

*Appendix C: Guidance and Skills Assessment Checklist for
Individuals Involved in Storage and Handling of the Pfizer-
BioNTech Covid-19 Vaccine*

NOTE: This training is in addition to guidance provided on routine storage and handling on the CDC website.

Update: [Pfizer-BioNTech vaccine may now be stored in a conventional freezer for up to 2 weeks or in the regular refrigerator at 2°C to 8°C \(35°F to 46°F\) for up to 31 days.](#) For freezer storage, it must be set to -25°C and -15°C. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

Specific training for [Storage and Handling of Pfizer-BioNTech COVID-19 Vaccine](#) is located on the CDC web site as well as on the [Pfizer-BioNTech manufacturer website](#). ALL guidance from CDC MUST be followed when storing and handling Pfizer BioNTech COVID-19 vaccine. Links to useful resources are linked below (note that some resources may not yet include the latest update on storing vials at conventional freezer temperatures):

1. [Storage and Handling Summary](#)
2. [Pfizer BUD Guidance and Labels](#)
3. [Freezer Storage Guidelines \(page 35\)](#)
4. [Delivery Checklist](#)
5. [Storage and Handling Labels](#)
6. [Vaccine Expiration Date Tracking Tool](#)
7. [Refrigerator Storage Temperature Log \(Celsius\)](#)
8. [Refrigerator Storage Temperature Log \(Fahrenheit\)](#)
9. [Ultra-Cold Vaccine Storage Temperature Log \(Fahrenheit\)](#)
10. [Ultra-Cold Vaccine Storage Temperature Log \(Celsius\)](#)
11. [Vaccine Storage Troubleshooting Record for temperature excursions](#)
12. [Dry Ice Safety](#)
13. [U.S Pharmacopeia \(USP\) COVID-19 Vaccine Storage and Handling Toolkit](#) (includes guidance for labeling individual syringes that are being transported off site)

Competency	Clinical skills, techniques, and procedures	Needs to Improve	Meets or Exceeds Expectations	Required Plan of Action
A Unpacking and moving vials to ULT Freezer or Using the Thermal Shipper (if	1. Upon receipt, disable GPS tracker by pressing the stop button on device. Inspect the package for damage and quantity. Report shipment issues immediately to supervisor.			
	2. Don dry ice gloves. Remove ice pod from shipper. Take vials out of payload sleeve to ULT freezer, this must be done in less than 5 minutes to prevent thawing.			

freezer is unavailable) for Pfizer-BioNTech COVID-19 vaccine <i>Only required for those involved in storage and handling</i>	3. When removing tray from thermal shipper, minimize the time the shipper is open to no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.			
	4. IF ULT FREEZER IS NOT AVAILABLE, Don dry ice gloves. Dispense ice pellets into shipper per icing instructions provided.			
	5. Close the box to ensure the box is sealed appropriately.			
	6. Add additional dry ice every five days accordingly.			
B <u>Storage and Handling outside ULT</u>	1. IF STORED IN FREEZER: Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. This beyond-use date replaces the manufacturer’s expiration date. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.			
	2. IF STORED IN FRIDGE: Fridge must be set to 2°C – 8°C (36°F and 46°F) for up to 31 days. Do NOT refreeze thawed vaccine.			
	3. IF STORED AT ROOM TEMPERATURE: Unpunctured vials cannot be kept at room temperature, up to 25°C (77°F), for more than 2 hours (including thaw time). The amount of time needed to thaw vaccine varies based on temperature and number of vials. Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours.			
	4. Vaccine vials should not be shaken. Right before use, the vaccinator should invert and evert the vials gently to mix. Take care not to shake any vials.			
	5. Report all wasted doses using the Vaccine Wastage Reporting Tool. This is required per the CDC agreement. https://redcap.vdh.virginia.gov/redcap/surveys/?s=YC743RTCMN			
C Vaccine Preparation & Dilution	Remove 1 vial for every 6 recipients. Thaw vaccine in the refrigerator or at room temperature. Amount of time needed to thaw vaccine varies based on temperature and number of vials. In refrigerator: Between 2°C and 8°C (36°F and 46°F). At room temperature (for immediate use): Up to 25°C (77°F).			

<p>Vials MUST be discarded if vaccine is not used within 6 hours of the time the vial is punctured and stored between 2-25° C (35-77° F) during this time. Unpunctured vials cannot be kept at room temperature (up to 25°C /77°F), for more than 2 hours (including thaw time). Unpunctured vials at room temperature must be diluted within 2 hours.</p>			
<p><i>Pfizer Vaccine must be diluted prior to use.</i></p>			
<p>1. Gather Supplies Required to Prepare Vaccine:</p> <ul style="list-style-type: none"> • 1 Vial Pfizer-BioNTech COVID-19 Vaccine • 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL) • 1 diluent syringe/needles (3 mL syringe/21 G needle rec.) • 6 dosing syringes/needles (1 ml syringe/IM injection needle) <i>1 vial = Six (6) 30 mcg doses in 0.3 ml injections</i> • Other ancillary materials such as swabs, gloves, PPE • Sharps container 			
<p>2. Invert vial gently ten times to mix. DO NOT shake. <i>The amount of time needed to thaw Pfizer-BioNTech COVID-19 Vaccine varies based on temperature and number of vials.</i></p>			
<p>3. Cleanse the stopper with single use antiseptic swab.</p>			
<p>4. Insert 1.8 ml of air into the 0.9% Sodium Chloride Injection, USP.</p>			
<p>5. With the needle still in the vial, withdraw 1.8ml of the 0.9% Sodium Chloride Injection, USP.</p>			
<p>6. Remove the needle from the Sodium Chloride and insert it into the thawed COVID-19 vaccine. Insert 1.8 ml of 0.9% Sodium Chloride Injection, USP (Bacteriostatic saline or other diluents must <u>not</u> be used).</p>			
<p>7. Ensure vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial.</p>			
<p>8. Remove the needle and discard the needle and syringe into the sharps container. IMPORTANT: Regardless of the volume of the diluent vial, it can only be used ONE TIME for dilution. (After 1.8 mL withdrawal, the remaining diluent MUST be discarded).</p>			
<p>9. Invert gently ten times to mix. Do not shake. If unable to get a 6th dose from the vial, report it as wastage.</p>			
<p>10. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter.</p>			

	11. Note the date and time the vaccine was mixed on the vial. Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), with minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours. <u>Discard any unused vaccine after 6 hours.</u> Do not return to freezer storage.			
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Plan of Action

Circle desired next steps and write in the deadline for completion, and date for the follow-up review.

1. Review site/clinic protocols.
2. Review manuals, textbooks, wall charts, or other guides.
3. Review package inserts.
4. Review vaccine storage and handling guidelines or videos.
5. Observe other staff with patients.
6. Read Vaccine Information Statements.
7. Be mentored by someone who has demonstrated appropriate skills.
8. Attend a skills training or other appropriate courses/training.
9. Other _____

File the Skills Assessment Checklist in the employee's personnel folder.

Plan of Action Deadline (if applicable): _____

Date of Next Review (if applicable): _____

Employee/Volunteer Signature & Date: _____

Supervisor Signature & Date: _____