

Transcript: COVID-19 Vaccination Provider Training Module 3

ULTRA-COLD VACCINES

12/14/2020

Welcome to Module 3 which focuses on ultra-cold vaccine. The information in this module is subject to change as more information is released and vaccine product information is updated.

As of early December, there is one product that requires storage at ultra-cold temperatures. Information related to ultra-cold vaccine is located in the COVID-19 Vaccine Provider Guide in Appendix A.

This chart is in the provider guide and is a brief high-level overview of the Pfizer BioNTech's ultra-cold 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. COVID-19 vaccines are not interchangeable with each other. Patients need to receive the same product they received the first time.

This vaccine comes in a 2ml glass preservative-free multi-dose vial. It contains 0.45ml of frozen liquid drug. Once diluted, which is also known as reconstitution, it has 5 doses per vial. Vials come in a tray that holds 195 vials. Each tray has 975 doses of vaccine. The vaccine arrives in a thermal shipping container, also called a thermal shipper, that holds a minimum of one tray or up to 5 trays. This shipper can be used for temporary ultra-cold storage if an ultra-cold storage unit is not available.

When transferring vaccine between ultra-cold environments, such as from the thermal shipping container to an ultra-cold storage unit, there are key timelines to follow. If the vial tray lid is open or a vial tray has less than 195 vials, the vaccine can be at room temperature for up to 3 minutes. If the lid is closed on a vial tray containing 195 vials, the vaccine can be at room temperature for up to 5 minutes. In these situations, after the vial trays are returned to frozen storage, they must remain in ultra-cold frozen storage for a least 2 hours before they can be removed again.

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This vaccine will arrive from the manufacturer in a thermal shipper packed in dry ice. It is heavy, weighing about 81 pounds. Staff unpacking the shipper need to work in a well ventilated area and wear waterproof insulated or cryogenic gloves and safety glasses with side shields or safety goggles. The shipper needs to be inspected upon arrival with the inspection completed within 5 minutes. During inspection, you want to confirm the quantity of vaccine and that no vials are broken. Transfer vaccine trays to ultra-cold storage in less than 5 minutes. The shipper has a GPS-enabled temperature monitoring device. Be sure to follow the manufacturer's instructions for its use.

As mentioned, this vaccine product arrives from the manufacturer in a thermal shipping container. Once received, there are four options for storing the vaccine. In Option 1, the vaccine can be moved from the shipping container to an ultra-cold freezer that maintains temperatures at -60 to -80 degrees Celsius or -76 to -112 degrees Fahrenheit and can be stored there for up to six months. A continuous temperature monitoring device must be used to monitor the temperature.

In Option 2, the thermal shipper can be used to maximize its use by re-icing the shipper with pelleted dry ice within 24 hours of receiving the ultra-cold vaccine. Re-ice the shipper at a minimum of every five days making sure dry ice is consistently refilled to the top of the container. On day 30, the vaccine is placed in the refrigerator at temperatures of 2 to 8°C or 36 to 46°F where it is stable for 120 hours or 5 days. This means the vaccine can be stored for 30 days at ultra-cold temperatures and 5 days at refrigerated temperatures for a total of 35 days. If the vaccine is not used by then, it must be discarded.

Option 3 is an example of a shorter timeframe for using the shipper. Upon receiving the vaccine, the shipper is re-iced within 24 hours. After five days of ultra-cold storage, the vaccine is placed in the refrigerator where it is stable for 120 hours or 5 days for a total of 10 days.

It's very important for you to know that the shipper can only be opened twice per day for no more than three minutes at a time. If the shipper is left open longer than 3 minutes, the recommendation is to re-ice it more frequently. You are required to keep a log of when the shipper is opened. The vaccine must be monitored with a continuous temperature monitoring device that can read ultra-cold temperatures. If you do not have a device on-site, follow the manufacturer's instructions for using the device that came with the shipper. Once you no longer need the shipper, follow the manufacturer's instructions for its return. If you do not have a standard way to access dry ice, refer to the email listed in the provider guide and include the necessary information.

MDH has specific guidance for Pfizer BioNTech vaccine if it is to be redistributed to another site. Ultra-cold 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.

Pfizer BioNTech COVID-19 vaccine is a two dose series administered 3 weeks apart at Day 0 and Day 21. There is a four day grace period for the second dose. If administered on day 17-21, it will still be considered a valid dose. If it has been more than 21 days since the first dose, the second dose should be administered at the earliest opportunity, but no doses need to be repeated. This vaccine is not interchangeable with other COVID-19 vaccine products. However, if two doses of different messenger RNA COVID-19 products are administered, no other additional doses of either vaccine is recommended at this time. Pfizer BioNTech COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines. If this vaccine is inadvertently

administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine. Report vaccination errors to the Vaccine Adverse Event Reporting System or VAERS!

Please review the provider guide for information on special populations. This includes persons with underlying medical conditions, immunocompromised persons, people who have previously received passive antibody therapy for COVID-19, adolescents, and pregnant and breastfeeding women. The guide also provides guidance for people with current or a history of COVID-19 infection. Further information to be included in CDC's guidance.

Contraindication for this vaccine includes a severe allergic reaction or anaphylaxis to any component of the Pfizer-BioNTech COVID-19 vaccine. For precautions, CDC considers a history of severe allergic reaction or anaphylaxis to any vaccine or injectable therapy as a precaution. A risk assessment should be done to determine the type of reaction and certainty of information. Persons who have had a severe allergic reaction to another vaccine or injectable therapy may still be vaccinated but they should balance the unknown risks of a severe allergic reaction against the benefits of vaccination. Allergies not related to vaccines or injectable therapies such as food, pet, environmental, or latex allergies; and oral medications including the oral equivalents of injectable medications, are not a contraindication or precaution to vaccination.

Planning is crucial so vaccine is managed safely and to avoid wasting doses. Once the vaccine is removed from ultra-cold storage, either to the refrigerator or at room temperature, it must be used within a certain amount of time. If you will not be using a whole tray, remove vials quickly. Wear unsterile gloves when handling frozen vials and place them in a container. When removing a tray from the thermal shipper, remember it can only be open twice a day for 3 minutes at a time. An entire tray will take about 3 hours to thaw; a smaller number of vials may thaw more quickly. You can thaw the vaccine at room temperature for 30 minutes if needed immediately. Vials may be held at room temperature for no more than 2 hours prior to reconstitution. Do not place thawed vaccine back into an ultra-cold storage unit or thermal shipper.

Just like other vaccines that require reconstitution, this vaccine must use only the diluent specified by the manufacturer. Each vial is reconstituted with 1.8 milliliter or ml of 0.9% Sodium Chloride Injection. The ideal size of the diluent vial for this vaccine is 2mls. If using a larger volume vial of 0.9% Sodium Chloride, it must be used for ONE TIME dilution. After removing 1.8ml, the remaining diluent is discarded. DO NOT use bacteriostatic saline or other diluents. The diluent for this vaccine will be provided in an ancillary mixing kit along with syringes, needles, and other needed supplies.

Reconstitute the vaccine just prior to administration following these steps. Invert the vial gently 10 times to mix its liquid content. It's important to not shake the vial. Clean the top of the 0.9% Sodium Chloride vial of diluent and the Pfizer BioNTech multi-dose vial with single-use alcohol swabs. Insert a 21 gauge or narrower needle into the diluent vial and withdraw 1.8 ml. Then, add 1.8ml of the diluent into the vaccine vial. Before removing the needle from the vial, equalize the pressure in the vial by withdrawing 1.8ml of air into the empty diluent syringe.

Remove the needle and syringe from the vial, invert the vial, and gently mix 10 times. Again, do not shake the vial. Record the date and time of reconstitution on the label provided. Store reconstituted vaccine between 2° to 25°C or 35.6° to 77°F, which are refrigerated to room temperatures. Discard any

unused vaccine within 6 hours after reconstitution. It's important to remember that administering this vaccine after 6 hours of being reconstituted may cause harm as it poses a risk of bacterial infection.

The dose administered to patients is 30mcg in a volume of 0.3ml given intramuscularly (IM). The second 0.3ml dose should be given 21 days after the first dose with the same product used the first time. Using aseptic technique, clean the vaccine vial stopper with a single-use alcohol swab. Using a 1ml syringe, withdraw a 0.3ml dose from the reconstituted Pfizer BioNTech vaccine MDV. Remember, each MDV will contain five doses. After removing the 5 doses, do not use any remaining vaccine left in the vial. Discard the vial appropriately. Before administering the vaccine, inspect each dose in the dosing syringe. Reconstituted vaccine will be in an off-white suspension. Confirm the vaccine in the syringe has no particles or is discolored. Verify the final dosing volume of 0.3ml prior to administration.

Check your understanding. Question 1. True or false? Pfizer vaccine can only be redistributed at refrigerator temperatures. Question 2. Pfizer vaccine must be used within ____ hours of reconstitution. 2? 6? 10? Answers. Question 1, True, Pfizer vaccine can only be redistributed at refrigerator temperatures. Question 2, Pfizer vaccine must be used within 6 hours of reconstitution.

Thank you for viewing this training and for vaccinating your patients! Be sure to view all the available resources related to the Pfizer BioNTech product. If you have other COVID-19 products at your site, view the applicable module and related appendix in the provider guide. Thank you again.



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