Interim COVID-19 Vaccine Provider Guide

INFORMATION TO PLAN FOR AND ADMINISTER COVID-19 VACCINE

Updated 1/14/2021

Information in this guide is current as of Jan. 14, 2021. The COVID-19 vaccine response is changing quickly. Please make sure you have the most current version of this document, which can be found at COVID-19 Vaccine Providers (www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html).
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Background

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. Immunization with a safe and effective COVID-19 vaccine is critical to reduce COVID-19-related illnesses, hospitalizations, and deaths. In the United States, the goal is to have enough COVID-19 vaccine for all people who wish to get vaccinated.

Early in the COVID-19 vaccination program, supply of vaccine will be limited. Initial vaccines will get Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) when enough data on their effectiveness and safety are collected. In a global health pandemic, an EUA allows the FDA to review information from a vaccine manufacturer to determine if a vaccine can be released early. They weigh the benefits of early release against the known and unknown risks of a vaccine. If at any time vaccine data shows more risk than benefit, an EUA is re-evaluated.

This guide provides a summary of the Centers for Disease Control and Prevention’s (CDC) COVID-19 vaccination recommendations, priority groups, and available products. For more details, read the Advisory Committee on Immunization Practices (ACIP) Recommendations (www.cdc.gov/vaccines/acip/recommendations.html).

Preparing to become a COVID-19 vaccine provider

Choosing to be a COVID-19 vaccine provider is an important step in helping to slow the spread of COVID-19 disease. The COVID-19 Vaccine Planning Provider Checklist (www.health.state.mn.us/diseases/coronavirus/vaccine/checklist.pdf) can help you consider the requirements for being a COVID-19 vaccine provider. If you plan to provide COVID-19 vaccine, you must register. Find more details at COVID-19 Vaccine Provider Registration (www.health.state.mn.us/diseases/coronavirus/vaccine/vaxreg.html).

A designated vaccine coordinator and back-up coordinator must attest to reading this COVID-19 Vaccine Provider Guide and to completing the On-Demand Trainings for Registered COVID-19 Vaccine Providers (www.health.state.mn.us/diseases/coronavirus/vaccine/training.html#demand). These positions are identified during the registration process.

COVID-19 vaccination phases

Vaccination with COVID-19 vaccine will be phased in according to vaccine availability and recommendations from CDC’s Advisory Committee on Immunization Practices (ACIP). CDC will allocate doses based on how much vaccine is available and what groups will receive early doses. The first groups to get the early vaccine doses include health care workers and long-term care staff and residents. Learn more at COVID-19 Vaccine Phases and Planning (www.health.state.mn.us/diseases/coronavirus/vaccine/plan.html).
COVID-19 vaccine ordering and distribution

- In the initial phase of COVID-19 vaccine distribution, when doses are limited, MDH will allocate and distribute vaccine orders to sites based on the high-priority patient population data submitted during the provider registration process. Before the vaccine order is shipped, MDH will send an email to you as an initial phase vaccination partner asking you to confirm your readiness to:
  - Receive a specific number of doses.
  - Safely store and handle the vaccine.
- Let MDH know if you cannot accept the vaccine at the time of notification due to issues such as staff for vaccination activities, storage capabilities, etc.
- **Second doses**: The second dose of both the Pfizer and Moderna vaccines are being held back at the federal level and will be made available at the appropriate time. You **DO NOT need to reserve any of your initial shipment for second doses**.
- Once COVID-19 vaccine doses become widely available, sites will directly request and order COVID-19 vaccine doses through the Minnesota Immunization Information Connection (MIIC).
  - Refer to MIIC’s [Creating and Viewing Vaccine Orders](https://www.health.state.mn.us/people/immunize/miic/managevax/ordering.pdf).
- During all phases of vaccine distribution, you will receive an order confirmation email when your order is created and a vaccine shipment confirmation email once vaccine doses ship. MDH will automatically send these emails to the contacts provided for each location in section B of the provider agreement.
- Enrolled and approved sites do not need to complete any additional registration with the vaccine manufacturer or distributor in order to receive doses.

COVID-19 vaccine supplies

COVID-19 vaccines and additional supplies will be distributed at no cost to providers registered for COVID-19 vaccination. Ancillary supplies will be packaged in adult and pediatric kits and will be automatically ordered in amounts to match vaccine orders. Each ancillary kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (22-25 gauge, 1 to 1.5 inch, depending on the population being vaccinated).
- Syringes, 105 per kit (ranging from 1-3 milliliters).
- Alcohol prep pads, 210 per kit.
- Four surgical masks and two face shields for vaccinators, per kit.
COVID-19 vaccination record cards for vaccine recipients, 100 per kit.

Vaccine Administration: Needle Gauge and Length

For vaccines requiring reconstitution, diluent will be included along with extra syringes, needles, and alcohol pads. The diluent will not come with the vaccine.

Note: Kits do not include sharps containers, gloves, or bandages.

If vaccine is distributed to a central location, providers can opt out of getting ancillary and mixing kits. For vaccines shipped directly from the manufacturer, a combined kit will be included that contains administration supplies (as noted above), mixing supplies, and diluent vials. For questions related to ancillary supply kits (e.g., missing supplies, etc.), email MDH at health.mdhvaccine@state.mn.us.

COVID-19 vaccine products

Vaccine products vary based on dosage, number of doses needed, intervals between doses, and how the vaccine must be stored and handled. There will likely be several COVID-19 vaccines out at the same time and more may become available as vaccine trials are completed. This will make COVID-19 vaccine more accessible, but it may also increase the risk of medication errors. Double-check the product-specific emergency use authorization fact sheet or package insert for age indication, route, dosage, and storage and handling requirements.

Refer to the correct appendix section in this guide for the COVID-19 vaccine(s) that you will be administering for detailed vaccine product information about shipping, storage, redistribution, vaccine recommendations, contraindications/precautions, side effects, and vaccine preparation.

Appendix A: COVID-19 Ultra-Cold Temperature Vaccine(s)
(www.health.state.mn.us/diseases/coronavirus/vaccine/guideappa.pdf)
Pfizer BioNTech

Appendix B: COVID-19 Frozen Vaccine(s)
(www.health.state.mn.us/diseases/coronavirus/vaccine/guideappb.pdf)
Moderna

Appendix C: COVID-19 Refrigerated Vaccine(s)
No refrigerated COVID-19 vaccines currently available.

COVID-19 vaccine storage and handling

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness.
Cold-chain storage and handling requirements for COVID-19 vaccine products will vary in temperature. Follow specific shipping, storage, and redistribution requirements for each vaccine product:

- Refrigerated vaccine: 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit).
- Frozen vaccine: minus 25 to minus 15 degrees Celsius (minus 13 to plus 5 degrees Fahrenheit).
- Ultra-cold vaccine: minus 80 to minus 60 degrees Celsius (minus 112 to minus 76 degrees Fahrenheit). Ultra-cold vaccines require dry ice and special storage. Ongoing stability testing may impact these requirements.

For CDC storage and handling recommendations and best practices, review CDC’s Vaccine Storage and Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html). The toolkit covers general recommendations for temperature monitoring, calibration certificates, and other important aspects for keeping vaccine safe.

If you are new to vaccine storage and handling, you may want to view CDC’s You Call the Shots module.


Expiration and beyond-use date (BUD)

All vaccines have expiration dates. Sometimes vaccines must be used before the expiration date listed on the label. This is referred to as the “beyond-use date” (BUD). For COVID vaccines, the beyond-use date is determined based on the date a vial is first entered (pierced) and the storage information in the EUA fact sheet (or package insert). The beyond-use date replaces the expiration date for multi-dose vials and reconstituted vaccines. With COVID-19 vaccines, the expiration date will change if the vaccine is modified or stored in a certain way. The person who makes a change to the vaccine (e.g., pierces the vial, reconstitutes it, moves it from the ultra-cold storage or freezer into the refrigerator) must document the beyond-use date on a label. Beyond-use date tracker labels are available on CDC’s website.

Keep in mind that several COVID-19 vaccine products do not contain any preservative and may expire hours after the vial is first punctured. Carefully read and follow the EUA fact sheet for health care providers and/or manufacturers’ websites for each vaccine product regarding expiration and beyond-use dates.

Managing out-of-range temperatures (excursions)

As with all vaccines, if COVID-19 vaccines are exposed to out-of-range temperatures, take immediate action. Mark the vaccine “do not use” until its usability is determined. If vaccine thaws, do not re-freeze.

- Contact MDH at 651-201-5414 to determine your next steps. Make sure to have specific information about temperatures, duration of excursion, etc. available.
When MDH is not available (e.g., closed on weekends, evenings, and holidays), CDC is taking COVID-19 vaccine calls 24 hours a day/seven days a week (including holidays) at 800-CDC-INFO (800-232-4636).

## Recommendations for mRNA COVID-19 vaccines

ACIP has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines for the prevention of COVID-19. Both vaccines are mRNA vaccines. These recommendations have been adapted from the [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).

### Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: Ages 16 years and older
- Moderna: Ages 18 years and older

### Administration

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 mL each): 21 days (three weeks) apart
- Moderna (100 µg, 0.5 mL): 28 days (one month) apart

People should not be scheduled for their second dose earlier than recommended. However, second doses administered within a grace period of four days earlier than the recommended date for the second dose are considered valid. Second doses administered earlier than the four-day grace period (in error), do not need to be repeated. There is no maximum interval between the first and second dose. Do not restart the series. Complete a VAERS report for all vaccine errors, including a second dose given earlier than recommended.

### Interchangeability with other COVID-19 vaccine products

The two currently authorized mRNA COVID-19 vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products. If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

ACIP does not state a product preference between the two currently authorized mRNA COVID-19 vaccines. Either COVID-19 vaccine can be used when indicated.
Co-administration with other vaccines

The COVID-19 vaccines should be **routinely** administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. There may be situations where mRNA COVID-19 vaccines and other vaccines may be administered within a shorter period, if the benefits of vaccination are believed to outweigh the potential unknown risks of co-administration, such as:

- Tetanus toxoid-containing vaccines as part of wound management.
- Vaccines given during an outbreak (e.g., measles or hepatitis A).
- Long-term care facility residents or health care personnel who received flu vaccine or other vaccinations prior to or upon admission or onboarding.

If mRNA COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine. This should not be a routine practice.

**Vaccination of people with a SARS-CoV-2 (COVID-19) infection or exposure**

**People with a history of COVID-19 infection**

Clinical trial data indicates that mRNA COVID-19 vaccines are safe in people with evidence of a prior COVID-19 infection. Vaccination should be offered to people regardless of a prior COVID-19 infection (with or without symptoms).

**People with known current COVID-19 infection**

Postpone vaccination of people with a known current COVID-19 infection until the person has recovered from acute illness (if they had symptoms) and criteria have been met for them to complete isolation. This recommendation applies to people who develop COVID-19 infection before receiving any vaccine doses and those who develop a COVID-19 infection after the first dose but before receiving the second dose.

While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Therefore, people with documented acute COVID-19 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

**People who previously received passive antibody therapy for COVID-19**

Based on the estimated half-life of antibody therapies for COVID-19 (i.e., monoclonal antibodies or convalescent plasma), vaccination should be deferred for at least 90 days. This is a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses. This recommendation applies to people who receive passive antibody therapy before receiving any COVID-19 vaccine doses and those who receive passive antibody therapy after the first dose but before the second dose, in which case the second dose should be delayed for at least 90 days after receiving the antibody therapy.
For people receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administering mRNA COVID-19 vaccines is unlikely to significantly interfere with the development of a protective antibody response (for vaccine administration either at the same time or any interval before or after receiving antibody therapies). Therefore, there is no recommended minimum interval between other antibody therapies and mRNA COVID-19 vaccination.

**People with a known COVID-19 exposure or during COVID-19 outbreaks**

The mRNA vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis (i.e., vaccination to prevent developing COVID-19 infection in someone with a known exposure). People in the community or outpatient setting who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended.

For people living in congregate health care settings, residents with a known COVID-19 exposure may be vaccinated. In these settings, health care personnel are already in close contact with residents and should use appropriate infection prevention and control procedures so that there are not additional exposures when administering COVID-19 vaccine. Residents of other congregate settings with a known exposure may also be vaccinated, in order to avoid delays and missed opportunities for vaccination given the increased risk for outbreaks in these settings.

**Special populations**

**People with underlying medical conditions:** People with underlying medical conditions who have no contraindications to vaccination are recommended to receive COVID-19 vaccine. Clinical trials showed similar safety and efficacy profiles in people with underlying medical conditions.

**Immunocompromised people:** Data is not currently available for vaccine safety and effectiveness in people with HIV infection or other immunocompromising conditions, or in people who take immunosuppressive medications or therapies. These people may still receive the COVID-19 vaccine if they have no contraindications to vaccination. But they should be counseled about the unknown vaccine safety and effectiveness, and that there is potential they will not have a full protective response to the vaccine. Antibody testing is not recommended to measure immunity to COVID-19 following mRNA COVID-19 vaccination.

At this time, people who have received a complete COVID-19 vaccine series when they were immunosuppressed do not need to be re-vaccinated once immune competence is restored.

**People with autoimmune conditions:** People with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

**People with a history of Guillain-Barré syndrome:** To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccine clinical trials. People with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
People with a history of Bell’s palsy: Cases of Bell’s palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccine clinical trials. However, the FDA does not consider these to be above the rate expected in the general population and has not concluded that these cases were causally related to vaccination. Since there is not more evidence, people with a history of Bell’s palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell’s palsy following mRNA COVID-19 vaccination should be reported to VAERS.

Adolescents (for Pfizer-BioNTech vaccine only): People who are 16 and 17 years old are eligible to be vaccinated under the EUA. While vaccine safety and efficacy data are limited, there is no reason to expect the safety and efficacy to be different than for adults. Adolescents aged 16-17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated, with parental consent.

- Note: there are a few exceptions to needing parental consent, see Minnesota Statutes, sections 144.341 and 144.432.

Pregnant women: Currently, there is no available data on the safety of COVID-19 vaccines in pregnant women. The manufacturer is following outcomes on women in the clinical trials who became pregnant. Based on current knowledge of mRNA vaccines, experts believe they are unlikely to pose a risk for people who are pregnant; however more data are needed.

- While the risk is low, pregnant women with COVID-19 have an increased risk of severe illness including ICU admission, mechanical ventilation, and death. They also might be at increased risk of adverse pregnancy outcomes, such as preterm birth.

- If a pregnant woman is part of a group that is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. Her health care provider can help her make an informed decision. Factors to consider include: community transmission, personal risk of contracting COVID-19, the risks to her and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

- Pregnant women who experience fever after vaccination may be counseled to take acetaminophen, since fever has been associated with adverse pregnancy outcomes. Acetaminophen may also be used for other post-vaccination symptoms. Routine testing for pregnancy prior to COVID-19 vaccination is not recommended. Women who are trying to become pregnant do not need to avoid pregnancy.

Lactating (breastfeeding) women: There are no data on the safety of COVID-19 vaccines in lactating women, or the effects on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. If a lactating woman is part of a group who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated.

Screening for contraindications and precautions

While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. Although investigations are ongoing, people with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for
anaphylaxis upon re-exposure to either of the currently authorized mRNA COVID-19 vaccines. An **immediate allergic reaction** to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria (hives), angioedema (painless swelling under the skin, often happens with hives), respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur **within four hours** following administration.

Resources are available to assist in screening patients prior to COVID-19 vaccination:


**Contraindications**

CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components.
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*.
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*.

*These people should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that they can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

People with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported after vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction (fainting) or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose).

A list of the ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines are included in this guide’s appendices A and B. Also, refer to CDC’s Appendix B at [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](https://www.cdc.gov/vaccines/covid-19/info-by-product/clincial-considerations.html).

Health care providers or health departments in the United States can request a consultation from the [Clinical Immunization Safety Assessment (CISA) Project](https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) at CISAeval@cdc.gov if they have a complex COVID-19 vaccine safety question about an individual patient living in the United States that is not addressed by CDC guidance.
Precautions

CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines. People with this history should be counseled about the unknown risks of developing a severe allergic reaction after COVID-19 vaccination and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered until further information on the risk of anaphylaxis is available. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination in these individuals:

- Risk of exposure to COVID-19 (e.g., because of living in a congregate setting, occupation).
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions).
- Whether the patient has previously been infected with COVID-19 and, if so, how long ago.
  - Note: Vaccination is recommended for people with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, people with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies.
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. Learn more at Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination (www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Neither contraindications nor precautions to vaccination

- The following are neither a contraindication nor precaution to mRNA COVID-19 vaccines:
  - Allergic reactions (including severe allergic reactions) not related to vaccines, injectable therapies, components of mRNA vaccines (including PEG), or polysorbates, such as:
    - Food, pet, venom, or environmental allergies.
    - Oral medications (including the oral equivalents of injectable medications).
  - Latex allergies: Neither vaccine’s product packaging contain natural rubber latex.
  - Egg or gelatin allergies: Neither product contains these ingredients.

For further discussion of risk assessment for mRNA COVID-19 vaccination, please refer to the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States (www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).
Observation period and anaphylaxis management

Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy or people with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other people should be observed for 15 minutes. Find more information on anaphylaxis management:

- CDC’s Appendix A (triage of persons presenting for mRNA COVID-19 vaccination) on Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States (www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
- Lab Tests to Collect Shortly After Severe Allergic Reaction/Anaphylaxis Following COVID-19 Vaccination (www.cdc.gov/vaccines/covid-19/clinical-considerations/testing-after-allergic-reaction.html)

Laboratory testing

Interpretation of SARS-CoV-2 test results in vaccinated people: For people who have received mRNA COVID-19 vaccine, the vaccine will not affect SARS-CoV-2 viral test results. Antibody testing is not currently recommended to assess for COVID-19 immunity or to assess the need for vaccination in unvaccinated people.

Interpretation of tuberculosis test results in vaccinated people: Inactive vaccines do not interfere with tuberculosis (TB) test results. Since mRNA COVID-19 vaccines are inactive, there is no immunologic reason to believe that either a tuberculin skin test (TST) or interferon gamma release assay (IGRA) blood test would affect the safety or effectiveness of mRNA COVID-19 vaccines. For health care personnel or patients who required baseline TB testing at the same time they are receiving mRNA COVID-19 vaccine:

- Perform TB symptom screening.
- If using the IGRA, draw blood for test prior to COVID-19 vaccination.
- If using the TST, place prior to COVID-19 vaccination.
- If COVID-19 vaccine has been given and testing needs to be performed, defer the TST or IGRA until four weeks after COVID-19 vaccine two-dose completion.

For health care personnel who require testing for other reasons and for more information related to laboratory tests, refer to Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States (www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).
COVID-19 vaccine administration

Based on their scope of practice, all people who administer vaccines should receive comprehensive, competency-based staff training and education, including the “rights of vaccine administration;” patient care before, during, and after vaccine administration; vaccine preparation; and skill validation.

Always use one needle, one syringe, only one time.

Learn more about safe injection practices at One & Only Campaign (www.cdc.gov/injectionsafety/one-and-only.html).

Reconstituting vaccine

Follow the specific instructions provided in the product information for reconstituting the vaccine. Vaccines should be reconstituted using only the specific diluent required by the manufacturer for that vaccine. Each diluent is specific to the corresponding vaccine in volume, sterility, pH, chemical balance, and purpose. If the wrong diluent is used, the vaccine dose is not valid and will need to be repeated using the correct diluent. Changing the needle between drawing vaccine from the vial and administering the vaccine is not necessary, unless the needle is contaminated or damaged, or the needle gauge is too large for vaccine administration (e.g., a 21-gauge needle used to reconstitute vaccine).

Intramuscular administration

Always adhere to strict aseptic practices while preparing and giving injectable vaccines. Use good hand hygiene. Hands should be cleaned with an alcohol-based waterless antiseptic hand rub or washed with soap and water before preparing vaccines for administration and between each patient contact.

Follow the “seven rights” of vaccine administration: right patient; right vaccine/diluent; right time; right dose; right route; right site; right documentation.

Choosing the correct anatomic site and appropriate needle length for intramuscular (IM) injections depends on age and body mass. For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue, but not so long as to involve underlying nerves, blood vessels, or bone.

Needle size and site of injection must be decided for each person based on the size of the muscle and the thickness of adipose tissue around the muscle. This is usually a 1 to 1.5-inch needle for adults.

Avoid shoulder injury related to vaccine administration (SIRVA) in adults by administering the vaccine correctly in the deltoid muscle. Giving the intramuscular injection too close to the shoulder joint can cause bursitis, fasciitis, and other injury. Report shoulder injury related to vaccine administration to the Vaccine Adverse Event Reporting System (VAERS).
• Place three fingers from the top of the shoulder. Have the patient lift their arm (you should be able to see and feel the deltoid muscle contract). Once you have located the middle of the muscle, have the patient relax their arm and give the injection at a 90-degree angle to the middle muscle point.

When injecting the vaccine into the patient, follow these steps:

• Clean the area to be injected in a circular motion using a sterile alcohol wipe. Start in the center and working outward.
• Insert the needle smoothly and quickly at a 90 degree angle (for intramuscular).
• Hold the syringe steady once the needle is in the tissue; moving it around the tissue may cause damage.
• Inject the vaccine – slowly, but smoothly.
• Withdraw the needle smoothly at the same angle it was inserted.
• Apply gentle pressure to the site with either an alcohol pad or a sterile gauze pad.
• Apply a bandage at the site if bleeding occurs1.

Resources

Vaccine administration resources for all people who vaccinate, including staff who are new to vaccination and staff who need a refresher:

• CDC: Immunization Education and Training (www.cdc.gov/vaccines/ed/index.html).
  ▪ You Call the Shots (www.cdc.gov/vaccines/ed/youcalltheshots.html).
    ▪ Watch the “Vaccine Administration” e-Learn.
  ▪ Intramuscular (IM) Injection: Sites (www.youtube.com/watch?v=PqSuCPnPYe).
• MDH: How to Administer IM (Intramuscular) Injections (www.health.state.mn.us/people/immunize/hcp/admim.pdf).

EUA fact sheets and Vaccine Information Sheets (VISs)

The FDA commissioner may authorize the use of vaccine during a public health emergency to protect the nation’s health, even though the vaccine is not yet licensed. Under emergency use authorizations (EUA), EUA fact sheets are used instead of vaccine information sheets, which are used when a vaccine is

licensed. You must provide a copy of either a fact sheet or a vaccine information sheet to the person receiving the vaccine prior to vaccination. Allow for any questions that a person getting vaccinated may have.

**EUA fact sheets**

- EUA fact sheets for vaccination providers are product-specific information sheets that replace the usual package insert. A separate fact sheet for vaccine recipients is similar to a licensed product’s vaccine information sheet.

- The EUA fact sheet for vaccine recipients explains the vaccine risks and benefits, specific vaccine product information and its use, and information from clinical trials that support the FDA’s emergency use authorization.
  - You are legally required to provide an EUA fact sheet to each recipient/parent/legal representative prior to vaccination. Be prepared to answer questions about the vaccine.

- EUA fact sheets are available on FDA, CDC, and vaccine manufacturer websites. Translated EUA fact sheets in multiple languages are on the FDA website:

**Vaccine information sheets (VIS)**

- Vaccines licensed through the FDA and added to the vaccine injury table are required to have a vaccine information sheet.

- Federal law requires that patients receive a vaccine information sheet prior to administration of a licensed vaccine.

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**COVID-19 vaccine second dose reminders**

Two doses of vaccine will be needed for most COVID-19 vaccine products. The interval between each dose depends on the vaccine product used.

Become familiar with the interval between vaccinations for the vaccine product you are using.

Make sure each person getting vaccinated knows how long they must wait between their first and second vaccination.

**Different COVID-19 vaccine products are not interchangeable. The same product must be used for both the first and second doses.**

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**Second dose reminders are critical**

Second dose reminders will be critical to ensure compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness. COVID-19 vaccination providers should make every attempt to schedule a
person’s second dose appointment when they get their first dose, or schedule both appointments when scheduling the first appointment. Ideas to help ensure second doses are given include:

- Complete a COVID-19 vaccination record card (vaccine manufacturer, lot number, date of first dose, and date second dose due) for each person who is vaccinated. Encourage them to keep the card, so they can check to make sure their second dose comes from the same manufacturer as their first dose.
  - If the patient has a smartphone, ask them to take a photo of their vaccination card and enter the date when the next vaccine is due into their electronic calendar.
- Use the Minnesota Immunization Information Connection to pull lists of people that need to complete the COVID-19 vaccine series (to be announced). Information on this functionality, when it is ready, will be available on MIIC User Guidance and Training Resources (www.health.state.mn.us/people/immunize/miic/train/index.html).
- Look at your emergency health record or vaccine management tool to see if there is a second dose reminder function already built in (e.g., patient portal).
- Use other methods, such as text messaging, phone calls, email, and mail.

### Post-vaccination care

#### Vaccine efficacy

Interim data from the clinical studies suggest that the mRNA COVID-19 vaccines are highly effective in preventing COVID-19 after someone receives two doses of a vaccine. Limited data are currently available regarding the efficacy of a single dose. Counsel patients on the importance of completing the two-dose series (of the same vaccine product) to optimize protection.

There are ongoing studies to research how effective the vaccine is at preventing asymptomatic COVID-19 infection, and if someone who is vaccinated can still pass the disease to others if infected.

CDC has resources on post vaccination considerations for health care workers and residents of long-term care facilities:

- [Post Vaccine Considerations for Residents](https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html)

#### Public health recommendations for vaccinated people

Since we currently have limited information on whether the available COVID-19 vaccines will reduce transmission in the general population, and we do not know how long protection lasts, vaccinated people should continue to follow all current public health guidance to protect themselves and others. This includes wearing a mask, staying at least 6 feet away from others, avoiding crowds, washing hands
often, following quarantine guidance after an exposure to someone with COVID-19, and following any applicable workplace or school guidance, including guidance related to personal protective equipment (PPE) use or COVID-19 testing.

**Post-vaccination instructions**

Preparing people for what to expect after vaccination and when to follow up with a health care provider is a best practice for vaccination and can ease a person’s anxiety. Patient instructions should include information specific to the product they are receiving. This information should include:

- What to expect after receiving the vaccine (common side effects), listed in the EUA fact sheet.
- When to contact their health care provider (such as signs of an allergic reaction or medical concerns that may or may not be related to vaccination).
- Importance of receiving the second dose to build an adequate immune response.
  - Uses text messaging and web surveys to check in with people who have received COVID-19 vaccine.
  - Allows participants to report side effects and health impacts following COVID-19 vaccination.
  - Provides second dose reminders (if needed).
  - Includes live phone follow-up through the Vaccine Adverse Event Reporting System, with people reporting a clinically significant event (e.g., missed work, unable to perform normal daily activities, seeking medical care) during any v-safe health check.
  - V-safe will be available in a Spanish version in January, with Korean, Vietnamese, and Simplified Chinese versions following shortly.
- It is important to instruct the patient on the need to continue to follow current COVID-19 guidance, such as wearing a mask, staying six feet away from others, avoiding crowds, and washing hands often. There is not enough information to know how well and for how long the vaccine works in the general population.

Administer vaccines in settings where staff are trained to recognize and respond to reactions. Immediate systemic reactions can include fainting (syncope) and severe allergic reaction (anaphylaxis).

**Treatment of post-vaccination symptoms**

- After receiving a COVID-19 vaccine dose, over-the-counter fever or pain medication (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be used for local or systemic symptoms, if medically appropriate. Refer to the applicable appendix to view side effects listed for each vaccine product.
It is not recommended to routinely take over-the-counter fever or pain medication to prevent symptoms following vaccination. The impact of the medications’ use on COVID-19 vaccine-induced antibody responses is not available at this time.

**Fainting (syncope)**

Patients are at risk for falls due to syncope during and after vaccine administration, which can result in serious injury. To decrease this risk, have a place for patients to sit down while they are vaccinated and be ready to lower them to a laying position, if needed. The Advisory Committee on Immunization Practices recommends providers observe the vaccinated person (sitting or lying down) for:

- **30 minutes** in people with a history of a severe allergic reaction (anaphylaxis) due to any cause.
- **15 minutes** for all other people to monitor for any immediate adverse reactions.

Know the signs someone has before fainting: pale complexion, weak, dizzy, and/or sweating.

**Allergic reaction (anaphylaxis)**

Anaphylactic reactions in people receiving the COVID-19 vaccine outside of clinical trials have been reported. While rare, these events highlight the importance of a quick and competent response. Refer to the Contraindications and Precautions sections for more information regarding adverse reactions.

Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

An allergic reaction to a vaccine is a life-threatening event. Know the early signs of anaphylaxis: throat closing sensation, swelling of throat, face or lips, hives, itching, stridor (high-pitched whistling sound), wheezing, coughing, dizziness, fainting, fast heart rate, low blood pressure, nausea, vomiting, diarrhea, and/or abdominal pain.

- People with a history of immediate allergic reaction of any severity to a vaccine or injectable therapy and people with a history of anaphylaxis (due to any cause) should be observed for **30 minutes** after vaccination.
- Observe all other people for **15 minutes** after vaccination to monitor for any immediate adverse reactions.

**Emergency preparation**

Learn more on how to prepare for anaphylactic reactions at CDC’s [Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination](www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html).

Some considerations:
Staff should be trained in CPR and be familiar with the signs, symptoms, and treatment of anaphylaxis.

Have the appropriate equipment and medication on hand. Have trained staff available to administer epinephrine and maintain an airway in settings where vaccinations are given.

Have a signed hard copy of a plan and protocol for the medical management of a vaccine reaction. Ensure staff review the plan and protocol and are ready to carry out before giving vaccinations or providing related services.

- The Immunization Action Coalition has examples of emergency plans. See Medical Management of Vaccine Reactions in Children and Teens (www.immunize.org/catg.d/p3082a.pdf) and Medical Management of Vaccine Reactions in Adults (www.immunize.org/catg.d/p3082.pdf) for more information.

Report vaccine adverse events and administration errors

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems with vaccines. Find more information at Report an Adverse Event to VAERS (https://vaers.hhs.gov/reportevent.html). Anyone can submit a VAERS report: a doctor, nurse, pharmacist, or any member of the general public. VAERS accepts all reports, even if you are not sure if a vaccine caused an adverse event.

- As part of the CDC COVID-19 Vaccination Program Provider Agreement, vaccination providers are required to report the following to VAERS:
  - Vaccine administration errors (whether associated with an adverse event or not).
  - Serious adverse events (even if not sure the vaccine caused the event).
  - Multisystem inflammatory syndrome (MIS) in children or adults.
  - Cases of COVID-19 that result in hospitalization or death.
- HIPAA permits reporting of vaccine adverse events and medical documentation to VAERS for public health purposes under 45 CFR § 164.512(b), as authorized by 42 USC 300aa-25.

Document administered doses

Give the vaccinated person and caregiver, if applicable, a completed COVID-19 vaccination record card that includes the name of the vaccine given, the date administered, and the name and location of the administering clinic. Providers should follow their usual documentation processes in the patient’s permanent medical record. Record administration information includes:

- Vaccine name.
- Date of administration.
- Vaccine manufacturer and lot number.
- Vaccination site and route.
- Name and title of the person who administered the vaccine.
COVID-19 vaccine reporting requirements

The Minnesota Immunization Information Connection (MIIC) (www.health.state.mn.us/miic) stores electronic vaccination records that combine vaccinations individuals received at different locations across the state.

Per the CDC provider agreement, product-specific COVID-19 vaccination data must be reported within 24 hours of vaccine administration. Data reported to MIIC in a timely manner will be routinely sent to the CDC in de-identified form to meet their data requirements and in a manner consistent with Minnesota laws. There are a number of data elements required for each COVID-19 vaccination that is administered.

Required data elements for COVID-19 vaccination reporting

This required data is subject to change.

Vaccine recipient data

- First name
- Middle name
- Last name
- Date of birth
- Sex
- Full address (street, street 2, city, county, state, ZIP code)

Vaccine administration data

- Administration date
- CVX code
- NDC (if known)
- MVX code
- Lot number
- Expiration date
- Body site
- Route of administration
- Responsible organization
- Administered at location
- Vaccination refusal (when appropriate)
When an organization administers a vaccine dose, please make sure it is entered into MIIC as an “administered dose” and not a historical dose. Historical means that the dose was given by another organization. Doses labeled historical can be edited by other organizations and users, while administered doses can only be edited by the organization that gave the patient that dose of vaccine.

Become familiar with MIIC. If your organization already submits data to MIIC via:

- Electronic data exchange: Review your messages to ensure you are sending timely messages and that those messages contain a CVX/CPT code pair or an NDC code. Verify that your organization has a process to routinely review rejection (ACK) messages.

- Upload file via the user interface: Ensure you are submitting a CVX/CPT code pair. A new spreadsheet template is available in MIIC and the latest user guide can be found at [General Immunization Upload Using the Spreadsheet Template](www.health.state.mn.us/people/immunize/miic/data/spreadsheet.pdf). Please download the template from MIIC each time you use it. Consider creating an electronic interface with MIIC to reduce staff burden and help ensure timely data reporting.

- Direct data entry: Ensure staff are selecting the correct option from the “Trade Name” drop-down menu. Strongly consider using one of the above reporting methods. Connecting to MIIC for electronic data exchange can reduce staff burden, especially during high-volume times.

- Minn. Stat. 144.3351 authorizes vaccine providers to share the required data elements with MDH, through MIIC, without consent. Patient consent must be obtained for reporting of other data elements, such as race and ethnicity.

Find Vaccine Administration Codes from CDC at [Code Sets](www.cdc.gov/vaccines/programs/iis/code-sets.html).

### Managing vaccine inventory

#### Reporting vaccine inventory

MDH will report inventory to CDC daily. To facilitate this reporting and to give visibility to inventory across the state, all COVID-19 vaccine that is redistributed needs to be reported to MDH within 24 hours of redistribution. Learn more about COVID-19 vaccine redistribution at [COVID-19 Vaccine: Redistribution and Off-site Vaccination Guide](www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf).

**Note:** All COVID-19 providers will be invited to enroll in VaccineFinder ([www.vaccinefinder.org](www.vaccinefinder.org)) in later phases of the response, where they can choose to make their location visible to users searching for locations that offer vaccinations.

#### Reporting vaccine wastage/spoilage and vaccine disposal

Tracking vaccine wastage is part of vaccine inventory. Sites will be asked to report wastage or spoilage of vaccine doses (e.g., exposure to out-of-range temperatures, vaccines in refrigerator past the allowed
time, doses drawn up and not used, doses remaining in vial at the time of the BUD expiration, vaccine
discoloration or particulates, etc.).

Registered COVID-19 providers can report vaccine wastage in MIIC. For now, please follow existing
guidance on reporting nonviable MDH vaccine to MIIC that is available at Vaccine Ordering and
Management in MIIC (www.health.state.mn.us/people/immunize/miic/managevax/index.html). An
updated version specific to reporting COVID-19 vaccine will be available soon.

To report wasted vaccine to MIIC, you will need to be set up with a MIIC user role that has ordering
privileges. Please contact health.mdhvaccine@state.mn.us with questions about getting set up to access
this feature in MIIC.

Expired or spoiled COVID-19 vials are not being returned to the manufacturer or McKesson.

COVID-19 vaccine and vials are not considered hazardous or infectious waste in Minnesota and may be
disposed into the normal solid waste. Requirements vary for other vaccines and pharmaceutical wastes.
For more information, contact the Minnesota Pollution Control Agency (www.pca.state.mn.us)
at 651-296-6300 or 800-657-3864 or email at info.pca@state.mn.us.

Billing and reimbursement

COVID-19 vaccine administration fee

- There is no cost for COVID-19 vaccine for vaccine providers or patients. Per the CDC provider
  agreement, vaccine providers must administer COVID-19 vaccine regardless of the vaccine
  recipient’s ability to pay COVID-19 vaccine administration fees or their insurance coverage status.
  There should be no out-of-pocket costs for COVID-19 vaccine.

- Insurance plans should reimburse providers for the administration fee. Vaccine providers may
  seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine
  administration fees for the vaccine recipient.

- For patients who have a Minnesota Health Care Plan (MHCP), providers will be reimbursed
  $10.86. As a reminder, vaccines are exempt from cost-sharing. Please contact the MHCP Provider
  Call Center at 651-431-2700 with any related questions.

- For uninsured patients, the vaccine provider can seek reimbursement for an administration fee
  from the Health Resources and Services Administration Provider Relief Fund at COVID-19 Claims
  Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine
  Administration for the Uninsured (www.hrsa.gov/coviduninsuredclaim).

For more information regarding COVID-19 billing, refer to the Centers for Medicare & Medicaid Services:

Providers may not seek any reimbursement directly from the patient, including through balance billing.
Find Vaccine Administration Codes from CDC at Code Sets (www.cdc.gov/vaccines/programs/iis/code-
sets.html).
The Minnesota Department of Health wants to thank all health care workers who have worked tirelessly during this pandemic. Providing COVID-19 vaccine to our population is the next challenge that we will all accomplish. Thank you in advance for your dedication and efforts in working to overcome the devastating effects of COVID-19.