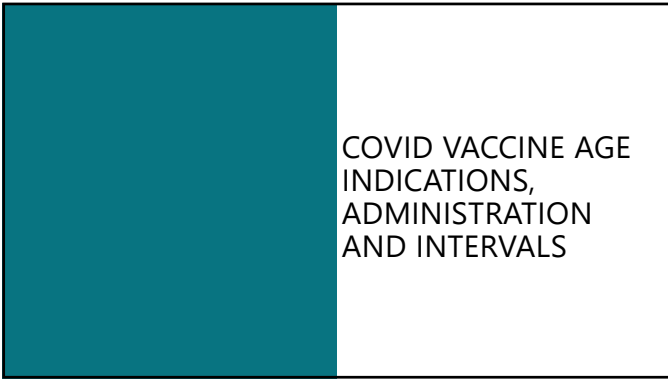
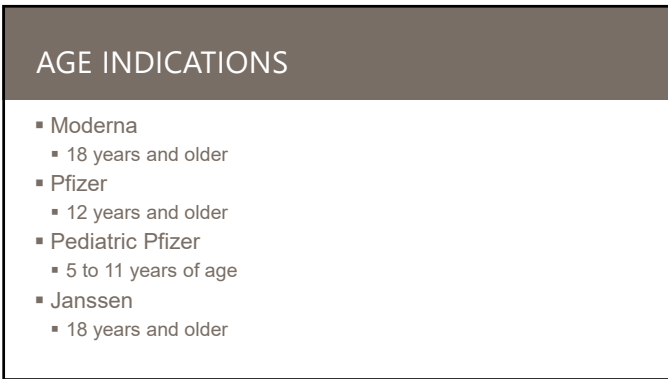


1



2



3

PRIMARY VACCINE INTERVALS

- Moderna
 - Second dose should be scheduled 28 days after first dose
- Pfizer
 - Second dose should be scheduled 21 days after first dose
- Pediatric Pfizer
 - Second dose should be scheduled 21 days after first dose
- Janssen
 - No second dose needed, one dose series

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VACCINE SERIES

- The Centers for Disease Control and Prevention (CDC) recommend that the booster is with the same dose the primary series was.
- However, if you do have a patient requesting a different vaccine than previously received, they can be vaccinated with that vaccine.

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Pfizer-BioNTech COVID-19 Vaccines
PRELIMINARY - SUBJECT TO CHANGING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (15 to 17 years old)	Future Pediatric Formulation
	Orange Prior to Use	Orange Prior to Use
Age Group	12 years and older	5 to 12 years**
Vial Cap Color	ORANGE	ORANGE
Dose	30mg	30mg
Injection volume	0.3 mL	0.3 mL
100 injection (before dilution)	0.6 mL	0.6 mL
Amount of diluent*	0.6 mL	0.3 mL
Amount of diluent**	0.6 mL	0.3 mL
Doses per vial (after dilution)	4 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
16.7 freeze (-60°C to -40°C)	6 months	6 months
Freeze (-20°C to 0°C)	2 months	6% [†]
Refrigerate (2°C to 8°C)	1 month	10 weeks

Q: Can the current adult/adolescent formulation (orange cap) be used to vaccinate children 5 to 12 years old until the vaccine is authorized for this age group?
A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.
People Cap - Adult/Adolescent: Authorized only for aged 12 years and older.

Orange Cap - Pediatric: Future authorization for aged 5- to 12 years. A separate vaccine formulation specific for a 0.3mL dose will be introduced.

NOTE: Use of the current adult/adolescent formulation (orange cap) to prepare doses for children 5 to 12 years would result in an injection volume for the 0.3mL dose of 0.3mL, which is both generally considered too small for typical IM injections and has not been studied.

*Diluent is 0.9% sterile sodium chloride injection, USP (see Instructions for Use) (NDC 1071022 01001001)
 **The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to 12 years old.

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BOOSTER DOSES

7

PFIZER AND MODERNA BOOSTER DOSES

- Indicated for:
 - 65 years and older
 - 18 years and older who live in a long term care setting
 - 18 years and older who have underlying medical conditions <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>
 - People who work or live in high-risk settings age 18- 64 years
- Booster should be 6 months after second dose
- **Moderna booster are 0.25mL**

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JANSSEN BOOSTER DOSE

- Indicated for:
 - 18 years and older
- Booster dose at least 2 months after your first dose

9

	STORAGE UNITS AND TEMPERATURE MONITORING DEVICES
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10

STORAGE UNITS
<ul style="list-style-type: none">▪ Freezer<ul style="list-style-type: none">▪ -50° to -15°C (-58° to 5°F)▪ Refrigerator<ul style="list-style-type: none">▪ 2° to 8°C (36° to 46°F)▪ CDC recommendation is to use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units can be compact, under-the-counter style or large.

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STORAGE UNITS
<ul style="list-style-type: none">▪ Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As long as the storage unit maintains the appropriate temperatures.▪ Dorm-style units cannot be used.

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THERMOMETERS

- The CDC recommends the use of a digital data logger (DDL).
- A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range.
- Min/Max thermometers are acceptable in the instance that the provider office cannot obtain a DDL.
- Mercury thermometers are not acceptable.

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TEMPERATURE DOCUMENTATION

- Check and record storage unit minimum and maximum temperatures at the start of each workday.
- Record:
 - Minimum/maximum temperature
 - Date
 - Time
 - Name of person who checked and recorded the temperature
 - Any actions taken if a temperature excursion occurred

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STORAGE BEST PRACTICES

- Vaccine should be stored in the unit away from the sides and front of the unit.
- Vaccine should not be stored in the vegetable crisper, in the door or under air vents.
- Thermometers should be placed in the middle of the unit with the vaccine.

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VACCINE STORAGE

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MODERNA

- Vaccine can be stored:
 - Freezer at -50° to -15°C (-58° to 5°F) for up to 6 months.
 - Refrigerator at 2° to 8°C (36° to 46°F) for up to 30 days. **DO NOT REFREEZE VACCINE.**
 - Room temperature for up to 24 hours prior to puncturing the vial.
- Vaccine should always be stored in the cartons the vaccine is shipped in. If taking out smaller quantities, they should be stored in a tray.

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MODERNA

- Vaccine thawing prior to administration:
 - Thaw in refrigerated conditions between 2°C to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let vial stand at room temperature for 15 minutes before administering or
 - Thaw at room temperature for 1 hour
- **Punctured vials need to be discarded after 12 hours.**

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JANSSEN

- Vaccine can be stored:
 - Long-term storage at -20°C for 2 years by manufacturer or distributor **ONLY**, not by end-user.
 - Unpunctured vials can be stored at 2°C to 8°C (36°F to 46°F) for up to 6 months. **DO NOT FREEZE VACCINE.**
 - Unpunctured vials can be stored at 9°C to 25°C (47°F to 77°F) for up to 12 hours.

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JANSSEN

- Vaccine thawing prior to administration:
 - Thaw in refrigerated conditions between 2°C to 8°C (36° to 46°F) for 2 hours. Let vial stand at room temperature for 15 minutes before administering or
 - Thawing vaccine at room temperature (maximally 25°C/77°F). A carton of 10 vials will take ~2 hours, and individual vials will take approximately ~1 hour.
- **Punctured vials need to be discarded after 6 hours.**

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JANSSEN

- After the first dose is withdrawn, hold vial between 2°C to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

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PFIZER

- Vaccine can be stored:
 - Ultra-cold freezer at temperatures of -90 to -60°C (-112 to -76°F) for up to 6 months in the trays.
 - Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks.
 - Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks. **NOTE Difference from routine frozen vaccines.**

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PFIZER

- Pfizer thermal shipper for the 1,170 package quantities at -90 to -60°C (-130 to -76°F) for up to 30 days with dry ice replenishment (from the warehouse) within the first 24 hours of receiving and then every 5 days up to 30 days, then vaccine would need to be either placed in an ultra-cold freezer, pharmaceutical freezer or the refrigerator.
- Refrigerator at 2° to 8°C (36° to 46°F) for up to 31 days in the Pfizer tray or another tray. **DO NOT REFREEZE VACCINE.**

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PFIZER

- Room temperature for no more than 2 hours prior to dilution, this is cumulative time for each vial. At that time vaccine will need to be placed in the refrigerator. After dilution vaccine can either be stored in the refrigerator or at room temperature.
- Vaccine should always be stored in the cartons the vaccine is shipped in. If taking out smaller quantities, they should be stored in a tray.

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PFIZER

- Vaccine thawing prior to administration:
 - Thaw for 3 hours at 2° to 8°C (36° to 46°F) or 30 minutes at room temperature
 - Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours or placed in the refrigerator
- **Punctured vials need to be discarded after 6 hours**

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PEDIATRIC PFIZER

- Vaccine can be stored:
 - Ultra-cold freezer at temperatures of -90 to -60°C (-112 to -76°F) for up to 6 months in the trays.
 - Refrigerator at 2° to 8°C (36° to 46°F) for up to 10 weeks in the Pfizer tray or another tray. **DO NOT REFREEZE VACCINE.**

DO NOT FREEZE
 Store at
 2° - 8° C (36° - 46° F)

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PEDIATRIC PFIZER

- Room temperature for no more than 12 hours prior to dilution, this is cumulative time for each vial. At that time vaccine will need to be placed in the refrigerator. After dilution vaccine can either be store in the refrigerator or at room temperature.

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PEDIATRIC PFIZER

- Vaccine thawing prior to administration:
 - Thaw for up to 4 hours at 2° to 8°C (36° to 46°F) or 30 minutes at room temperature
 - Using either thawing method, vials must reach room temperature before dilution and must be diluted within 12 hours or placed in the refrigerator
- **Punctured vials need to be discarded after 12 hours**

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TEMPERATURE EXCURSIONS

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Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturer's package insert is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.

Notify

- Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
- Notify staff by labeling exposed vaccines, DO NOT USE, and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

- Document details of the temperature excursion:
 - Date and time
 - Storage unit temperature (including minimum/maximum temperature during the time of the event, if available)
 - Room temperature, if available
 - Name of the person completing the report
 - General description of the event (i.e., what happened)
 - If using a digital data logger (DDL), determine the length of any excursions that have been detected.
 - Inventory of affected vaccines
 - List of items in the unit other than vaccines (including water bottles)
 - Any problems with the storage unit and/or affected vaccines before the event
 - Other relevant information

Contact

- Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- Be prepared to provide the manufacturer or immunization program with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursion	
Merck	1 800 672 6332
Sandoz/Pfizer	1 800 672 2463
Novartis/AbbVie	1 800 675 5243
Pfizer	1 800 428 1985
Seqirus	1 855 338 4988

Correct

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- Check the basics, including:
 - Power supply
 - Unit location
 - Thermostat settings
- If the excursion was the result of a temperature fluctuation, refer to the chapter "Vaccine Storage and Temperature Monitoring Equipment" in CDC's Vaccine Storage and Handling Toolkit for detailed guidance on adjusting storage unit temperature to the appropriate range.
- If you believe the storage unit has failed, implement your emergency vaccine SOPs. Never allow vaccines to remain in a malfunctioning unit.

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TEMPERATURE EXCURSION

- Manufacturer phone listing
https://www.health.nd.gov/sites/www/files/documents/Files/MSS/Immunizations/Storage_Handling/VaccineManufacturerPhoneList.pdf
- Online excursion report form
https://ndhealth.co1.qualtrics.com/jfe/form/SV_5chLQNgm1ts45y5

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STORAGE AND HANDLING POWER SUPPLY

- Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff not to unplug units
- Label fuses and circuit breakers to alert staff and contractors not to turn off power supply



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VACCINE TRANSPORT

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VACCINE TRANSPORT

- Vaccine transport is discouraged whenever possible.
- If providers must transport vaccine, data loggers must be used at all times.
 - Transport temperature charts must be submitted to the immunization program anytime VFC vaccine is transported.
 - Temperatures should be checked every 30 minutes.
- VFC or state-supplied vaccine must be transported in qualified coolers.
- Never leave vaccine unattended in a car for long periods of time, and never store in a trunk.

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VACCINE TRANSPORT CONTINUED

- All vaccines transfers (between providers) must be approved by the immunization program.
- Vaccine should never be stored in a transport cooler for more than 8 hours.
- Frozen vaccine must be transported in a frozen transport cooler, cannot use dry ice or transport refrigerator.

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VACCINE EXPIRATION

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VACCINE EXPIRATION DATES

- Janssen vaccine expiration date www.vaxcheck.jnj

JANSSEN
Please refer to this website for the expiration date <https://vaxcheck.jnj>

- Moderna vaccine expiration date <https://www.medinfo.modernatx.com/tools>

MODERNA
Please refer to this website for the expiration date <https://www.medinfo.modernatx.com/tools>

- Pfizer refer to the vial



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VACCINE EXPIRATION DATES

- Pediatric Pfizer refer to the vial for the manufacture date and add 6 months to that date.



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NORTH DAKOTA IMMUNIZATION PROGRAM

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POST-TEST

- Post-test
 - Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_3CWsX6hgTUBZRS6
 - Successfully complete the five-question post-test to receive your certificate
 - Credit for this session available until December 8, 2021
- This presentation will be posted to our website: www.ndhealth.gov/immunize

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