

# Transcript: COVID-19 Vaccination Provider Training Module 4

## FROZEN VACCINES (MODERNA)

12/22/2020

Welcome to the COVID-19 frozen vaccines module of MDH's COVID-19 Provider Trainings. If you have not completed Modules 1 and 2, please exit and complete those modules first. Remember to have your COVID-19 Vaccine Provider Guide with you as you view these trainings.

Information regarding Moderna COVID-19 vaccine is in Appendix B in the MDH Interim COVID-19 Vaccine Provider Guide. The information in this module is subject to change as more information is released and vaccine product information is updated. Please refer to the provider guide for the most current information.

This chart is in the provider guide and is a brief high-level overview of Moderna's frozen vaccine. Note the initial age indication, dose, route, and schedule. This vaccine has strict storage and handling requirements that must be followed so the vaccine remains viable and safe to use. Some things to note is that the COVID-19 vaccines are not interchangeable with each other, vaccine must be used within six hours once the vial has been punctured, and thawed vaccine cannot go back into the freezer.

Moderna COVID-19 vaccine is shipped frozen to the ordering facility at minus 20 degrees Celsius or minus 4 degrees Fahrenheit. Confirm vaccine vial quantity is correct and no vials are broken. Vaccine is in preservative-free multi-dose vials. A minimum order is 100 doses in a single carton. Moderna vaccine may be stored frozen for six months at minus 25 to minus 15 degrees Celsius or minus 13 to plus 5 degrees Fahrenheit until it's ready to use. Do not store on dry ice. For sites who also store varicella-containing vaccines, this temperature range is tighter. Once vaccine is removed from the freezer, it can be stored at refrigerator temperatures of 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit for up to 30 days. **Do not refreeze this vaccine once thawed!** Vials that are not punctured can be stored between 8 degrees to 25 degrees Celsius or 46 to 77 degrees Fahrenheit for up to 12 hours. Punctured vials must be discarded if the vaccine is not within used 6 hours from first entry.

MDH has specific guidance for vaccine if it is to be redistributed to another site. Frozen vaccine must be redistributed at refrigerated temperatures. Follow the COVID-19 Vaccine Redistribution and Off-site vaccination guide on the MDH website. The link is in the provider guide.

Each vial will have a lot number and a manufacturing date. To determine the expiration date of the vaccine vial, go to the Moderna website for expiration dates, enter the lot number, and press submit.

Remember, once the vial has been pierced, the vial will have a new beyond-use date or BUD that needs to be listed on the vial. Refer to the provider guide for more information on beyond-use dates.

Moderna COVID-19 vaccine is a two-dose series administered one month or 28 days apart. When scheduling patients for their second dose, schedule them at 28 days or later. The second dose has a grace period where the vaccine can be given 4 days early and still is considered valid. This vaccine is not interchangeable with other COVID-19 vaccine products. The vaccine should be administered alone with a minimum interval of 14 days before or after administration of any other vaccines. Refer to the provider guide for information if these recommendations were not followed. Lastly, if an administration error occurs, it is important to report it to the Vaccine Adverse Event Reporting System or VAERS.

The Interim COVID-19 Vaccine Provider Guide has information specific for COVID-19 mRNA vaccines. Refer to the main guide for information on special populations and people with known current or a history of COVID-19 infection.

It is a contraindication for people to receive the Moderna COVID-19 vaccine if they have a known history of a severe allergic reaction or anaphylaxis to any component of the vaccine. An ingredient list for the Moderna vaccine is listed in the provider guide. For precautions, any person with a history of severe allergic reaction or anaphylaxis to any vaccine or injectable therapy may receive the vaccine, but a risk assessment should be done to balance the risk versus benefit of vaccination. Allergies not related to vaccines or injectable therapies are not a contraindication or precaution and examples of these allergies are listed in the guide. Observe persons with a history of anaphylaxis (due to any cause) for 30 minutes and all other persons for 15 minutes following vaccination. Refer to the link in the guide for CDC's Interim Clinical Considerations for Use of mRNA COVID-19 vaccine.

Adverse reactions reported in a clinical trial after administration of Moderna COVID-19 vaccine include injection site pain, redness, and/or swelling; fatigue or feeling tired; headache; myalgia or muscle pain; arthralgia or joint pain; chills; nausea; vomiting; axillary or armpit swelling or tenderness; and fever. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 vaccine.

The vaccine's multiple-dose vial contains a frozen suspension that must be thawed prior to administration. It does not contain preservative which is why it must be discarded 6 hours after puncturing the vial. Use aseptic technique when working with vaccines. When you are preparing to vaccinate, remove the required number of vials from storage and thaw each vial before use. There are two options for thawing. First option is to thaw the vial for 2 hours and 30 minutes in refrigerated conditions between 2° to 8°C or 36° to 46°F. After thawing, let the vial stand at room temperature for 15 minutes before administering. The second option is to thaw vials at room temperature for one hour at temperatures between 15° to 25°C or 59° to 77°F. After thawing, do not refreeze vaccine.

To prepare vaccine doses, gently swirl the vial after thawing and between each withdrawal. **It is very important to not shake the vial.** This vaccine does not require reconstitution. Vaccine will be in a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the vials for other particulate matter and/or discoloration prior to administration and do not administer if present. Clean the stopper with a single-use alcohol swab.

To continue, use a 1 milliliter or 3 milliliter syringe, and withdraw a 0.5 milliliter dose from the multi-dose vial. After the first dose has been withdrawn from the multi-dose vial, the punctured vial should be stored between 2 to 25 degrees Celsius or 36 to 77 degrees Fahrenheit in the refrigerator or at room temperature for up to 6 hours. **Discard any unused vaccine after six hours from first puncture regardless of storage.** Do not refreeze this vaccine. Record the date and time on the Moderna COVID-19 vaccine vial label when the vial was first entered or pierced. CDC has beyond-use labels available on their Moderna webpage.

Before administering the vaccine, visually inspect each dose of the Moderna COVID-19 vaccine in the dosing syringe. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection verify the final dosing volume of 0.5 mL. Confirm there are no other particulates and that no discoloration is observed. Do not administer if the vaccine is discolored or contains other particulate matter. Administer the Moderna COVID-19 vaccine intramuscular.

There are a lot more resources coming available on both the CDC and Moderna websites that include materials for vaccine preparation, vaccine administration, and storage and handling. MDH will update our website with materials, so please check our site as well as the others frequently. When viewing the provider guide online, click on the links to go directly to the websites.

Check your understanding. Question 1. True or False: Moderna's frozen vaccine is stored at the same temperature as varicella-containing products.

2. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for \_\_\_\_\_ minutes following vaccination. Options: a. 15; b. 30; c. 45; d. 60

Answers to the questions. Question 1: False, Moderna vaccine's temperature range is -25° to -15°C (-13° to 5°F) which is narrower than for the range for varicella-containing vaccines which can be stored down to -50°C or -58°F. Question 2: B, Observe patients for 30 minutes to monitor for signs of anaphylaxis. Have appropriate medical treatment immediately available.

Finally, the MN Dept 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.



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