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 variants (caused by mutations) will affect the efficacy of vaccines in the long run. Pfizer, Moderna, and Johnson & Johnson have reported that their
vaccines produce immune responses that recognize and neutralize variant strains, although there was a reduction in antibodies that neutralize some variants. The FDA and CDC continue to monitor this situation.

The Delta variant, which originated in India, is a highly contagious COVID-19 strain. It has become the dominant variant in the U.S. and globally. Recent research suggests that Delta has a faster replication rate, a reduced incubation period, and greater viral shedding - all factors that contribute to Delta being more infectious (1000x higher viral load compared to original strain) and more transmissible (64% more transmissible than Alpha). Delta may also cause more severe outcomes in comparison to previous variants, with increased risk of hospitalization and death.

On September 23, 2021, the CDC recommended that certain populations receive a booster shot of Pfizer’s COVID-19 vaccine at least six months after the completion of their Pfizer vaccine primary series. With the Delta variant surging and cases of COVID-19 increasing significantly across the United States, a booster shot will help provide continued protection against severe disease in these populations who are especially at risk for severe COVID-19. For example:

- Because residents in long-term care (LTC) settings live closely together in group settings and are often older adults and/or have underlying medical conditions, they are at increased risk of infection and severe illness from COVID-19.
- The risk of severe illness from COVID-19 increases with age, and can also increase for adults of any age with certain underlying medical conditions. This is why CDC recommends that individuals 50 to 64 with underlying medical conditions receive a Pfizer booster shot. Individuals 18-49 with underlying medical conditions may also receive a booster if they determine the personal benefits outweigh the risks.
- While COVID-19 vaccine effectiveness against severe disease remains high for healthcare personnel and other essential workers, those with even mild illness often cannot work. In addition, some individuals may care for or live with at-risk people, such as the immunocompromised, and others may live in a congregate setting such as a homeless shelter or correctional facility where there is higher risk for transmission. For these reasons – as well as continued strain on the U.S. healthcare infrastructure due to the widely circulating Delta variant – CDC recommends that adults at high risk of disease from occupational and institutional exposures to COVID-19 get the Pfizer booster based on their individual benefits and risks.

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

For more information on the Delta Variant and COVID-19 vaccine, please click here.
201) “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. The CDC has determined that the vast majority of the deaths reported following COVID-19 vaccination were not caused by the COVID-19 vaccine. (The rare exception is the few cases of TTS and GBS leading to death following receipt of the Johnson and Johnson vaccine.)

202) I heard that there are many reports of people who were vaccinated and then died. Is this true?
A common piece of misinformation is that COVID-19 vaccines have caused thousands of deaths. This claim is misleading. It is important to remember that just because a death occurred following vaccination, it does not mean the vaccine caused the event. There are an average of 8,000 deaths every day in the U.S., and with thousands of COVID-19 vaccines being administered to the public daily in our country, the likelihood of a death occurring in those who have received a vaccine is not unexpected. That does not mean that the death was caused by getting vaccinated against COVID-19.

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

The fact that we are seeing these events following COVID-19 vaccine being reported through VAERS shows us that our vaccine safety monitoring system is working. The United States has the most comprehensive vaccine safety monitoring program in the world to detect adverse events.
following vaccination and investigate any death that follows vaccination to determine if the events could be connected. Thus far, there is no evidence to suggest that COVID-19 vaccination is associated with an increased risk of death following receipt of the Pfizer and Moderna COVID-19 vaccines, and the risk is extremely rare following receipt of the Johnson & Johnson vaccine.

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

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

- **These reports do not establish causality** - A report to this system doesn’t prove that the identified vaccine (e.g. COVID-19 vaccine) *caused* the adverse event described (e.g. death). *NO proof* that the event was caused by the vaccine is required in order for VAERS to accept the report. While these reports may be temporally related (e.g. happened close together) that does not mean they are causally related (e.g. one event caused the other).

**203) “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.

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

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

205)  “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.

206)  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. Both Pfizer and Moderna used fetal cells to test the science behind their vaccine platforms.
  ○ The following organizations assert that the mRNA COVID-19 vaccines 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.
  ○ Two major Islamic scholars’ councils including the Fiqh Council of North America and the Assembly of Muslim Jurists of America have studied the vaccine at great length and have concluded that they are halal or lawful.
● 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.
- For additional information on how to address this topic with patients, please see Helping patients with ethical concerns about COVID-19 vaccines in light of fetal cell lines used in some COVID-19 vaccines.

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

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

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

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

**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