STAY SAFE MN

# Interim COVID-19 Vaccine Provider Guide

## INFORMATION FOR HANDLING AND ADMINISTERING COVID-19 VACCINE

Updated 12/28/2022

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)*.

# Table of Contents

Interim COVID-19 Vaccine Provider Guide ..... 1
Background ..... 4
Use of this guide ..... 4
Training requirements ..... 4
COVID-19 vaccine ordering and distribution ..... 5
Actions your site can take to prepare ..... 5
Determining your COVID-19 vaccine order ..... 5
Redistribution ..... 6
COVID-19 vaccine supplies ..... 6
COVID-19 vaccine products ..... 7
Additional primary dose for moderately or severely immunocompromised people ..... 12
Booster doses ..... 12
Booster doses for moderately or severely immunocompromised people ..... 13
COVID-19 vaccine storage and handling ..... 13
Expiration date and beyond-use date (BUD) ..... 14
Managing out-of-range temperatures (excursions) ..... 14
Information to include when reporting a vaccine excursion ..... 15
Clinical considerations for authorized vaccines ..... 15
MDH-specific guidance on COVID-19 vaccine recommendations ..... 15
Resources for screening patients before COVID-19 vaccination ..... 15
Verify patient COVID-19 immunization data ..... 15
COVID-19 vaccine administration ..... 16
Emergency use authorization (EUA) fact sheets and vaccine information sheets (VISs) ..... 17
EUA fact sheets ..... 17
Vaccine information sheets (VIS) ..... 17
COVID-19 vaccine reminders ..... 17
Post-vaccination care ..... 18
Vaccine efficacy ..... 18
Post-vaccination instructions ..... 18
Treatment of post-vaccination symptoms ..... 19
Allergic reaction (anaphylaxis) ..... 19
Report vaccine adverse events and administration errors ..... 20
Document administered doses ..... 21

COVID-19 vaccine reporting requirements ..... 21
Data elements for COVID-19 vaccination reporting ..... 21
Managing vaccine inventory ..... 22
Reporting vaccine inventory ..... 22
Reporting vaccine wastage and spoilage ..... 22
Security and disposal of vaccine vials ..... 23
Billing and reimbursement ..... 23
COVID-19 vaccine administration fee ..... 23

# 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.

Initial vaccines were authorized by emergency use authorizations (EUA) from the Food and Drug Administration (FDA) when enough preliminary data on their effectiveness and safety was 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. Information about effectiveness and safety continues to be collected. If at any time vaccine data shows more risk than benefit, an EUA is re-evaluated.

Providers are responsible for adhering to all requirements outlined in the CDC COVID-19 Vaccination Program Provider agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, the Advisory Committee on Immunization Practices (ACIP), and FDA. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA is a violation of the provider agreement and could expose providers to the following risks:

- Administration of the product may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive doses may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how vaccines provided by the United States government (USG) may be used. Providers administering doses outside the published recommendations are violating the CDC Program provider agreement potentially impacting their ability to remain a provider.
- Administration fees may not be reimbursable by third party payers.

# Use of this guide

Anyone who handles and/or administers COVID-19 vaccine should read this guide. Bookmark this guide for easy reference and check back often for updates. Updates are highlighted in the weekly COVID-19 vaccine provider bulletin. Sign up at COVID-19 Vaccine Provider Updates (www.health.state.mn.us/diseases/coronavirus/vaccine/vaxbulletin.html).

## Training requirements

The vaccine coordinator and back-up coordinator at each registered site are required to read this COVID-19 vaccine provider guide and watch MDH's online COVID-19 Vaccination Providers Training. These individuals are identified during the registration process. Other people storing, handling, and administering COVID-19 vaccines are highly encouraged to complete the training and read this guide to strengthen their competency in using these vaccines. Access the training at COVID-19 Vaccine Trainings for Health Professionals (www.health.state.mn.us/diseases/coronavirus/vaccine/training.html).

### Roles and responsibilities

- The vaccine coordinator, at every enrolled provider site, is responsible for ensuring that staff handling and administering vaccine are properly trained and fully competent on storage, handling, preparation, and administration of the vaccine as applicable to their role.
- The coordinator can host an internal training and/or require all staff to complete the trainings that can be found at COVID-19 Vaccine Trainings for Health Professionals (www.health.state.mn.us/diseases/coronavirus/vaccine/training.html).

- Staff new to vaccinating may need additional hands-on training provided by the vaccine coordinator or other clinical staff at the registered site.

**Providers should track, maintain documentation, and monitor the training status of staff.**

# COVID-19 vaccine ordering and distribution

Registered COVID-19 providers directly request COVID-19 vaccines in the Minnesota Immunization Information Connection (MIIC). Learn more on how to request special event vaccine in MIIC User Guidance and Training Resources (www.health.state.mn.us/people/immunize/miic/train/index.html) under "Vaccine Ordering and Management." Before requesting COVID-19 vaccine, please read the considerations below.

## Actions your site can take to prepare

- Determine who within your organization will request COVID-19 vaccine in MIIC. This may involve a conversation with your organization's leadership.
- Check with your vaccine ordering staff to identify if they have a MIIC user role with ordering privileges. Login to MIIC and view your user role at the top of the home page. If your role ends with the words "with ordering" then you will have access to place COVID-19 vaccine requests in MIIC.
- If you do not have a user role "with ordering," consult with your MIIC administrator to update your role. Typically, there is a MIIC user at each site who is designated as a MIIC administrator. This person oversees the MIIC accounts for the staff at their site. If you have an administrator role, you can create user roles for your staff. Refer to Managing Users: MIIC User Guidance and Training Resources (www.health.state.mn.us/people/immunize/miic/train/admin.pdf).
- If you do not have staff with that role, contact health.mdhvaccine@state.mn.us for assistance.

## Determining your COVID-19 vaccine order

Order **the total number of doses** your site will need for the next couple of weeks. **MDH will NOT automatically ship second, third or booster doses to sites**.

COVID-19 vaccine requests need to be made in specific multiples of the following shipment packaging sizes:

- Pfizer-BioNTech COVID-19 vaccines/COMIRNATY
  - Pfizer-BioNTech EUA COVID-19 – 12+ yrs - Monovalent Primary Series – Gray Cap - 30 multi-dose vials of 6 doses – DO NOT DILUTE: requests must be made in 180 dose increments. Less than 180 doses cannot be shipped.
  - Comirnaty BLA COVID-19 – 12+ yrs - Monovalent Primary Series 12+ - Gray Cap - 30 multi-dose vials of 6 doses – DO NOT DILUTE: requests must be made in 180 dose increments. Less than 180 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19 – 5-11 yrs – Monovalent – Orange Cap - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19 – Under 5 yrs – Monovalent – Maroon Cap - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19 – 12+ yrs – Bivalent Booster – Gray Cap - 30 multi-dose vials of 6 doses – DO NOT DILUTE: requests must be made in 180 dose increments. Less than 180 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19 – 12+ yrs – Bivalent Booster – Gray Cap-single dose vial-DO NOT DILUTE: requests must be made in 50 dose increments. Less than 50 doses cannot be shipped.
  - Pfizer-BioNTech COVID-19 – 5-11 yrs – Bivalent Booster – Orange Cap - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.

  - Pfizer-BioNTech COVID-19-6m-4years—Bivalent—Maroon Cap - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
- Moderna COVID-19 vaccines/Spikevax
  - Moderna EUA COVID-19 – 12+ yrs – Monovalent Primary Series - Red Cap Blue Border - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Spikevax BLA COVID-19 – 12+ yrs – Monovalent Primary Series – Red Cap Blue Border - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Moderna COVID-19 – 6-11 yrs – Monovalent – Blue Cap Purple Border - 20 multi-dose vials of 5 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Moderna COVID-19 – Under 6 yrs – Monovalent – Blue Cap Magenta Border - 10 multi-dose vials of 10 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Moderna COVID-19 – 6+ yrs – Bivalent Booster – Blue Cap Gray Border - 20 multi-dose vials of 5doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
  - Moderna COVID-19-6m-5years-Bivalent – Dark Pink Cap Yellow Border - 10 multi-dose vials of 2 doses: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.
- Novavax COVID-19 vaccine
  - Novavax COVID-19 – 12+ yrs - 10 multi-dose vials of 10 doses - DO NOT DILUTE: requests must be made in 100 dose increments. Less than 100 doses cannot be shipped.

The person who places the vaccine order, as well as the primary and back-up contacts provided for each location listed in section B of the provider agreement, will receive an order confirmation email from MIIC when the order is created and a vaccine shipment confirmation email when vaccine doses ship. The vaccine manufacturer will send details on shipment tracking to the primary contact noted in section B of the provider agreement as soon as the package leaves their warehouse. If you would like to update the contacts for your site, please email health.mdhvaccine@state.mn.us. Enrolled and approved sites do not need to complete any additional registration with the vaccine manufacturer or distributor to receive doses.

COVID-19 vaccine providers **do not** need to be enrolled in the Minnesota Vaccines for Children (MnVFC) program to vaccinate people ages 6 months through 18 years with COVID-19 vaccine.

## Redistribution

If you redistribute COVID-19 vaccine, you must sign a redistribution agreement. To receive a redistribution agreement or to determine if your site is covered by an agreement, please email health.mdhvaccine@state.mn.us. **Sites must strictly follow the components of the agreement during redistribution and off-site vaccination.** Providers can request redistributed doses or list excess inventory using the COVID-19 Vaccine Redistribution Dashboard (https://app.smartsheet.com/b/publish?EQBCT=356419d9e62a427991faa57d6d17c0f2).

Learn more at www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf). For information on transporting COVID-19 vaccine, refer to Transporting COVID-19 Vaccines (www.health.state.mn.us/diseases/coronavirus/vaccine/transport.pdf).

# COVID-19 vaccine supplies

COVID-19 vaccines and supplies for administration are distributed at no cost to providers registered for COVID-19 vaccination. Ancillary supply kits are automatically ordered in amounts to match vaccine orders. Each ancillary kit will contain these supplies:

- Needles (22-25 gauge, 1 to 1.5 inch, depending on the population being vaccinated).

- Syringes (ranging from 1-3 milliliters).
- Alcohol prep pads.
- Surgical masks and face shields for vaccinators.
- COVID-19 vaccination record cards for vaccine recipients.
- CDC: Vaccine Administration: Needle Gauge and Length (www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf).

Pediatric ancillary kits are available with the same supplies as adult kits, except they include 1-inch needles only. Diluent, mixing needles and syringes, and extra alcohol pads will be included in the ancillary kit for vaccines requiring reconstitution. Note: kits do not include sharps containers, gloves, or bandages.

Providers can opt out of getting ancillary kits for vaccines that don't require diluent for vaccine shipments coming from MDH. For vaccines that require reconstitution, a combined kit will be included that contains administration supplies (as noted above), mixing supplies, and diluent vials. If you redistribute vaccine, you also need to redistribute the ancillary supplies. Single dose vial vaccines do NOT come with ancillary kits.

For questions or problems related to ancillary supply kits (e.g., missing supplies, etc.), contact:

- Pfizer vaccine: McKesson MedSurg to report by email SNSSupport@McKesson.com.
- Moderna/Janssen/Novavax vaccine: McKesson Specialty at 833-343-2703 or by email COVIDVaccineSupport@McKesson.com.

To report defective or faulty medical equipment (e.g., syringes, needles), visit the FDA's MedWatch Online Voluntary Reporting Form (www.accessdata.fda.gov/scripts/medwatch/) and complete **FDA Form 3500** for health professionals.

# COVID-19 vaccine products

Several COVID-19 vaccines are currently available and more may become available as vaccine trials are completed. Having multiple products makes COVID-19 vaccine more accessible, but it also increases the risk of medication errors. Double check the product specific EUA provider fact sheet or package insert for age indication, route, dosage, and storage and handling requirements. The currently FDA-approved or FDA-authorized COVID-19 vaccines are summarized below. None of the current vaccines are live-virus vaccines or contain any preservatives. Any COVID-19 vaccine can be used when indicated.

On May 5, 2022, the FDA limited the use of Janssen (Johnson & Johnson) COVID-19 vaccine to only certain people as referenced in the product's EUA fact sheet. The Pfizer-BioNTech, Moderna, and Novavax COVID-19 vaccines are recommended over Johnson & Johnson (J&J).

The J&J vaccine is associated with a rare but serious adverse event that includes death that has been observed among all ages and genders. For this reason, the CDC vaccine advisory group specifically states a preference of Pfizer-BioNTech, Moderna, and Novavax COVID-19 vaccines in place of the J&J vaccine. Pfizer-BioNTech, Moderna, and Novavax COVID-19 vaccine should be offered even if completion of the second dose is uncertain. For instances where J&J may be appropriate, refer to Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A. Guidance for use of Janssen COVID-19 Vaccine (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a).

## Pfizer-BioNTech COVID-19 vaccines/COMIRNATY
## Monovalent, Primary Series

| Description | Gray cap – do not dilute | Orange cap – dilute before use | Maroon cap – dilute before use |
|---|---|---|---|
| Age indication | 12 years and older | 5 through 11 years | 6 months through 4 years*** |
| Dose and route | 0.3 mL (30 mcg) IM | 0.2 mL (10 mcg) IM | 0.2 mL (3 mcg) IM |
| Primary series schedule | 0, 3-8 weeks** | 0, 3-8 weeks** | 0, 3-8 weeks**, at least 8 weeks (Bivalent vaccine-see below) |
| Amount of diluent* needed per vial | **NO DILUTION** | 1.3 mL | 2.2 mL |
| Doses per vial | 6 doses per vial | 10 doses per vial (after dilution) | 10 doses per vial (after dilution) |
| **Storage Conditions** | | | |
| ULT Freezer (-90°C to -60°C/-130°F to -76°F) | Until the expiration date | Until the expiration date | Until the expiration date |
| Freezer (-25°C to -15°C/-13°F to 5°F) | **DO NOT STORE** | **DO NOT STORE** | **DO NOT STORE** |
| Refrigerator (2°C to 8°C/35°F to 46°F) | 10 weeks or until expiration date | 10 weeks or until expiration date | 10 weeks or until expiration date |
| Room Temperature (8°C to 25°C/46°F to 77°F) | 12 hours (including any thaw time) | 12 hours prior to dilution (including any thaw time) | 12 hours prior to dilution (including any thaw time) |
| After First Puncture (2°C to 25°C/36°F to 77°F) | Discard after 12 hours | Discard after 12 hours | Discard after 12 hours*** |
| Comments | Recommended to use the same vaccine product to complete the primary series (and for an additional dose for people with certain immunocompromising conditions, if indicated). | Recommended to use the same vaccine product to complete the primary series. (and for an additional dose for people with certain immunocompromising conditions, if indicated). | Recommended to use the same vaccine product to complete dose 1 and 2 of primary series. |

*Diluent sterile 0.9% Sodium Chloride Injection USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

**An 8-week interval is suggested between dose one and two for some people ages 6 months to 64 years of age, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Novavax and Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

***** Vial labels and cartons may not list correct age range authorization and time frame storage conditions, refer to the EUA fact sheet for correct information.**

## Pfizer-BioNTech-**Bivalent** COVID-19 vaccines

| **Description** | **Maroon cap-Bivalent (Primary series)** | **Orange cap-Bivalent (Booster)** | **Gray cap-Bivalent (Booster)** |
|---|---|---|---|
| Age indication | 6 months-4 years | 5-11 years | 12 years and older |
| Dose and route | 0.2 mL (3mcg) IM | 0.2 mL (10 mcg) IM | 0.3 mL (30 mcg) IM |
| Primary series schedule | At least 8 weeks after dose 2 of monovalent | N/A | N/A |
| Booster schedule | N/A | Given at least 2 months after completion of primary series or last booster dose | Given at least 2 months after completion of primary series or last booster dose |
| Amount of diluent* needed per vial | 2.2 mL | 1.3 mL | **NO DILUTION** |
| Doses per vial | 10 doses | 10 doses per vial | 6 doses per vial or single dose vial |
| **Storage Conditions** | | | |
| ULT Freezer (-90°C to -60°C/-130°F to -76°F) | Until the expiration date | Until the expiration date | Until the expiration date |
| Freezer (-25°C to -15°C/-13°F to 5°F) | **DO NOT STORE** | **DO NOT STORE** | **DO NOT STORE** |
| Refrigerator (2°C to 8°C/35°F to 46°F) | 10 weeks or until expiration date | 10 weeks or until expiration date | 10 weeks or until expiration date |
| Room Temperature (8°C to 25°C/46°F to 77°F) | 12 hours (including thaw time | 12 hours (including thaw time) | 12 hours (including thaw time) |
| After First Puncture (2°C to 25°C/36°F to 77°F) | Discard after 12 hours | Discard after 12 hours | Discard after 12 hours |
| Comments | | | |

*Diluent sterile 0.9% Sodium Chloride Injection USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

# Moderna COVID-19 vaccines/Spikevax
## Monovalent, Primary series

| Description | Red cap – light blue border | Dark blue cap-purple border | Dark blue cap-magenta border |
|---|---|---|---|
| Age indication | 12 years and older | 6 through 11 years**** | 6 months through 5 years |
| Dose and route | 0.5 mL (100 mcg) IM | 0.5 mL (50 mcg) IM | 0.25 mL (25 mcg) IM |
| Primary series schedule | 0, 4-8 weeks* | 0, 4-8 weeks* | 0, 4-8 weeks* |
| Doses per Vial | 10-dose (maximum 11 doses)**<br><br>**Do not** mix with any diluent. | 5 doses per vial **<br><br>**Do not** mix with any diluent. | 10 doses per vial **<br><br>**Do not** mix with any diluent. |
| **Storage Conditions** | | | |
| Freezer<br>(-50°C to -15°C/-58°F to 5°F) | Until expiration date | Until expiration date | Until expiration date |
| Refrigerator<br>(2°C to 8°C/36°F to 46°F) | 30 days or until expiration date | 30 days or until expiration date | 30 days or until expiration date. |
| Room Temperature (8°C to 25°C/46°F to 77°F) | Up to 24 hours (unpunctured vials) | Up to 24 hours (unpunctured vials) | Up to 24 hours (unpunctured vials) |
| After First Puncture (2°C to 25°C/46°F to 77°F) | Discard after 12 hours | Discard after 12 hours | Discard after 12 hours |
| Comments | Recommended to use the same vaccine product to complete the primary series (and for an additional dose for people with certain immunocompromising conditions, if indicated).<br><br>Do not refreeze. | Recommended to use the same vaccine product to complete the primary series (and for an additional dose for people with certain immunocompromising conditions, if indicated).<br><br>Do not refreeze. | Recommended to use the same vaccine product to complete the primary series (and for an additional dose for people with certain immunocompromising conditions, if indicated).<br><br>Do not refreeze. |

* An 8-week interval is suggested between dose one and two for some people ages 6 months to 64 years of age, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Novavax and Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

**If a full dose cannot be withdrawn from the vial, discard the vial and contents. **Never "pool" or combine excess vaccine from multiple vials to obtain a dose.**

**** **Dark blue cap-purple border vials labeled "BOOSTER DOSES ONLY" is only authorized to provide primary series doses for people 6 through 11 years of age and should not be used to give booster doses (use bivalent vaccine for boosters). Refer to the EUA fact sheet for indications of use.**

## Moderna **Bivalent Booster** COVID-19 vaccines

| **Description** | **Dark pink cap-Bivalent (Booster)** | **Dark blue cap-Bivalent (Booster)** |
|---|---|---|
| Age indication | 6 months through 5 years | 6 through 11 years<br>or<br>12 years and older |
| Dose and route | 0.2 mL (10mcg) | 0.25 mL (25 mcg) IM<br>or<br>0.5mL (50 mcg) IM |
| Primary series schedule | N/A | N/A |
| Booster schedule | Given at least 2 months after completion of primary series | Given at least 2 months after completion of primary series or last booster dose |
| Amount of diluent* needed per vial | **Do not** mix with any diluent. | **Do not** mix with any diluent. |
| Doses per vial | 2 doses per vial** | 5 to 10 doses per vial** |
| **Storage Conditions** | | |
| Freezer (-25°C to -15°C/-13°F to 5°F) | Until expiration date | Until expiration date |
| Refrigerator (2°C to 8°C/35°F to 46°F) | 30 days or until expiration date | 30 days or until expiration date |
| Room Temperature (8°C to 25°C/46°F to 77°F) | Up to 24 hours (unpunctured vials) | Up to 24 hours (unpunctured vials) |
| After First Puncture (2°C to 25°C/36°F to 77°F) | Discard after **8** hours | Discard after 12 hours |
| Comments | Do not refreeze. | Do not refreeze |

**If a full dose cannot be withdrawn from the vial, discard the vial and contents. **Never "pool" or combine excess vaccine from multiple vials to obtain a dose.**

### Novavax COVID-19 vaccine

| Age indication | Primary dose route | Primary schedule | Presentation/preparation | Storage and handling | Notes |
|---|---|---|---|---|---|
| 12 years and older | 0.5 mL (5 mcg/ 50 mcg adjuvant) IM | 0, 3- 8 weeks** | Multi-dose vial: 10 doses per vial<br>**Do not** mix with any diluent. | Refrigerator: 2° to 8° C (36° to 46° F)<br>▪ Unpunctured vials: until expiration date.<br>▪ Punctured vials: 6 hours<br>▪ Do Not freeze | Recommended to use the same vaccine product to complete the primary series. |

****** An 8-week interval is suggested between dose one and two for some people ages 6 months to 64 years of age, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Novavax and Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

### Johnson & Johnson's Janssen COVID-19 vaccine*

| Age indication | Primary dose route | Primary schedule | Presentation/preparation | Storage and handling | Notes |
|---|---|---|---|---|---|
| 18 years and older | 0.5 mL IM | Single dose | Multi-dose vial: 5 doses per vial<br>No reconstitution required.<br>No preservative. | Refrigerator: 2°C to 8°C (36°F to 46°F):<br>▪ Unpunctured vials: until expiration date.<br>▪ Punctured vials: 6 hours.<br>▪ Room temperature: up to 12 hours (unpunctured vials).<br>▪ Punctured vials: 2 hours. | Not interchangeable with other COVID-19 vaccines for the primary dose. |

*The Janssen COVID-19 vaccine is authorized for use under an EUA for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in people 18 years of age and older who elect to receive the Janssen COVID19 vaccine because they would otherwise not receive a COVID-19 vaccine.

## Additional primary dose for moderately or severely immunocompromised people

Antibody response after vaccines, including COVID-19 vaccines, is likely to be suboptimal in people with altered immunocompetence at the time of vaccination. Therefore, an additional dose was added to the primary series for moderately or severely immunocompromised people. Refer to: CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are moderately or severely immunocompromised (www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised) for more specific information on this population.

## Booster doses

People ages 6 months and older are recommended to receive 1 bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized primary series or previously received monovalent booster dose(s) with the following exception: **children 6 months–4 years who receive a 3-dose Pfizer-BioNTech primary series are not authorized to receive a booster dose at this time regardless of which Pfizer-BioNTech vaccine (i.e., a monovalent or bivalent) was administered for the third primary series dose**.

The original monovalent mRNA vaccines are not authorized as a booster dose.

A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in **limited situations** in people ages 18 years and older who completed any FDA-approved or FDA-authorized monovalent primary

series, have not received any previous booster dose(s), and are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

### COVID-19 vaccines: booster dose and volume

| Vaccine manufacturer | Age indication | Booster dose | Booster volume |
|---|---|---|---|
| Pfizer-BioNTech Bivalent (orange cap) | 5-11 years | 10 mcg | 0.2 mL |
| Pfizer-BioNTech Bivalent (gray cap) | 12 years and older | 30 mcg | 0.3 mL |
| Moderna Bivalent (dark pink cap) | 6 months-5 years | 10 mcg | 0.2 mL |
| Moderna Bivalent (dark blue cap) | 6-11 years | 25 mcg | 0.25 mL |
| Moderna Bivalent (dark blue cap) | 12 years and older | 50 mcg | 0.5 mL |
| Novavax Monovalent | 18 years and older | 5 mcg / 50 mcg adjuvant | 0.5 ml |

Before administering a booster dose, vaccine providers should check a person's age, the recommended dose volume, and the correct dose interval for that product. After giving a booster dose, update the patient's vaccine card or complete a new one reflecting all doses of COVID-19 vaccine they have received. If a second card is needed, staple the two cards together.

Providers should continue to prioritize vaccinating those who have not been vaccinated and need to complete their primary series.

## Booster doses for moderately or severely immunocompromised people

Because the immune response following COVID-19 vaccination may differ in moderately or severely immunocompromised people, the primary series for immunocompromised people is 3 doses. For details on booster doses in this population, including specifics on booster dose timing, refer to CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are moderately or severely immunocompromised (www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised).

# 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.

Storage and handling requirements for COVID-19 vaccine products vary. Follow specific shipping, storage, and handling requirements for each vaccine product in their respective package insert or EUA fact sheet for healthcare providers at FDA: COVID-19 Vaccines (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines).

Vaccine must be stored in dedicated refrigeration/freezer units. Find more information on CDC's storage and handling recommendations at Vaccine Storage and Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html). Storing vaccine in the freezer of a combination household unit is not recommended. If your facility provides frozen vaccine, you must have a separate freezer.

Refer to Vaccination at Satellite, Temporary, or Off-site Locations (www.health.state.mn.us/diseases/coronavirus/vaccine/guideappd.pdf) for storage and handling guidance, including many helpful resources for transporting vaccine and monitoring temperatures.

Providers new to vaccine storage and handling, should view CDC's, You Call the Shots module. Learn more at CDC: CE Instructions for WB4417: Immunization: You Call the Shots-Module Ten-Storage and Handling—2021 (www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp).

## Expiration date and beyond-use date (BUD)

In certain conditions vaccines must be used before the actual expiration date. This is referred to as the beyond-use date (BUD). The BUD is determined based on the storage conditions and the time a vial is first punctured for COVID-19 vaccines. The person that performs the step in the administration process that changes the BUD (e.g., punctures the vial, reconstitutes it, moves it from the freezer to refrigerator, etc.) must document the new BUD on a label. BUD tracker labels are available on CDC's website.

Check expiration dates and beyond-use dates closely. **Discard the vaccine based on the earliest date, whether that is the manufacturer's labeled expiration date or the BUD.**

**Example:** Undiluted Pfizer 5-11 years vaccine (orange cap) can be stored for 10 weeks in the refrigerator. If it was placed in the refrigerator on December 20, its BUD is February 28. However, if the vaccine vial's expiration date is February 8, then it needs to be discarded at the end of the day on February 8.

Keep in mind that COVID-19 vaccine products do not contain any preservative and therefore can't be used after a certain number of 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's Immunization Program Monday through Friday between 8:00 a.m. and 4:30 p.m. at 651-201-5414 to determine your next steps. Make sure to have specific information about temperatures, duration of excursion, etc. available.

Contact information for vaccine manufacturers:

- **Moderna:**
  Phone: 1-866-MOD-ERNA or 1-866-663-3762
  Email: excursions@modernatx.com
- **Pfizer:**
  Pfizer U.S. Medical Information
  Phone: 1-800-438-1985
- **Janssen:**
  Phone: 1-800-565-4008 or 908-455-9922
  Email: JSCCOVIDTEMPEXCURSION@its.jnj.com
- **Novavax:**
  Phone: 1-844-668-2829
  Email: Fill out our contact form (www.novavax.com/contact-us/email-us)

Some vaccine manufacturers have online temperature excursion tools you may use:

- Moderna: Storage & temperature excursion for Moderna COVID-19 vaccine (https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page)
- Janssen COVID-19 Vaccine – Stability – Temperature Excursion (Vials) (www.janssenmd.com/janssen-covid19-vaccine/interactive-content/stability-information)

Contact MDH even if you have contacted the vaccine manufacturer or used their online temperature excursion tool and the issue was resolved.

## Information to include when reporting a vaccine excursion

- Your email address and phone number.
- Storage condition at the time of excursion (e.g., frozen storage, refrigerated storage, or room temperature).
- Duration of excursion.
- Interim disposition of affected vials (e.g., returned to freezer or refrigerator, moved to another storage unit, or maintained at room temperature).
- Visual inspection, noting any change in the vaccine's state (e.g., frozen vials that thawed or thawed vials that were re-frozen).
- If the vaccine is determined to be nonviable (not usable) it should be discarded immediately. Report these doses as nonviable vaccine to MDH in the Minnesota Immunization Information Connection (MIIC). Refer to the section below on reporting vaccine wastage and spoilage for instructions.

# Clinical considerations for authorized vaccines

ACIP has issued interim recommendations for the use of COVID-19 vaccines for the prevention of COVID-19. These recommendations are published in CDC: Use of COVID-19 Vaccines in the United States (www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html). CDC is updating these recommendations frequently as new vaccines are authorized and information changes. A summary of recent changes and the date they were last updated is at the top of the webpage.

## MDH-specific guidance on COVID-19 vaccine recommendations

### Use of immune-based tests for tuberculosis (TB) infection:

COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before, after or during the same visit as COVID-19 vaccination. Find additional information at CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Special populations (www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#special-populations) and Regulations for TB Control in Minnesota Health Care Settings (www.health.state.mn.us/diseases/tb/rules/healthcare.html).

## Resources for screening patients before COVID-19 vaccination

- Template: COVID-19 Vaccine Screening and Agreement on COVID-19 Vaccine Providers (www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html).
- CDC: Prevaccination Checklist for COVID-19 Vaccines (www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf).

# Verify patient COVID-19 immunization data

Prior to administering a dose of COVID-19 vaccine, please review the patient's immunization history. The primary source of COVID-19 vaccine administration data should be the Minnesota Immunization Information Connection (MIIC). If the data for a patient is not in MIIC, other acceptable sources include:

1. Their CDC vaccination card.

2. An official document from a health care provider or another state's Immunization Information System (IIS) with day, month, year, and product administered as well as the patient's name and date of birth.
3. Electronic documentation from a health care provider or another state's Immunization Information System (IIS) such as the MyChart app or another consumer access application (app) that includes day, month, year, and product administered as well as the patient's name and date of birth.
4. A patient's U.S. Department of State's Vaccination Documentation form DS-3025 that includes a patient's verified past immunizations.

**Verbal presentations of data are not acceptable.** Please enter immunization data from these acceptable sources into a patient's record in your electronic health record (EHR) or directly into MIIC.

Remember that in addition to Minnesota data, MIIC regularly receives data for Minnesota residents for doses administered in Iowa, Wisconsin, and North Dakota. A patient may not yet be in MIIC because they have recently moved to Minnesota or do not have any recent immunizations administered in Minnesota. If a patient is found in MIIC, their associated immunization data still may not be in MIIC for several reasons, including: they received an immunization in another state/country that does not regularly send data to MIIC, the provider who administered the dose didn't enter it into their systems or MIIC, the data was entered by the provider into their systems but has not yet been sent to MIIC, the patient has opted out of MIIC, or the patient has locked their record to another provider.

For more information, review MIIC user guidance for looking up a client at Client Search and Printing Immunization Records (www.health.state.mn.us/people/immunize/miic/train/clientsearch.html) and entering immunization data at Adding Immunizations Not Using Inventory (www.health.state.mn.us/people/immunize/miic/train/addnoinv.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.

- 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)
  - CDC: COVID-19 Vaccination Training Programs and Reference Materials (www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf)
  - CDC: You Call the Shots (www.cdc.gov/vaccines/ed/youcalltheshots.html)
    Watch the "Vaccine Administration" e-Learn
  - CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases (www.cdc.gov/vaccines/pubs/pinkbook/index.html)
    Known as the "Pink Book"
  - How to Administer IM (Intramuscular) Injections (www.health.state.mn.us/people/immunize/hcp/admim.pdf)
  - Intramuscular (IM) Injection: Sites (https://youtu.be/PqSuCPnPeYE)
  - Preparing COVID-19 Vaccines for Administration (www.health.state.mn.us/diseases/coronavirus/vaccine/adminprep.pdf)
  - Preparing to Vaccinate Young Children: COVID-19 (www.health.state.mn.us/diseases/coronavirus/vaccine/pedstips.html)

- COVID-19 Vaccine Trainings for Health Professionals (www.health.state.mn.us/diseases/coronavirus/vaccine/training.html#supp)
  Immunization Basic Principles supplemental on-demand training for vaccine providers
- COVID-19 PPE and Source Control Grids (www.health.state.mn.us/diseases/coronavirus/hcp/ppegrid.pdf)
- One & Only Campaign (www.cdc.gov/injectionsafety/one-and-only.html)

# Emergency use authorization (EUA) fact sheets and vaccine information sheets (VISs)

## EUA fact sheets

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

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 give an EUA fact sheet to each recipient/parent/legal representative prior to vaccination. Be prepared to answer questions about the vaccine.

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

- Comirnaty and Pfizer-BioNTech COVID-19 Vaccine (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine)
  - Note: there may be different EUA fact sheets for each Pfizer formulation.
- Spikevax and Moderna COVID-19 Vaccine (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine)
  - Note: there may be different EUA fact sheets for each Moderna formulation.
- Novavax COVID-19 Vaccine, Adjuvanted (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted).
- Janssen COVID-19 Vaccine (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine)

## 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.

# COVID-19 vaccine reminders

For COVID-19 vaccines that need more than one dose for a primary series, it is important that people receive all doses, and that doses are the same vaccine product. Make every effort to keep the primary series doses within the recommended interval. If the interval is missed, the dose should be given as soon as possible, and the series does not need to be restarted. Providers should refer to: CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Overview of COVID-19 vaccination (www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines) to understand the interval between each dose for COVID-19 vaccine products that require more than one dose for a primary series and for booster doses.

Vaccination reminders are critical to ensure compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness. Use these tips for COVID-19 vaccine reminders:

- Make sure each person getting vaccinated knows how long they must wait in between their vaccinations.
- Make every attempt to schedule the next dose appointment at the time of the first dose, or schedule both appointments when scheduling the first appointment.
- Complete a COVID-19 vaccination record card (vaccine manufacturer, lot number, date of dose received, and the date the next dose is due) for each person who is vaccinated. Encourage them to keep the card and bring it to the next dose appointment.
- If the patient has a smartphone, ask them to take a photo of their vaccination card and/or enter the date when the next vaccine is due into their electronic calendar.
- Encourage enrollment in V-safe After Vaccination Health Checker (www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html), which use free text messaging to receive COVID-19 vaccine dose reminders.

**Using Minnesota Immunization Information Connection (MIIC) for vaccine reminders:**

- Record all vaccinations in MIIC within 24 hours after vaccine administration.
- Pull lists of people that need to complete the COVID-19 vaccine primary series or receive booster doses using the MIIC client follow-up functionality in MIIC. Information on client follow-up for COVID-19 vaccine is available at Client Follow-Up (www.health.state.mn.us/people/immunize/miic/train/followup.html).
- Partner with MDH to text your clients who are overdue for COVID-19 vaccines (second doses, additional doses, booster doses). This program is free to the participating provider and does not take a lot of resources to implement. Typically, a 30-minute conference call is all that's needed to set up the texting activity. For more information, please email the MIIC Help Desk at health.miichelp@state.mn.us. Please find more information on this project here at Reminder/Recall Using Text Messages (www.health.state.mn.us/diseases/coronavirus/vaccine/remindrecall.pdf).
- Look at your electronic health record or vaccine management tool to identify if there is a next 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

All COVID-19 vaccines currently approved or authorized in the United States (Pfizer-BioNTech, Moderna, Novavax, and Janssen) are effective at preventing severe disease, hospitalizations, and death from COVID-19.

## 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 and expectation. Patient instructions should include information specific to the product they are receiving. This information should include:

- 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).
- For vaccine(s) requiring two doses, the importance of receiving the second dose of vaccine to build an adequate immune response.
- What it means to be up to date with your COVID-19 Vaccines refer to: CDC: Stay Up to Date with Your COVID-19 Vaccines (www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html)

- The v-safe fact sheet and poster, found at CDC: V-safe Print Resources (www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html). V-safe is a CDC reporting tool that uses smartphones for active monitoring for COVID-19 vaccine safety and is available in multiple languages.
  - Learn more at V-safe After Vaccination Health Checker (www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html).

## 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 EUA fact sheet for recipients to view side effects listed for each vaccine product.

It is not recommended to routinely take over-the-counter fever or pain medication prior to vaccination to prevent symptoms following vaccination.

## 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. Antihistamines should not be taken before vaccination to prevent allergic reactions, as they do not prevent anaphylaxis and might mask cutaneous (skin) symptoms. Refer to CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Contraindications and precautions (www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications) 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 can be a life-threatening event. Know the early signs of anaphylaxis: throat closing sensation, swelling of throat, face or lips, hives or itching, stridor (high-pitched whistling sound), wheezing, coughing, dizziness, fainting, fast heart rate, low blood pressure, nausea, vomiting, diarrhea, and/or abdominal pain. CDC has a helpful poster on Recognizing and Responding to Anaphylaxis (www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf).

### Observation periods following vaccination

Providers should consider the following observation periods pertaining to every dose of vaccine given, including additional and booster doses.

- Consider waiting 30 minutes:
  - People with a contraindication to one type of COVID-19 vaccine who are receiving another type that has been deemed a precaution (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Novavax or Janssen vaccine).
  - History of non-severe, immediate (less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine*.
  - History of immediate allergic reaction of any severity to non-COVID-19 vaccines or injectable therapies.
  - History of anaphylaxis (due to any cause).
- Consider waiting 15 minutes: all other people, particularly adolescents.

* Non-severe allergic reactions may include urticaria or hives beyond the injection site and angioedema with visible swelling involving lips, facial skin, or skin in other locations.

Note: any angioedema affecting the airway, such as the tongue, uvula, or larynx, is considered a severe allergic reaction and a contraindication for COVID-19 vaccination.

### Emergency preparation

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). Learn more about how to prepare for anaphylactic reactions at CDC: Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination (www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.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.
  - COVID-19 vaccination locations should have at least three doses of epinephrine available at all times and a way to quickly replace doses.
- Have a signed hard copy of a plan and age-appropriate protocols for the medical management of a vaccine reaction. Ensure staff review the plan and protocol and are ready to carry it out before giving vaccinations or providing related services.
  - The Immunization Action Coalition has examples of emergency plans. Refer to Medical Management of Vaccine Reactions in Children and Teens in a Community Setting (www.immunize.org/catg.d/p3082a.pdf) and Medical Management of Vaccine Reactions in Adults in a Community Setting (www.immunize.org/catg.d/p3082.pdf) for more information.

## Report vaccine adverse events and administration errors

As with licensed vaccines, vaccines under an Emergency Use Authorization have the same requirements to report to the Vaccine Adverse Event Report System (VAERS) any situations, including serious adverse events, that occurred after vaccination. This is regardless of determination of cause. As part of the CDC COVID-19 Vaccination Program Provider Agreement, vaccination providers are required to report the following to VAERS:

- Vaccine administration errors, even if they did not involve an adverse effect.
- Serious adverse events:
  - Death.
  - A life-threatening adverse event.
  - An event requiring hospitalization or prolonged hospitalization.
  - Prolonged impact on a person's ability to perform daily activities.
  - A congenital anomaly/birth defect.
  - A significant medical event that may cause harm to a person and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults.
- Cases of COVID-19 (including vaccine breakthrough cases) that result in hospitalization or death.

Learn more about VAERS at CDC: Vaccine Adverse Event Reporting System (VAERS): How VAERS works (www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html#anchor_1616772696807. To submit an event, go to VAERS: Report an Adverse Event (vaers.hhs.gov/reportevent.html). There is a checklist on this page to help gather information needed when submitting a report (VAERS 2.0 Checklist [vaers.hhs.gov/docs/VAERS 2.0_Checklist.pdf]).

HIPAA permits reporting of vaccine adverse events and medical documentation to VAERS for public health purposes under 45 CFR, section 164.512(b), as authorized by 42 USC 300aa-25.

### Resources to assist clinicians in possible COVID-19 vaccine-related adverse events

**Urgent consults:** Health care providers can contact the CDC Emergency Operations Center at 770-488-7100 if they need an urgent COVID-19 vaccine safety consultation. In case of a health emergency, providers should call 911.

**Complex health situations following COVID-19 vaccination:** For complex vaccine safety questions, health care providers or health departments in the United States can request a consultation from the CDC: Clinical Immunization Safety Assessment (CISA) Project (www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) COVIDvax clinicians. For non-urgent concerns, providers may Contact CDC-INFO (wwwn.cdc.gov/DCS/ContactUs/Form).

## 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 lot number, 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 vaccine administration information such as:

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

If a vaccinated person misplaces their COVID-19 vaccination record card, providers that administered the vaccine should replace their card if requested.

# 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 for each COVID-19 vaccination that is administered.

## Data elements for COVID-19 vaccination reporting

These data elements are 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)
- Race/ethnicity*

*MDH requires providers to enter available race/ethnicity information into MIIC as part of their regular reporting for all patients who are getting vaccinated.

### Vaccine administration data

- Administration date
- CVX code
- CPT code (note: For Moderna boosters to be reported as a booster and not a third dose, the corresponding CPT code **MUST** be included)

- NDC (if known)
- MVX code
- Lot number
- Expiration date
- Body site
- Route of administration
- Responsible organization
- Administered at location
- Vaccination refusal (when appropriate)

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, as well as an MVX code. Verify that your organization has a process to routinely review rejection (ACK) messages.
- Upload the file via the user interface: Ensure you are submitting a CVX/CPT code pair, as well as the manufacturer code. 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.

Minnesota Statutes, chapter 144.3351 authorizes vaccine providers to share the required data elements with MDH, through MIIC, including race and ethnicity. Find Vaccine Administration Codes from CDC at Data Code Sets (www.cdc.gov/vaccines/programs/iis/code-sets.html). For more information on entering correct COVID-19 product information into MIIC, please review this resource: Entering COVID-19 Product Information in MIIC (www.health.state.mn.us/people/immunize/miic/train/entercovidproduct.pdf).

If you have any questions, please contact the MIIC Help Desk at health.miichelp@state.mn.us.

# Managing vaccine inventory

## Reporting vaccine inventory

MDH reports inventory to CDC weekly. To facilitate this reporting and identify inventory across the state, all COVID-19 vaccine that is redistributed needs to be reported to MDH within one week 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).

## Reporting vaccine wastage and spoilage

Tracking vaccine wastage is part of vaccine inventory. Sites are 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 vials at the time of the beyond use date (BUD) expiration, vaccine discoloration or particulates, unable to get the recommended number of doses out of a vial, etc.). Any vaccine determined to be nonviable (not usable) should be discarded immediately.

Registered COVID-19 providers must report vaccine wastage in MIIC within one week of wastage. There are two ways to report wastage/spoilage. Choose one method of reporting:

- Preferred: Submit this information in MIIC. More information is available at Reporting Nonviable COVID-19 Vaccine to MIIC (www.health.state.mn.us/diseases/coronavirus/vaccine/nonviablereport.pdf).

- If your organization is not able to use the preferred method of reporting via MIIC, you may use the PDF form, Minnesota Department of Health COVID-19 Nonviable Vaccine Form (www.health.state.mn.us/diseases/coronavirus/vaccine/nonviableform.pdf).

To report wasted vaccine to MIIC, you 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. When entering nonviable COVID-19 vaccine into MIIC, you may receive an email about returning vaccine. Please disregard the email. Returning vaccine is our process only for other, non-COVID-19 vaccines.

## Security and disposal of vaccine vials

It is no longer recommended to dispose of COVID-19 vaccine and vials as normal solid waste. Due to the increased threat of fake or counterfeit vaccines, CDC convened an interagency working group of medical professionals, suppliers, and law enforcement. The working group recommends vaccination sites take appropriate steps to properly dispose of empty and wasted vaccine vials and product packaging. The following recommended actions will protect empty and wasted COVID-19 vaccine vials and packaging from counterfeit efforts:

- Action 1 (**preferred method**): Treat vials and packaging similarly to medical waste by placing in red sharps container; or
- Action 2: Deface all, or safely crush, materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced, dispose with regular waste.

Vaccines are only available and administered through state-authorized vaccination locations. Non-medical companies or private people are not authorized to provide, sell, or administer vaccines. Any offers related to the sale or use of COVID-19 vaccines, not from a medical provider, should be considered suspicious and reported to the appropriate state or jurisdiction. This may include: State or local department of health, the U.S. Department of Health and Human Services, the Office of the Inspector General (oig.hhs.gov) online or at 1-800-HHS-TIPS, or Submit a Tip (www.fbi.gov/tips) to the Federal Bureau of Investigation.

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 for vaccine recipients. 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. As a reminder, COVID-19 vaccines are exempt from cost-sharing. MHCP also covers vaccine counseling that occurs during visits and for those COVID-19 vaccines they can administer. For details, refer to the MHCP Provider Manual: Immunizations and Vaccinations (www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136660). Please contact the MHCP Provider Call Center at 651-431-2700 with any related questions.

CDC will consider taking appropriate measures, including the possibility of rescinding the CDC provider agreement if a provider engages in any of the following:

- Administering COVID-19 vaccine at any out-of-pocket cost to the recipient.
- Denying anyone vaccination, or differentially reducing appointment access, based on the vaccine recipient's coverage status or network status.
- Charging an office visit or other fee if COVID-19 vaccination is the sole medical service provided.
- Requiring additional medical services to receive COVID-19 vaccination.
- Seeking any reimbursement, including through balance billing, from the vaccine recipient.

Additional resources:

- For more information on provider requirements visit CDC COVID-19 Vaccination Program Provider Requirements and Support (www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html).
- For more information regarding COVID-19 billing, refer to the Centers for Medicare & Medicaid Services: COVID-19 (www.cms.gov/covidvax-provider).
- Find vaccine administration codes from CDC at Data 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. Thank you for your dedication and efforts in working to overcome the devastating effects of COVID-19.