Department of
Public Health
CITY OF PHILADELPHIA

Pfizer COVID Vaccine for 5–11-year-olds
&
COVID Vaccine Management Updates

***Just a reminder that guidelines for the COVID-19 vaccines are constantly evolving as the manufacturers and regulatory authorities get new information. Check your email regularly for updates from our team.**

Not getting our updates?
Email Vaccines@phila.gov to be added to our contact list.

Objectives

- Familiarize providers with the new Pfizer COVID vaccine for children 5 to 11 years of age
- Discuss access and consent for the COVID vaccine
- Provide guidance on booster dose eligibility and administration
- Provide an update on COVID vaccine management
- Share available resources

Pfizer COVID Vaccine for 5-11 Year Olds: Product Overview

Pfizer Pediatric Formulation

- Approved for children 5 years of age through 11 years of age
- Diluent will arrive as single-use 10ml vials
  - 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic) – DO NOT USE OTHER DILUENTS
- Ancillary kits will contain 25g/1ml syringes
- No ultra-cold storage is required to receive the Pfizer 5-11 vaccines

Description	Pfizer Pediatric Formulation
	Dilute Prior to Use
Age Group	5 to <12 years**
Vial Cap Color	ORANGE
Dose	10 mcg
Injection Volume	0.2 mL
Fill Volume (before dilution)	1.3 mL
Amount of Diluent* Needed per Vial	1.3 mL
Doses per Vial	10 doses per vial (after dilution)
Storage Conditions	
ULT Freezer (-90°C to -60°C)***	6 months
Freezer (-25°C to -15°C)	N/A
Refrigerator (2°C to 8°C)	10 weeks

Pfizer Pediatric Formulation: Diluent

- Orders of Pfizer pediatric vaccine include ancillary kits that contain 10mL diluent vials.
  - **These vials must only be used once** and **be discarded with the remaining content after each use**.
  - **Do not puncture diluent vials more than once.**

Ordering for this formulation

Starting Tuesday, 11/9/2021 sites will be able to order 100 dose packages of Pfizer 5-11 formulation (10 vials of 10 doses vials per order)

Order by Wednesday at 5:00 pm

Submit your order, temperature logs and reconciliation in PhilaVax to receive vaccine the following week

Monday – Wednesday Delivery

Orders will be delivered the following week Monday, Tuesday or Wednesday.

Delivery of this formulation

VACCINE WILL ARRIVE AT ULTRA-COLD TEMPERATURES ON DRY ICE**

VACCINE SHOULD BE STORED IN AN ULTRA-COLD FREEZER* OR MOVED TO THE FRIDGE

VACCINES SHOULD BE LABELED WITH A 10-WEEK BUD STICKER IF STORED IN THE FRIDGE.

*If vaccine arrives thawed, it cannot be placed at Ultra-low temps. It must be placed in the fridge!
**The shipper that is used to deliver the vaccine cannot be utilized for ultra-low cold storage.

Dos and Don’ts of Pfizer 5-11 Storage

DO

- Place doses in your regular fridge
- Place doses in an ultra-cold freezer (if you have one)
- Store doses for 10 weeks
- Return the DDL that comes with the thermal shipper to Pfizer

DO NOT

- Store in the freezer
- Use the thermal shipper for storage
- Use doses after the 10-week expiry
- Throw away DDL that comes with the thermal shipper

Wastage for this formulation

- Wastage should be reported for **anything less than 10 doses per vial** here:

  https://forms.monday.com/forms/bab1924c8fca2f668d1cc745b1476ecd?r=use1

Pfizer for 5-11 Preparation & Administration

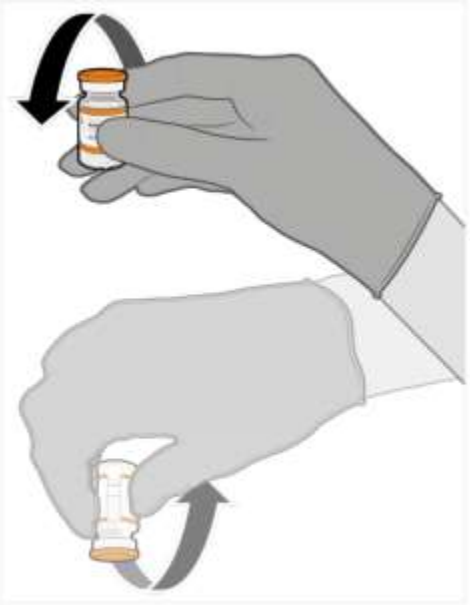
Pfizer Vaccine for 5-11 yo Preparation

Orange Cap

- ✓ Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states "Age 5y to < 12y."

- ✓ Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - ✓ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
  - ✓ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
  - ✓ Vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 12 hours prior to use.

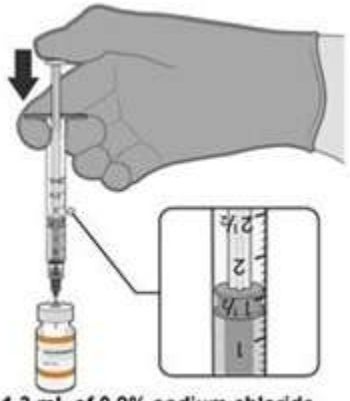
Pfizer Vaccine for 5-11 yo Preparation Orange Cap (con't)



Gently × 10

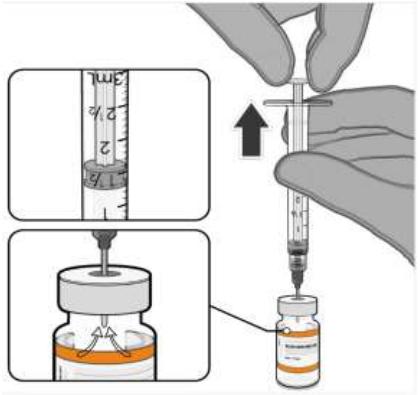
- ✓Before dilution invert vaccine vial gently 10 times.
- ✓**Do not shake**.
- ✓Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- ✓Do not use if liquid is discolored or if other particles are observed.

Pfizer Vaccine for 5-11 yo Preparation Orange Cap (con't)



1.3 mL of 0.9% sodium chloride injection

- ✓ Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- ✓ Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- ✓ Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- ✓ Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.



Pull back plunger to 1.3 mL to remove air from vial.

- ✓ Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.
- ✓ Discard any remaining saline and syringe. Do not use a single vial of saline to dilute more than one vial of vaccine.

Pfizer Vaccine for 5-11 yo Preparation Orange Cap (con't)

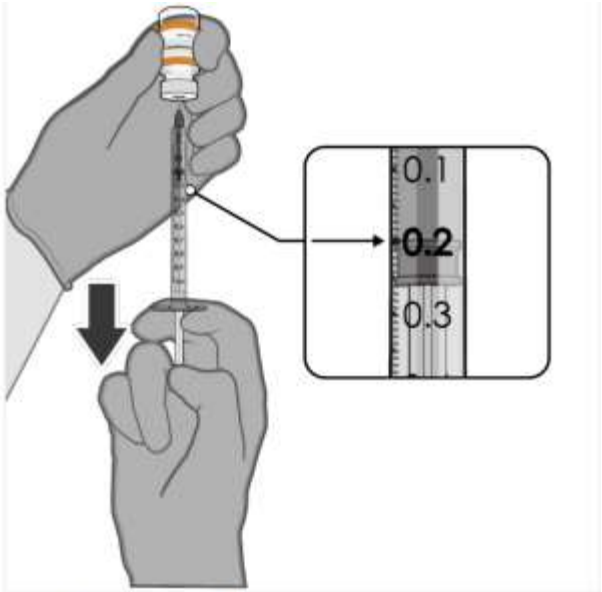
Gently × 10

- ✓ Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- ✓ **Do not shake.**
- ✓ Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

Use within 12 hours after dilution.

- ✓ Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- ✓ Store between 2°C to 25°C (36°F to 77°F).
- ✓ Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- ✓ Discard any unused vaccine 12 hours after dilution.

Pfizer Vaccine for 5-11 yo Administration Orange Cap



Withdraw 0.2 mL dose of vaccine.

- ✓ Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- ✓ Each dose must contain 0.2 mL of vaccine.
- ✓ If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
  - ✓ **Do not pool excess vaccine from multiple vials.**
- ✓ Immediately administer intramuscularly.

Training and Additional Tips for Success:

Pfizer Vaccine preparation and dosages are very different from other vaccines, so training and monitoring are key.

- ✓ Post the dilution directions and formulation chart near the vaccine preparation area.
- ✓ Double check the child's age, formulation and dosage when preparing the vaccine – use the formulation charts for reference.
- ✓ **Tighten** all luer lock connections before preparing vaccine.
- ✓ A 10 mL vial of 0.9% Sodium Chloride is distributed with each vial of Pfizer vaccine. The correct diluent must be used, and properly drawn up.
- ✓ The diluent and 3mL syringes/needles labeled for mixing vaccine in the ancillary supply kit are **for single use only. Do not reuse the 3ml syringes. Only puncture each diluent vial once. Discard after use.**
- ✓ The vials are small! Make sure needle tip is ABOVE the fluid level when equalizing the pressure AND BELOW the fluid level when drawing up.
- ✓ Check the fluid level in the vial before and after dilution.

Take your time and ask questions!

Vaccine Access

Eligibility for COVID Vaccine

- **Anyone in the approved age range, with no contraindications who presents for vaccination is eligible to receive vaccine**
  - The eligibility requirements for Vaccines for Children (VFC) **DO NOT** apply for COVID vaccine.
- **There is no charge for the COVID-19 vaccine**
  - COVID-19 vaccine was purchased by the federal government, therefore there is no charge or co-pay to anyone receiving the vaccine
  - Insurance is not required to be vaccinated
- **Proof of citizenship is not required to be vaccinated**
- **COVID vaccines can be co-administered with other vaccines**

Consent for Vaccination

On May 14, 2021, the Philadelphia Board of Health updated the Emergency Order Concerning COVID-19 Vaccine Information Statements to allow **individuals 11 years of age and older to consent to his or her own immunization with a COVID-19 vaccine under an Emergency Use Authorization (EUA), without the approval or consent of a parent or guardian.** In this case, an EUA Fact Sheet for Recipients and Caregivers substitutes for a Vaccine Information Statement (VIS).

COVID Vaccine Boosters

Why Boosters?

- Studies show after getting vaccinated against COVID-19, protection against the virus and the ability to prevent infection with the Delta variant may decrease over time.
- Data from clinical trials show that a **booster shot increased the immune response** in trial participants.

With an increased immune response, people should have improved protection against COVID-19, including the Delta variant.

mRNA Boosters

Eligibility Guidance:

Booster Dose	Six months after your second dose			
	Recommended if you are over the age of 65 or live in a nursing home	Recommended if you are aged 50 - 64 with underlying medical conditions that put you at risk of serious complications from COVID	You should consider a booster if you are age 18 - 64 and work as a healthcare worker, teacher, or work in a higher-risk occupational or institutional setting	You should consider a booster if you are age 18 - 49 and have underlying medical conditions

Administration	Pfizer 18 and up	Moderna 18 and up
Booster dose volume	0.3 mL	0.25 mL*

* Half the primary series dose

Janssen (J&J) Boosters

Booster Dose	**Two or more months after your first dose**
	Anyone 18 or older

<u>Administration:</u>
Full dose of 0.5 mL

Booster Summary: Eligibility & Administration

Vaccine	Pfizer	Moderna	Johnson & Johnson
Dose 1	Recommended for everyone 12 and older	Recommended for everyone 18 and older	Recommended for everyone 18 and older
Dose 2	Three weeks after your first dose	Four weeks after your first dose	No second dose recommended - considered fully vaccinated
Additional Dose	Four weeks after your second dose ONLY if you have certain immune deficiencies		No additional dose recommended
If you are eligible for a booster dose, you can receive a booster of any brand of vaccine. There is some evidence that a Moderna booster after Johnson & Johnson may be more protective than getting a second Johnson & Johnson dose.			

Vaccine	Pfizer and Moderna				Johnson & Johnson
Booster Dose	Six months after your second dose				Everyone who received J&J is eligible to receive a booster two months after their first dose
	Recommended if you are over the age of 65 or live in a nursing home	Recommended if you are aged 50 - 64 with underlying medical conditions that put you at risk of serious complications from COVID	You should consider a booster if you are age 18 - 64 and work as a healthcare worker, teacher, or work in a higher-risk occupational or institutional setting	You should consider a booster if you are age 18 - 49 and have underlying medical conditions	

	Pfizer *18 and up	Moderna 18 and up	Janssen (J&J) 18 and up
Dosage of booster	0.3 mL	0.25 mL*	0.5 mL

* Half the primary series dose

Heterologous (Mix and Match) Booster Dose

- A single booster dose of any of the FDA approved or authorized COVID-19 vaccines may be administered as a heterologous booster dose following completion of primary vaccination with a different FDA approved or authorized COVID-19 vaccine. Individual benefit-risk assessment may inform which booster product to administer.

- The dosing interval of a heterologous booster dose should be the same as authorized for vaccine booster doses for eligible persons (i.e., a heterologous booster dose should be administered at least 6 months following a primary series of Pfizer-BioNTech or Moderna and at least 2 months following a primary single-dose Janssen vaccine).

- Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose. In such situations, people who are moderately and severely immunocompromised may receive a total of four COVID-19 vaccine doses.

- Heterologous dosing is acceptable for booster doses only. It should not be considered for primary vaccine series or 3rd doses for moderately to severely immunocompromised persons.

Managing Multiple COVID Vaccine Products

COVID Vaccine Vials Snapshot

Manufacturer/Age range	Pfizer 5 to <12 years	Pfizer 12 and up	Moderna 18 and up	Janssen (J&J) 18 and up
Vial Picture/ Cap Color				
Injection Volume	0.2 mL	0.3 mL	0.5 mL	0.5 mL
Doses per Vial	10	6	14	5
Storage Conditions				
ULT Freezer [below -76°F (below -60°C)]	6 months	9 months	N/A	N/A
Freezer [-13°F to 5°F (-25°C to -15°C)]	N/A	2 Weeks	Until expiration date	N/A
Refrigerator [36°F to 46° F(2°C to 8°C)]	10 weeks	1 month (31 days)	30 days	Until expiration date

Understanding COVID Vaccine Dates

Storage before puncture	**Pfizer 5 to <12 years**	**Pfizer 12 and up**	**Moderna 18 and up**	**Janssen (J&J) 18 and up**
Expiration date location	6 months from the printed manufacture date	On vial	QR code on carton	QR code on carton
Valid when stored	ULT [below -60°C (below -76°F)]	ULT [below -60°C (below -76°F)]	Freezer [-25°C and -15°C (-13°F and 5°F)]	Fridge [2°C and 8°C (36°F and 46°F)]
Beyond Use Date (BUD) guidelines	Fridge [2°C and 8°C (36°F and 46°F)] for up to 10 weeks	Freezer [-25°C and -15°C (-13°F and 5°F)] for up to 2 weeks	Fridge [2°C and 8°C (36°F and 46°F)] for up to 30 days	N/A
		Fridge [2°C and 8°C (36°F and 46°F)] for up to 1 month (31 days)]	Room Temperature [8°C and 25°C (46° and 77°F)] for a total of 24 hours	

Understanding COVID Vaccine Dates: Pfizer Orange Cap Expiration Date

- Pfizer COVID-19 Vaccine: 5 through 11 years formulation (orange cap)
  - Formulation does NOT have expiration printed on vial
  - Instead, each vial has the lot number and **date of manufacture printed on the label**
  - **Date on the label is NOT the expiration date**
- **Pfizer does not have an expiration date look-up tool.** The QR code on the label is a link to the EUA factsheet.
- Peds (5–11) has a **6-month expiration** if held frozen **at ULT**
  - MFG date + 6 months = expiration date
    - This includes the month of manufacture—e.g., 8/2021 includes August. It does not start in September.
    - The expiration date (01/2022 in this example) will be in PhilaVax when you accept your shipment.

Understanding COVID Vaccine Dates: Beyond Use Date (BUD)

- The BUD date <u>cannot</u> be beyond the expiration date:

✓	Today	BUD	Expiration date	

✗	Today		Expiration date	BUD

- Vaccine <u>cannot</u> be used after the expiration date no matter where it was stored
  - Ex. If your Pfizer vaccine expired today and has been stored in an ULT freezer it <u>cannot</u> be moved to freezer or fridge for future administration.
- As new stability data becomes available the expiration date may be extended for the different vaccines.

Handling Open Vials

	Pfizer 5 to <12 years	Pfizer 12 and up	Moderna 18 and up	Janssen (J&J) 18 and up	
Storage temperature after puncture	Refrigerated to Room Temperature 2°C to 25°C (36°F to 77°F)	Refrigerated to Room Temperature 2°C to 25°C (36°F to 77°F)	Refrigerated to Room Temperature 2°C and 25°C (36°F and 77°F)	Refrigerated 2°C and 8°C (36°F and 46°F)	Room Temperature 9°C and 25°C (47°F and 77°F)
Time until must discard	12 hours	6 hours	12 hours	6 hours*	2 hours*

*Total time not to exceed 6 hours.

(A Few) Lessons Learned

- **Write it down.** There is a lot to keep track of for the COVID vaccines. Over the course of this response PDPH has developed (and revised) a number of documents to track the movement of vials for clinics. ***Find what works for your practice.***

- **Don't mix vials with different Beyond Use Dates (BUD) or Lot Numbers.**

- **Post the Vaccine Overview and Formulation Chart** in your vaccine preparation area and reference it often when preparing doses.

Reporting Wastage

Manufacturer	Dose	Was the dose extracted in full?	Is it counted as waste?
Pfizer	6th dose	Yes	No
		No	Yes
Moderna 11 dose vial	10th dose	Yes	No
		No	Yes
	11th dose	Yes	No
		No	No
Moderna 15 dose vial	13th dose	Yes	No
		No	Yes
	14th dose	Yes	No
		No	Yes
	15th dose	Yes	No
		No	No
J&J/Janssen	5th dose	Yes	No
		No	Yes

- **All COVID-19 vaccine providers are required to report COVID-19 vaccine wastage to the Philadelphia Department of Public Health (PDPH) daily.** Wastage includes any EUA approved dose per vial that is not administered for any reason.
- **For Pfizer, wasted doses will be considered anything under 6 doses drawn per vial.**
- The wastage reporting guide and link to the reporting form can be accessed here: https://vax.phila.gov/index.php/notices/covid-19-vaccine-wastage-guidance-2/
- ***Wastage does not negatively impact a provider but is simply a means for accounting for inventory.***

Moderna 14 Wastage

Continue to report wastage of whole doses up to 14 doses.

- Example: Moderna 14 – If 4 doses are administered from a single vial, 10 doses should be reported as waste through currently existing channels.

Do NOT count half doses as waste when reporting.

- Example: During a full day in a clinic, 1 primary dose is administered, and 5 booster half-doses are administered from a Moderna 14 vial.

COUNT the **total** number of doses administered, regardless of volume or series and subtract this from the total number of identified doses in the vial. For a Moderna 14 dose vial – a total of 6 people are vaccinated (1 primary and 5 booster shots); 14 - 6 = 8 doses wasted.

Vial size – number of vaccines administered = waste

DO NOT PUNCTURE VIAL MORE THAN 20 times!!

Modern 14 Wastage Table

Half Doses \ Full doses	0	1	2	3	4	5	6	7	8	9	10	11	12	13
0	14	13	12	11	10	9	8	7	6	5	4	3	2	1
1	13	12	11	10	9	8	7	6	5	4	3	2	1	0
2	12	11	10	9	8	7	6	5	4	3	2	1	0	
3	11	10	9	8	7	6	5	4	3	2	1	0		
4	10	9	8	7	6	5	4	3	2	1	0			
5	9	8	7	6	5	4	3	2	1	0				
6	8	7	6	5	4	3	2	1	0					
7	7	6	5	4	3	2	1	0						
8	6	5	4	3	2	1	0							
9	5	4	3	2	1	0								
10	4	3	2	1	0									
11	3	2	1	0										
12	2	1	0											
13	1	0				No Waste Reported								
14	0													
15														
16														
17														
18														
19														
20														

Green Area = No Waste Reported

Vaccine Overview

[COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals (cdc.gov)]

COVID-19 Vaccine

Quick Reference Guide for Healthcare Professionals

The table below provides basic information on the proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States. For additional information and detailed clinical guidance go to the manufacturer's and CDC's webpages listed.

		Pfizer	Moderna	Janssen
GENERAL	EUA	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
GENERAL	CDC Vaccine Information	www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
GENERAL	Manufacturer Contact Information	**Website:** www.cvdvaccine.com **Medical information:** 800-438-1985 **Customer service:** 800-879-3477	**Website:** www.modernatx.com **Medical information:** 866-663-3762	**Website:** www.vaxchecks.com **Medical information:** 1-800-565-4008
STORAGE & HANDLING	How supplied	**Multidose vial:** 6 doses	**Multidose vial:** Maximum of 11 doses **Multidose vial:** Maximum of 15 doses	**Multidose vial:** 5 doses
STORAGE & HANDLING	Diluent	0.9% sodium chloride (preservative-free, normal saline) provided in the ancillary kit. Do NOT use other diluent.	None	None
STORAGE & HANDLING	Storage Temperatures: Before Puncture	**Between:** -80°C and -60°C (-112°F and -76°F) until the expiration date -25°C and -15°C (-13°F and 5°F) for up to 2 weeks 2°C and 8°C (36°F and 46°F) for up to 5 months (31 days).	**Between:** -50°C and -15°C (-58°F and 5°F) until the expiration date 2°C and 8°C (36°F and 46°F) for up to 30 days 8°C and 25°C (46° and 77°F) for a total of 24 hours	**Between:** 2°C and 8°C (36°F and 46°F) until the expiration date.
STORAGE & HANDLING	Storage Temperatures: After puncture	**Between:** 2°C to 25°C (36°F to 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.	**Between:** 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.	**Between:** 2°C and 8°C (36°F and 46°F) for up to 6 hours. 8°C and 25°C (47°F and 77°F) for up to 2 hours. Discard any unused vaccine after these time frames.
STORAGE & HANDLING	Transport Temperatures: Before Puncture	**Between:** -80°C and -60°C (-112°F and -76°F) -25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F)	**Between:** -50°C and -15°C (-58°F and 5°F) 2°C and 8°C (36°F and 46°F) for up to 12 cumulative hours.	**Between:** 2°C and 8°C (36°F and 46°F)
STORAGE & HANDLING	Transport Temperatures*: After Puncture	**Between:** 2°C to 25°C (36°F to 77°F) for up to 6 hours.	**Between:** 2°C and 25°C (36°F and 77°F) for up to 12 hours.	**Between:** 2°C and 8°C (36°F and 46°F) for up to 6 hours.
	Type of Vaccine	mRNA	mRNA	Viral vector
	Age Indications	12 years of age and older	18 years of age and older	18 years of age and older
	Schedule†	2 doses, separated by 21 days. Both doses must be Pfizer-BioNTech vaccine	2 doses, separated by 28 days. Both doses should be Moderna vaccine	1 dose only
	Dosage	0.3 mL	0.5 mL	0.3 mL
	Needle gauge/length	**12 through 18 years of age:** 22–25 gauge, 1" **19 years of age and older:** 22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"

*CDC recommends transporting vaccine at refrigerated or frozen temperatures.

†COVID-19 vaccines and other vaccines may be administered on the same day, as well as within 14 days of each other. When deciding if to administer COVID-19 vaccines and other vaccines, providers should consider whether the patient is believed to be at risk of becoming infected or recommended vaccines, their risk of vaccine-preventable diseases (e.g., during an outbreak), and the reactogenicity profile of the vaccines.

06/30/2021

COVID-19 Vaccine

Quick Reference Guide for Healthcare Professionals

		Pfizer	Moderna	Janssen
VACCINE ADMINISTRATION	Route	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
VACCINE ADMINISTRATION	Site	Deltoid	Deltoid	Deltoid
VACCINE ADMINISTRATION	Thawing Frozen Vaccine	**Between:** 2°C and 8°C (36°F and 46°F) or Room temperature up to 25°C (77°F) **Do NOT** refreeze thawed vaccine.	**Between:** 2°C and 8°C (36°F and 46°F) or 8°C to 25°C (46°F to 77°F) **Do NOT** refreeze thawed vaccine.	N/A
VACCINE ADMINISTRATION	Mixing Vaccine	Mix vaccine with 1.8 mL of 0.9% sodium chloride (preservative-free, normal saline)	**Do NOT** mix with any diluent	**Do NOT** mix with any diluent
VACCINE ADMINISTRATION	Contraindications/ Precautions	**Contraindications** • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine • Immediate allergic reaction† of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine **Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 vaccine (see footnote).* Persons who have a contraindication to Janssen COVID-19 vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).† **Precautions** • Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine. • History of an immediate allergic reaction† to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies) ◦ This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction. • People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa. (see footnote).† • Moderate to severe acute illness See Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html		
VACCINE ADMINISTRATION	Post-Vaccination Observation	**30 minutes:** Persons with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy or a history of anaphylaxis (from any cause) **15 minutes:** All other persons		
VACCINE ADMINISTRATION	Most common adverse events	**Injection site:** pain, swelling, redness **Systemic:** fatigue, headache, muscle pain, chills, fever, joint pain	**Injection site:** pain, swelling, redness **Systemic:** fatigue, headache, muscle pain, chills, fever, nausea, joint pain	**Injection site:** pain, redness, swelling **Systemic:** fatigue, headache, muscle pain, nausea, fever

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

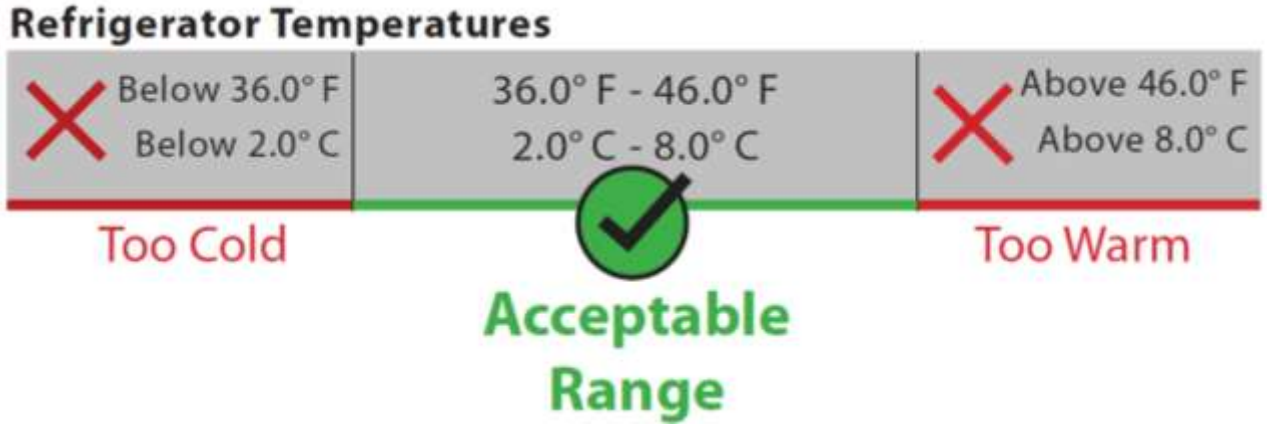
†Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments who also request a consultation from the Clinical Immunization Safety Assessment (CISA) via Project https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

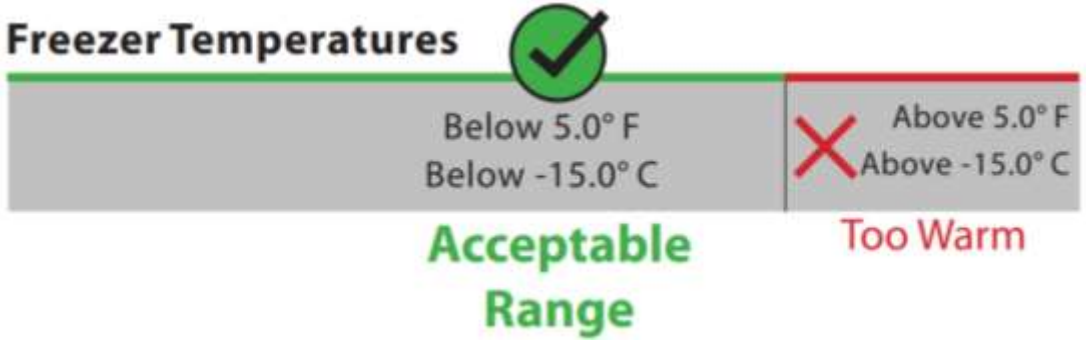
- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose but have a contraindication to a second dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

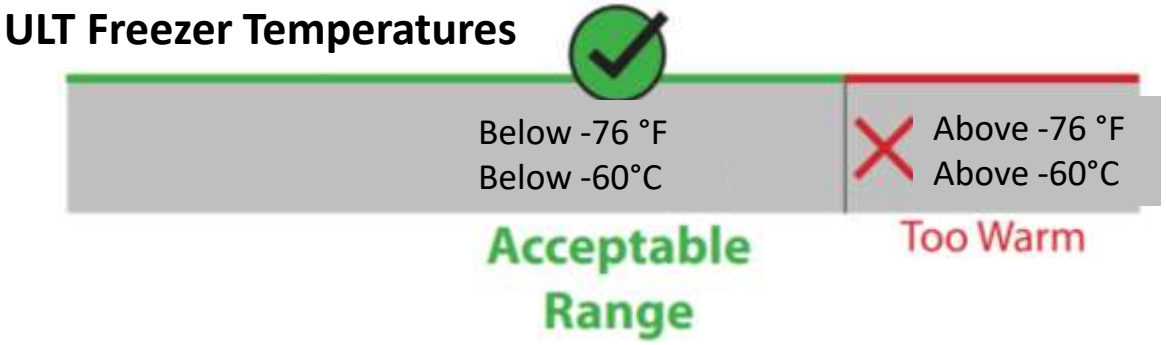
06/30/2021

COVID Vaccine Storage & Handling: Updates and Reminders

Vaccine Temperature Ranges







Storage and Handing Page

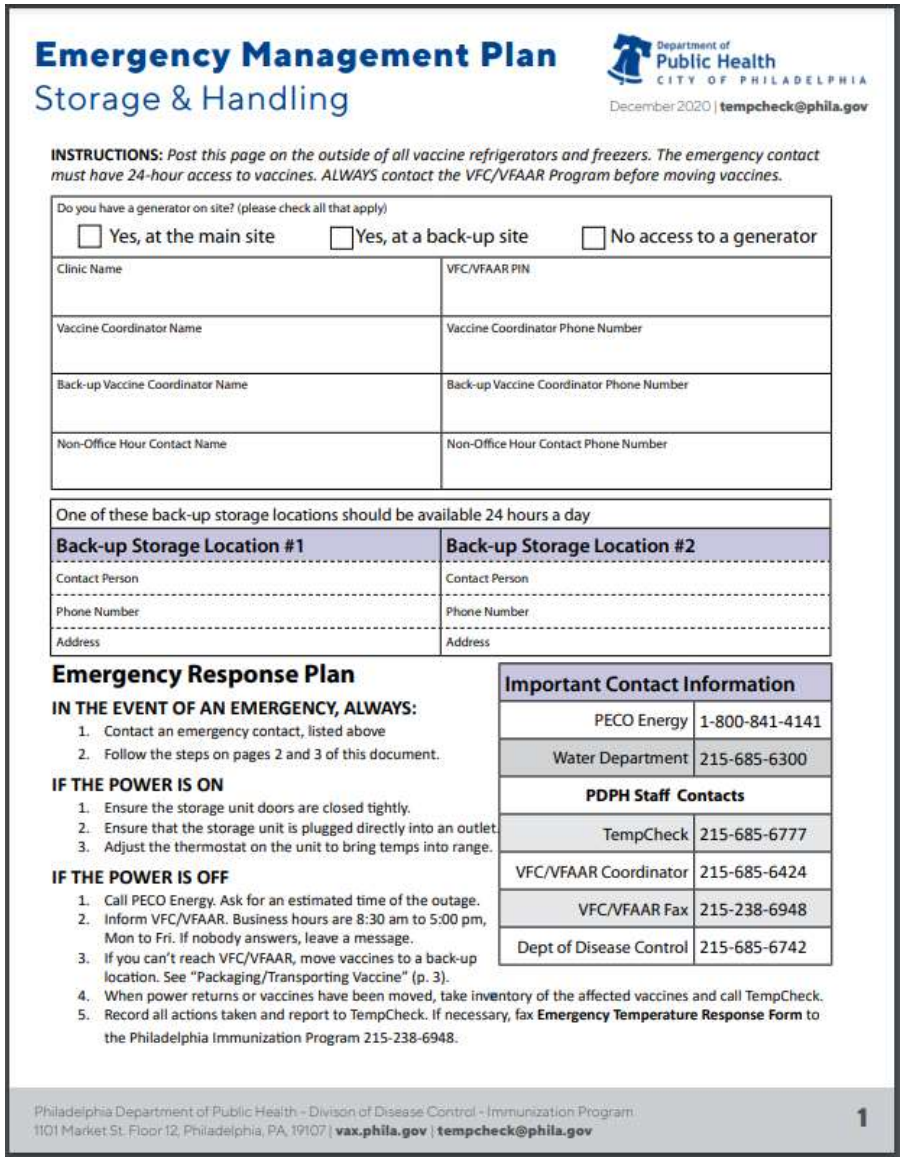
- Provides answers to most storage and handling questions.
- Access to downloadable resources:
  - Paper Temperature Logs
  - Vaccine Management Plan
  - Emergency Management Plan
  - Out of Range Temperature Response
  - Recommendations for Outdoor clinics

https://vax.phila.gov/index.php/storage-handling/

Temperature Documentation: Electronic

- Temperature data must be reported to the Immunization Program:
  - Every time you place an order
  - Whenever there is an out-of-range temperature alarm (aka temperature excursion)
  - Every 30 days (if you have not placed an order or had a temperature excursion)

Emergency Management Plan (EMP)



Emergency Management Plan
Storage & Handling

Department of Public Health
CITY OF PHILADELPHIA
December 2020 | **tempcheck@phila.gov**

INSTRUCTIONS: *Post this page on the outside of all vaccine refrigerators and freezers. The emergency contact must have 24-hour access to vaccines. ALWAYS contact the VFC/VFAAR Program before moving vaccines.*

Do you have a generator on site? (please check all that apply)
☐ Yes, at the main site ☐ Yes, at a back-up site ☐ No access to a generator

Clinic Name	VFC/VFAAR PIN
Vaccine Coordinator Name	Vaccine Coordinator Phone Number
Back-up Vaccine Coordinator Name	Back-up Vaccine Coordinator Phone Number
Non-Office Hour Contact Name	Non-Office Hour Contact Phone Number

One of these back-up storage locations should be available 24 hours a day

Back-up Storage Location #1	Back-up Storage Location #2
Contact Person	Contact Person
Phone Number	Phone Number
Address	Address

Emergency Response Plan

IN THE EVENT OF AN EMERGENCY, ALWAYS:
1. Contact an emergency contact, listed above
2. Follow the steps on pages 2 and 3 of this document.

IF THE POWER IS ON
1. Ensure the storage unit doors are closed tightly.
2. Ensure that the storage unit is plugged directly into an outlet.
3. Adjust the thermostat on the unit to bring temps into range.

IF THE POWER IS OFF
1. Call PECO Energy. Ask for an estimated time of the outage.
2. Inform VFC/VFAAR. Business hours are 8:30 am to 5:00 pm, Mon to Fri. If nobody answers, leave a message.
3. If you can't reach VFC/VFAAR, move vaccines to a back-up location. See "Packaging/Transporting Vaccine" (p. 3).
4. When power returns or vaccines have been moved, take inventory of the affected vaccines and call TempCheck.
5. Record all actions taken and report to TempCheck. If necessary, fax **Emergency Temperature Response Form** to the Philadelphia Immunization Program 215-238-6948.

Important Contact Information	
PECO Energy	1-800-841-4141
Water Department	215-685-6300
PDPH Staff Contacts	
TempCheck	215-685-6777
VFC/VFAAR Coordinator	215-685-6424
VFC/VFAAR Fax	215-238-6948
Dept of Disease Control	215-685-6742

Philadelphia Department of Public Health - Division of Disease Control - Immunization Program
1101 Market St. Floor 12, Philadelphia, PA, 19107 | **vax.phila.gov** | **tempcheck@phila.gov**
1

- Must be:
  - Posted the on or near the site's vaccine storage units.
  - Updated whenever there are changes at the site or updates to the document.
  - Familiar to all staff who work with the vaccines.
- Last two pages outline the steps for emergency transport

Emergency Vaccine Transport Checklist

Sites need to be prepared and not wait for an emergency!

Make sure they have all the needed supplies on hand in case vaccine needs to be moved.

Wherever the vaccines go, the DDL goes!

Purpose Built Cooler

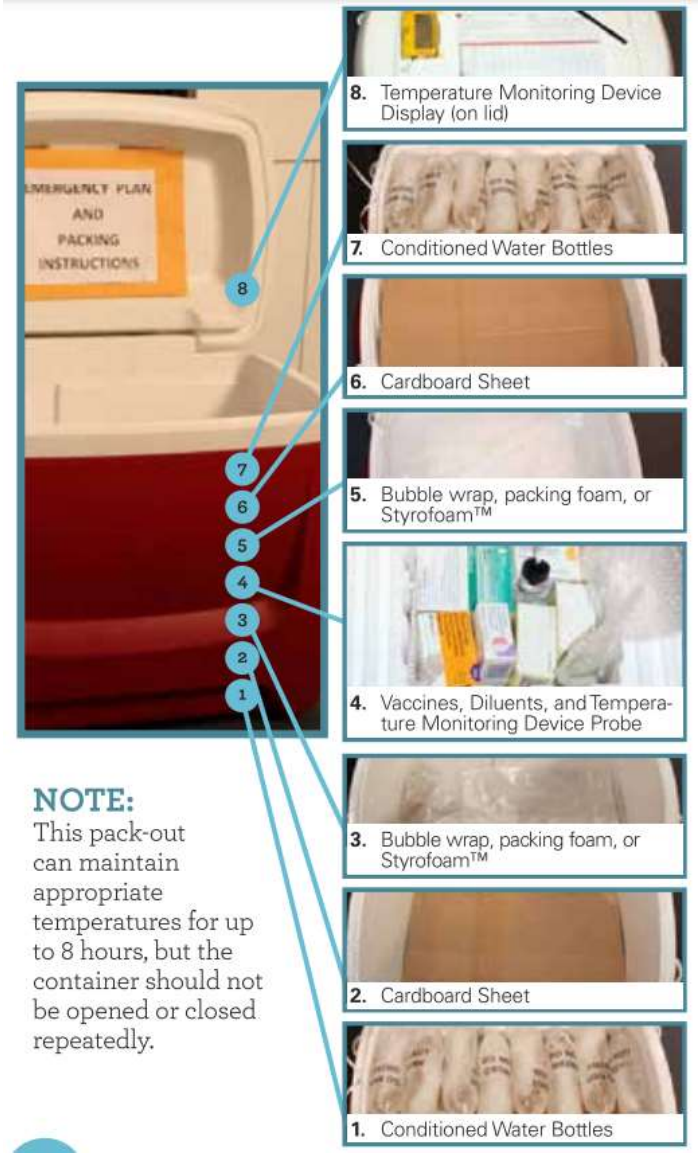
OR

Hard-sided cooler with…

- Conditioned water bottles
- Ice packs (for frozen vaccine)
- Bubble wrap and 2 layers of corrugated cardboard
- DDL (in an emergency, sites should remove the one monitoring their unit to go with the vaccine and request a back-up DDL from our office.

- NEVER use icepacks or dry ice with refrigerated vaccines

The Vaccine's original Styrofoam packaging can be used as a last resort



Vaccine Transport

- You must:
  - Have a signed redistribution agreement before moving COVID doses to another site
  - Always get permission before transporting federally funded vaccine

- For non-emergency vaccine transport, please contact VaxontheGo@phila.gov to request cooler for vaccine transport

Resources

Immunization Program COVID-19 Vaccine Page

Visit our web page for the most up to date information on COVID vaccine access in Philadelphia:

https://vax.phila.gov/index.php/covid-19/

Resources for Parents and Patients

- The CDC website for children and adolescents can be accessed here:

COVID-19 Vaccines for Children and Teens | CDC

(https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Frecommendations%2Fadolescents.html)

- Booster dose guidance:
  - CDC: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html
  - PDPH: https://www.phila.gov/2021-09-24-covid-vaccine-booster-doses-are-now-approved/

- Materials are available to order from our program, many translated in a several languages, here: https://philadph.formstack.com/forms/covid19_vaccine_materials_ordering_form

COVID Vaccine Resources For Providers

- COVID-19 Vaccine FAQs for Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/hcp/faq.html
- CDC Provider Training & Education page: https://www.cdc.gov/vaccines/covid-19/training-education/index.html
- Immunization Action Coalition (IAC) COVID Vaccine resource page: https://www.immunize.org/covid-19/
- COVID Vaccine Overview: https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf?ACSTrackingID=USCDC_11_8-DM58233&ACSTrackingLabel=ACIP%3A%20Vaccine%20Recommendation%20Updates%20-%205%2F25%2F2021&deliveryName=USCDC_11_8-DM58233

Pfizer (5 -11) **(will provide updates as info is released)**

- Pfizer-BioNTech website: https://www.cvdvaccine-us.com/
- CDC Pfizer Webpage: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
- Pfizer EUA for Recipients: https://www.fda.gov/media/153717/download
- Pfizer EUA for Healthcare Providers: https://www.fda.gov/media/153714/download
- BUD Tracking Label: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/Pfizer_PED_BUD-Labels.pdf

Pfizer (12+)

- Pfizer-BioNTech website: https://www.cvdvaccine-us.com/
- CDC Pfizer Webpage: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
- Pfizer EUA (12 -15): https://www.fda.gov/media/153713/download
- Pfizer EUA for Healthcare providers: https://www.fda.gov/media/153716/download
- Prescribing information (16+): http://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf
- BUD Tracking Label: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

Moderna 18 and up

- Moderna Website: https://www.modernatx.com/
- CDC page: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
- FDA: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine
- EUA: https://www.fda.gov/media/144638/download
- BUD Tracking Label: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/bud-tracking-labels.pdf

Janssen (aka Johnson & Johnson or J&J) 18 and up

- Janssen Website: https://www.janssencovid19vaccine.com/hcp.html
- CDC Product page: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
- FDA Product page: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
- EUA: https://www.fda.gov/media/146305/download

PDPH Storage and Handling Resources

- **Storage and Handling page:** https://vax.phila.gov/index.php/storage-handling/
- **Storage and Handling Toolkit:** https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- **DDL Start Stop Guide:** https://vax.phila.gov/wp-content/uploads/2020/12/v1DDLStopStartGuide_SH_11-30-20.pdf
- **Emergency Management Plan:** https://vax.phila.gov/wp-content/uploads/2021/03/v1EmergencyManagementPlan_SH_12-3-201-1.pdf
- **Transport Guide:** https://vax.phila.gov/wp-content/uploads/2021/05/v2VaccineTransportGuide_COVID19Program_3-16-21.pdf
- **Outdoor Clinic Guide:** https://vax.phila.gov/wp-content/uploads/2021/08/v7OutdoorVaxClinics_COVID19_8-19-21.pdf

Questions?