

## STORAGE AND HANDLING 21 SEPTEMBER 2023

#### **Topics** Covered

- Vaccine Storage
- Temperature Monitoring
- Temperature Excursions
- Available Presentations of COVID-19 Vaccine
  - Novavax
  - Moderna
  - Pfizer
- Ultra Cold Considerations
- Clearing Out Unauthorized COVID-19 Vaccine
- Resources

#### Vaccine Storage

- Position vaccines and diluents 2 to 3 inches from the sides of the unit
- Store each type of vaccine or diluent in its original packaging and in a separate container
- Label shelves and containers to clearly identify where each type of vaccine and diluent is stored
- Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates
- Ensure all inventories from CVP, AVP and Private Purchase vaccines are separated and Clearly Marked

### Temperature Monitoring

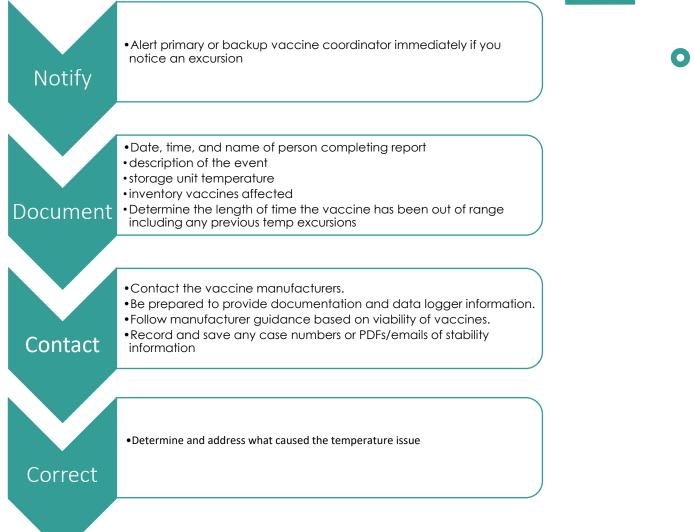
- All units should have a Temperature Monitoring Device
  - Ensure digital data logger (DDL) is working properly and the storage isn't full
  - DDL should be recalibrated every 2-3 years
- ALWAYS keep backup paper temperature logs
- When submitting temperature logs make sure to review:
  - The correct month is being uploaded
  - The correct units is being uploaded
  - All days of the month are included
  - If there are excursions on the temperature log it needs to be noted and the excursion process followed

#### Temperature Monitoring

COVID-19 vaccine must be kept within certain temperature ranges. Acceptable temperatures are displayed below for each type of storage unit:

	Acceptable range (C)	Acceptable range (F)
Ultracold freezer	-90° to –60° C *	-130° to –76° F
Standard freezer	-50° to –15° C	-58° to 5° F
Refrigerator	2° to 8° C	36° to 46° F

#### Addressing Temperature Excursions



#### • <u>Vaccine Temperature Excursion Guide</u> (wa.gov)

#### 2023-2024 COVID-19 Vaccine Product Characteristics and Information

Vaccine Manufacturer/Brand Name	Age Group	Vial Cap/ Label Color	Dose	Dose Volume	Amount of Diluent Needed per Vial	Doses per Vial
Pfizer-BioNTech/Comirnaty 2023-2024 Formula adolescent/adult single-dose vial	12 years+	Gray	30 mcg	0.3 mL	NO DILUTION	10/package
Pfizer-BioNTech 2023-2024 Formula pediatric single-dose vial	5-11 years	Blue	10 mcg	0.3 mL	NO DILUTION	10/package
Pfizer-BioNTech 2023-2024 Formula pediatric/infants multi-dose vial	6 months- 4 years	Yellow	3 mcg	0.3 mL	1.1 mL	3
Moderna/Spikevax 2023-2024 Formula adolescent/adult single-dose vial	12 years +	Dark Blue	50 mcg	0.5mL	NO DILUTION	10/package
Moderna 2023-2024 Formula pediatric single-dose vial	6 months-11 years	Dark Blue Cap/	25 mcg	0.25mL	NO DILUTION	10/package
Novavax adolescent/adult primary series	12 years +	Royal Blue	5 mcg rS and 50 mcg of Matric-M adjuvant	0.5 mL	NO DILUTION	10
Deauthorized: Pfizer-BioNTech adolescent/adult bivalent	12 years +	Gray	30 mcg	0.3 mL	NO DILUTION	6
Deauthorized: Pfizer-BioNTech adolescent/adult bivalent single-dose vial	12 years +	Gray	30 mcg	0.3 mL	NO DILUTION	10/package
Deauthorized: Pfizer-BioNTech pediatric bivalent	5-11 years	Crange	10 mcg	0.2 mL	1.3 mL	10 (after dilution)
Deauthorized: Pfizer-BioNTech pediatric/infants bivalent	6 months- 4 years	Maroon	3 mcg	0.2 mL	2.2 mL	10 (after dilution)
Deauthorized: Moderna adolescent/adult bivalent	12 years +	Dark Blue Cap/     Gray Label	50 mcg	0.5mL	NO DILUTION	5
Deauthorized: Moderna pediatric bivalent	6 months- 11 years	Dark Blue Cap/     Gray Label	25 mcg	0.25 mL	NO DILUTION	10
Deauthorized: Moderna pediatric/infants bivalent	6 months- 5 years	Magenta Cap/	10 mcg	0.2mL	NO DILUTION	2



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Please review CDC's interim COVID-19 immunization schedule for ages 6 months and older.

# Knowledge Check #1

#### Novavax

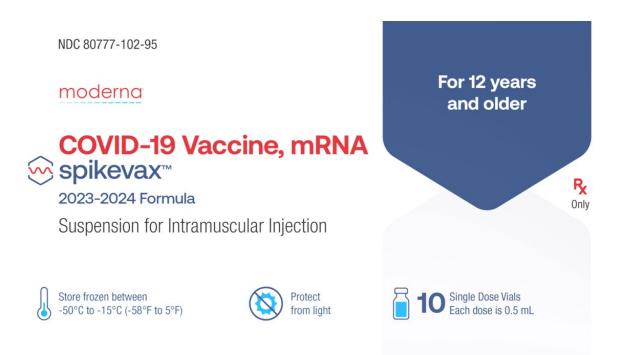
- UNPUNCTURED VIALS
  - Store between 2C° to 8°C (36F° to 46°F) until the expiration date
- PUNCTURED VIALS
  - Store between 2C° to 8°C (36F° to 46°F) up to 6 hours. Discard vial and any remaining vaccine after 6 hours.

No new updates at this time

Novavax COVID-19 Vaccine | CDC

#### Moderna





Moderna COVID-19 Vaccine (2023-2024 Formula) 6 Months Through 11 Years of Age	SPIKEVAX (COVID-19 Vaccine, mRNA) (2023-2024 Formula) 12 Years of Age and Older	
Roterne ODVID-19 Ver Roterne ODVID-19 Ver	<b>O.5 mL</b> single dose vial	0.5 mL single dose pre-filled syringe
NDC 80777-287-07	NDC 80777-102-04	NDC 80777-102-01
Individual single dose vial	Individual single dose vial	Individual single dose pre-filled
		syringe
NDC 80777-287-92	NDC 80777-102-95	
Carton of 10 single dose vials	Carton of 10 single dose vials	NDC 80777-102-96 Carton of 10 single dose pre-filled syringes
		NDC 80777-102-93 Carton of 10 single dose, blister- sealed pre-filled syringes

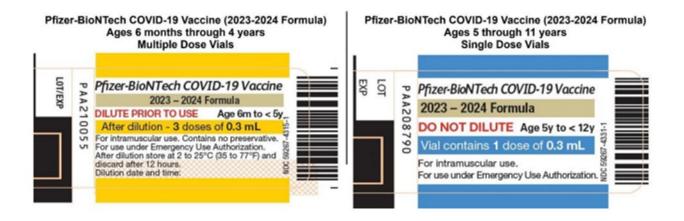
#### Moderna

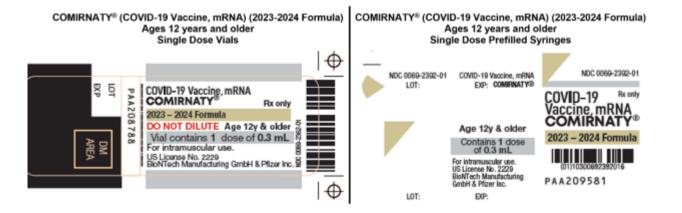
- UNPUNCTURED VIALS
  - Store in **Refrigerator 2°C and 8°C (36°F and 46°F)** for up to 30 days
  - Store in Freezer -50°C and -15°C (-58°F and 5°F) until the expiration date
  - Unpunctured vials may be held between 8°C and 25°C (46°F and 77°F) for a total of 24 hours.
- **DO NOT** refreeze thawed vaccine
- No Dilute necessary

#### Moderna

- Vial Expiration Checker
- Moderna COVID-19 Vaccine | CDC
- Moderna COVID-19 Vaccine: Transporting Vaccine (cdc.gov)

#### Pfizer-BioNTech





#### Pfizer-BioNTech

- UNPUNCTURED VIALS
  - Store in **Refrigerator** for up to 10 weeks
  - Store in **Ultra-Cold Freezer** until the expiration date
  - **DO NOT** store in a regular freezer
  - Unpunctured vials may be held between 8°C and 25°C (46°F and 77°F) for a total of 12 hours.
- PUNCTURED VIALS
  - Up to 12 hours
- Vaccines and diluents must be unpacked, stored at recommended temperatures, and documented immediately after arrival.
- Frozen vaccine must be thawed prior to use. Thaw vaccine between 2°C and 8°C (36°F and 46°F) or between 8° C and 25° C (46° F and 77° F). The amount of time needed to thaw vaccine varies based on the temperature and number of vials.

	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) DILUTE BEFORE USE	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) D0 NOT DILUTE
Age Group	6 months through 4 years <sup>a</sup>	5 through 11 years <sup>a</sup>
<b>Cap Color &amp; Label</b> Cap colors and labels with matching borders	FelioNTech COVID-19 2023 - 2024 Formula TE PRIOR TO USE Age for Visition - 3 doses of 0.3 m Endor Emergency Use Author Statuscular use. Contains no pre- sudde Emergency Use Author Statuscular use. Contains no pre- sudde Emergency Use Author Thom To USE Age formula Thom To USE Age for the USE Age formula Thom To USE Age for the USE Age for t	Blue Blue Blue Blue Blue 2023 - 2024 Formula Not DILUTE Age 5y too Contains 1 dose of 0.3 Becular use. Blue
Dose	3 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL
Dilution	1.1 mL⁵	DO NOT DILUTE
Doses per Vial	<b>Multiple Dose Vial</b> <sup>c,d</sup> : 3 doses per vial (after dilution)	<b>Single Dose Vial</b> e: 1 dose per vial
	Storage Conditions	
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months <sup>e</sup>	12 months <sup>e</sup>
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	DO NOT STORE	DO NOT STORE
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	10 weeks	10 weeks
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	12 hours prior to first puncture <sup>f,g</sup>	12 hours prior to use <sup>f</sup>
After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]	Discard 12 hours after dilution. <sup>e</sup>	N/A

	DO NOT DILUTE	PREFILLED SYRINGE	
Age Group	12 years and older	12 years and older	
<b>Cap Color &amp; Label</b> Cap colors and labels with matching borders	D-19 Vaccine, mRNA 2023 - 2024 Formula 2023 - 2024 Formula 2024 Formula 2024 Formula 2024 Formula 2024 Formula 2024 Formula 2024 Formula 2025 Formu	NDC 0069-2392-01 COVID-19 Vaccine, mRNA LOT: COVID-19 Vaccine, mRNA EXP: COMIRNATY® NDC 0069-2392-01 COVID-19 Rx only Recently Cover 19 Vaccine, mRNA COVID-19 Rx only	
Dose	30 mcg	30 mcg	
Dose Volume	0.3 mL	0.3 mL	
Dilution	DO NOT DILUTE	N/A	
Doses per Vial/Syringe	Single Dose Vial <sup>a</sup>	Single Dose Prefilled Syringe <sup>b</sup>	
	Storage Conditions		
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	18 months <sup>c</sup>	9 months°	
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	DO NOT STORE DO NOT STORE		
Refrigerator [2 °C to 8 °C (35 °F to 46 °F)]	Up to 10 weeks	Up to 10 weeks	
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	A total of 12 hours	Refer to product labeling <sup>d</sup>	
After Puncture [2 °C to 25 °C (35 °F to 77 °F)]	N/A	N/A	

#### Pfizer-BioNTech

- Pfizer-BioNTech COVID-19 Vaccines | CDC
- Expiry checker
- Pfizer Transportation Guide
- Pfizer Storage and Handling-Label
- <u>Pfizer-BioNTech COVID-19 Vaccine: Storage and Beyond-Use Date Tracking</u>
   <u>Labels (cdc.gov)</u>
- <u>Pfizer-BioNTech COVID-19 Vaccine: Transporting Vaccine for Vaccination</u> <u>Clinics Held at Satellite, Temporary, or Off-Site Locations Procedure (cdc.gov)</u>

### Ultra Cold Storage Considerations

- Use a DDL with and air probe or probe designed specifically for ultra cold temperatures
- Diluent will arrive in a separate shipment

#### Wasting/Clearing out Unauthorized COVID-19 Vaccine

#### Log into WA IIS:

- Expand Lot Numbers tab
- Select Reconciliation
- Please report these unused doses as waste in the IIS using
  - Physical inventory insert 0
  - Category select Expired
  - Reason select Open Multidose Vial
  - Scroll down to bottom and select save

\*If you have inventory showing 0, select box stating inactive on right side, scroll to bottom and select save( this will remove from inventory list)

\*Please discard unused vaccines according to your local medical waste guidelines\*

# Knowledge Check #2



# Childhood Vaccine Program Main Contact Information <u>WAChildhoodVaccines@doh.wa.gov</u> Phone: (360)236-2829 Fax: (360)236-3811

## Additional Resources

#### Resources

- Storage and Handling Summary Documents
  - <u>Pfizer</u>
  - <u>Moderna</u>
  - <u>Novavax</u>
- CDC Vaccine Storage and Handling Toolkit
  - <u>https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html</u>
- Training and Education
  - <u>https://www.cdc.gov/vaccines/covid-19/training-education/index.html</u>
- Vaccine Adverse Event Reporting System
  - <u>https://vaers.hhs.gov/index.html</u>

#### CDC Resources

- How to report an adverse event to VAERS
  - Go to <u>vaers.hhs.gov</u> and submit a report online
  - For help call 1-800-822-7967, email info@vaers.org
  - Video instructions <u>https://www.youtube.com/watch?v=sbCWhcQADFE</u>
- How to contact CDC at CDC-INFO
  - Go to <a href="https://www.cdc.gov/cdc-info/index.html">https://www.cdc.gov/cdc-info/index.html</a>
  - Call 1-800-CDC-INFO (1-800-232-4636)
- Safety Information resources
  - <u>https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html</u>
  - <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html</u>

#### Provider Education Resources

- <u>2023-2024 COVID-19 Vaccine Product Characteristics and Information (wa.gov)</u>
- What is a Vaccine Expiration Date? TRAIN Learning Network
- What is a Vaccine Beyond-Use Date or Time? TRAIN Learning Network
- <u>The Difference Between a Vaccine Expiration Date and Beyond-Use Date or Time</u> (BUD) - TRAIN Learning Network
- How to Report Wastage of the COVID-19 Vaccine in IIS



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