



WELCOME TO THE NILE WEBINAR FOR NOVEMBER 2021!

Immunize Nevada is a nonprofit 501c3 coalition that is widely recognized as Nevada's trusted resource for immunization information and community health outreach for all ages. We accomplish this by fostering education and statewide collaboration with a variety of health partners and collaborators.





You may view upcoming web trainings at ImmunizeNevada.org/NILE-webinars

Thank you for joining us today!





HOUSEKEEPING ITEMS

Connectivity Issues	Please log back in and we'll continue where we left off.	
Have a Question?	Locate the Q & A box and type them there. We will address questions throughout the presentation.	
CEU Claiming	Nursing/Pharmacy/CHW CEUs: Complete the post-event survey. Certificates will be emailed within one week of the live presentation.	
Recording & Slides	The recorded webinar and slides will be posted to ImmunizeNevada.org/NILE-webinars .	



DISCLAIMER

Immunize Nevada's NILE webinars are made possible by the generosity of speakers who donate their time and expertise to benefit the coalition. The expectation and goal is for community partners to gain knowledge on immunization/infectious disease-related topics through a non-branded, unbiased presentation.

The opinions expressed are those of today's presenter and do not necessarily reflect those shared by Immunize Nevada or its partners.



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COVID 19 Vaccines

Division of Public and Behavioral Health
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11/10/2021

Helping people. It's who we are and what we do.



Agenda

1. Introduction
2. Presentation Objectives
3. Pfizer COVID 19 Vaccines
4. Moderna COVID 19 Vaccine
5. Janssen COVID 19 Vaccine
6. Additional Dose and Booster Dose Recommendations
7. Adverse Events
8. Questions
9. Resources
10. Contact Information



Objectives

Participants will gain an understanding of:

- COVID-19 Vaccines- Similarities and Specifics
- Vaccine specific storage requirements for COVID-19 vaccines at Ultra Cold, Frozen, and Refrigerated temperatures
- Vaccine handling considerations
- Current recommendations for booster/additional doses
- Adverse Event and Reporting



COVID-19 Vaccines Similarities

Pfizer BioNTech, Moderna, And Janssen

All COVID 19 vaccines continue to be:

- Safe, effective, and reduce the risk of severe illness, hospitalization, and death.
- Continuously tested and approved for use in appropriate age groups.
- Recommended to all persons identified in the age groups of the vaccine-specific Emergency Use Authorization.
- Under continuous review for efficacy and adverse reactions.
- Co-administered at same visit with other recommended age-appropriate vaccines.
- Fragile and require cold chain storage and continuous temperature monitor recording.
- Supplied with ancillary kits necessary for vaccine administration (including needles, syringes, alcohol, face shields, masks, diluent if applicable, needle/syringe guides and documentation cards).



Pfizer BioNTech aka “COMIRNATY” ADULT and ADOLESCENT DOSE

- **Type**
 - mRNA
 - Vial cap will be purple
- **Efficacy**
 - 95% after completion of second dose
- **Age groups**
 - 12 through 15yrs of age (authorized under EUA)
 - 16 years and older (approved- COMIRNATY)
- **Dose/Dosage/Route**
 - 30 micrograms / **0.3 mL** dose volume / Intramuscular (IM) injection into the deltoid muscle
- **Primary series**
 - Complete after 2 doses of Pfizer, with minimum 21-day interval between doses

*****NOT INTERCHANGABLE WITH THE PEDIATRIC PFIZER COVID 19 VACCINE*****

Storage

- Minimum order of 1,170 doses, for direct shipment, in dry ice container at ultra cold temperatures
- May arrive frozen or refrigerated if local redistribution option is used
- **Ultra-cold unit only**
 - Until labeled expiration date
- **Freezer**
 - 2 weeks maximum, then must be moved to refrigerator
- **Refrigerator**
 - Maximum 31 days, then discard unused vials.

*****Vaccine must not be refrozen once moved to refrigerator*****



Vaccine Handling Considerations

Vaccine stored at ultra cold temperatures or frozen temperatures must be thawed before use:

- Thaw unpunctured vials in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to one month or at room temperature for immediate use up to 25°C (77°F).
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours, or returned to the refrigerator.
- Do NOT refreeze thawed vaccine.
- Before mixing, check the expiration dates of the vaccine and diluent. **NEVER** use expired vaccine or diluent.
- Thermal shippers must be returned within 10 days of receipt.



Vaccine Handling Considerations Continued

- With the vaccine at room temperature, gently invert the vial 10 times. Do **NOT** shake the vial. If the vial is shaken, contact the manufacturer.
- The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.
- Keep mixed vaccine between 2°C and 25°C (36°F and 77°F) and administer within 6 hours.
- Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- Discard any unused vaccine after 6 hours. Do not return to freezer storage.
- If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents.
- Do **NOT** combine vaccine from multiple vials to obtain a dose.



Pfizer BioNTech PEDIATRIC Dose

- **Type**

- mRNA
- Vial cap will be **orange**

- **Efficacy**

- 90% in the 5yrs through 11yr age group

- **Age groups**

- 5 years through 11 years of age (authorized under EUA)

- **Dose/Dosage/Route**

- 10 micrograms / **0.2 mL** dose volume / Intramuscular (IM) injection into the deltoid muscle

- **Primary series**

- 2 doses, at 21-day minimum interval

*****NOT INTERCHANGABLE WITH THE ADULT/ADOLESCENT PFIZER COVID 19 VACCINE*****

- **Storage**

- Minimum order of 100 doses, for direct shipment, in dry ice container at ultra cold temperatures
- May arrive refrigerated if local redistribution option is used
- **Ultra-cold** unit up to 6 months past labeled manufactured date
- **Refrigerator** up to 10 weeks

*****PEDIATRIC PFIZER DOSES MAY NOT BE STORED IN THE FREEZER*****

Vaccine Handling Considerations

Vaccine stored at ultra cold temperatures must be thawed before use:

- Thaw vaccine in the refrigerator or at room temperature.
- Unpunctured vials may be stored in the refrigerator for up to 10 weeks.
- Unpunctured vials may be stored at room temperature between 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to mixing.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date labels to track storage time at refrigerated temperatures.
- Before mixing, check the expiration dates of the vaccine and diluent. **NEVER** use expired vaccine or diluent.
- Thermal shippers do not need to be returned.





Vaccine Handling Considerations Continued

- With the vaccine at room temperature, gently invert the vial 10 times.
- Do **NOT** shake the vial. If the vial is shaken, contact the manufacturer.
- The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.
- Keep mixed vaccine between 2°C and 25°C (36°F and 77°F) and administer within 12 hours.
- If the amount of vaccine remaining in the vial cannot provide a full 0.2 mL dose, discard the vial and contents.
- Do **NOT** combine vaccine from multiple vials to obtain a dose.



Pfizer BioNTech COVID 19 Vaccine Comparison

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	<i>Dilute Prior to Use</i>	<i>Dilute Prior to Use</i>
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks



Moderna (mRNA-1273)

Moderna 10 dose vial

**Moderna 14 dose vial
(currently phasing out)**



MODERNA

- **Type**
 - mRNA
- **Efficacy**
 - 93% after completion of second dose of Moderna
- **Age groups**
 - Person 18 years and older
- **Dose/Dosage/Route**
 - 100 micrograms / **0.5 mL** dose volume / Intramuscular (IM) injection into the deltoid muscle
- **Primary series**
 - Complete after 2 doses, at 28-day minimum interval of Moderna vaccine

Storage

- Minimum order of 140 doses, for direct shipment, will arrive under frozen conditions
- Moderna COVID-19 Vaccine multiple-dose vials are stored **frozen** between 50° to -15°C (-58° to 5°F).
- Store in the original carton to protect from light.
- Do not store on dry ice or below -50°C (-58°F).
- Unpunctured vials can be stored **refrigerated** between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

****Do not refreeze once thawed****

Vaccine Handling Considerations

Vaccine stored at frozen temperatures must be thawed before use:

- Thaw vaccine in the refrigerator or at room temperature
- Refrigerator: Between 2°C and 8°C (36°F and 46°F). Unpunctured vials may be stored in the refrigerator for up to 30 days
- Room temperature: Between 8°C and 25°C (46°F and 77°F) unpunctured vials may be held at room temperature for up to 12 hours
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures
- Punctured vials may be stored between 2°C and 25°C (36°F and 77°F) for up to 12 hours.
- After a vial is punctured 20 times it should be discarded even if the 12-hour time limit has not been met.

Vaccine Handling Considerations Continued

- With the vial upright, gently swirl the vaccine.
- Do **NOT** shake. If the vial is shaken, contact the manufacturer. (Note: Gently swirl the vaccine before withdrawing subsequent doses)
- Examine the vaccine. It should be white to off-white in color and may contain white particles. Do not use if liquid contains other particulate matter or is discolored.
- Discard vial when there is not enough vaccine to obtain a complete 0.5 mL dose
- Do **NOT** combine residual vaccine from multiple vials to obtain a dose.



Janssen (J&J)



JANSSEN / J & J

- **Type**

- Vector Virus

- **Efficacy**

- 63.3%

- **Age groups**

- 18 years and older

- **Dose/Dosage/Route**

- 5×10^{10} viral particles / **0.5mL** dose volume/
Intramuscular (IM) injection in the deltoid
muscle

- **Primary series**

- Complete after a single dose

*****DOES NOT REQUIRE RECONSTITUTION*****

Storage

- Minimum order of 100 doses, for direct shipment, will arrive in refrigerated conditions
- Unpunctured vials can be stored in the **refrigerator** between 2°C and 8°C (36°F and 46°F) until the expiration date or Beyond Use Date (BUD)

*****MUST NOT BE STORED
IN A FREEZER*****

Vaccine Handling Considerations

- With the vial upright, **gently swirl the vaccine for 10 seconds**. (Note: Gently swirl the vaccine before withdrawing subsequent doses).
- **Do NOT shake**. If the vial is shaken, contact the manufacturer.
- Examine the vaccine. It should be colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid contains particulate matter or is discolored.
- Note the date and time the vial was first punctured.
- Punctured vials can be stored between 2°C and 8°C (36°F and 46°F) for up to 6 hours or at room temperature (up to 25°C or 77°F) for 2 hours.
- If the amount of vaccine remaining in the vial cannot provide a full 0.5 mL dose, discard the vial and contents
- Do **NOT** combine vaccine from multiple vials to obtain a dose



COVID-19 Vaccines for Moderately to Severely Immunocompromised People

- People with moderately to severely compromised immune systems are especially vulnerable to COVID-19 and may not build the same level of immunity to 2-dose vaccine series compared to people who are not immunocompromised.
- CDC recommends that people with moderately to severely compromised immune systems receive an **additional dose** of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 Vaccine.
- A third dose of the same mRNA vaccine should be used.
- This additional dose is intended to improve immunocompromised people's response to their initial vaccine series.
- There is not enough data at this time to determine whether immunocompromised people who received J&J/Janssen COVID-19 vaccine also have an improved antibody response following an additional dose of the same vaccine.

What You Need to Know About Booster Eligibility

Pfizer-BioNTech or Moderna

Who:

- 65 years or older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings

When:

- At least 6 months after the second shot

Janssen/ J&J

Who:

- 18 years and older

When:

- At least 2 months after the first shot

CDC's recommendations now allow for mix and match dosing of booster shots. The patient may choose which COVID-19 vaccine they would like to receive as a booster shot.

****NOTE: Moderna booster dosing is .25 mL, half the size of a primary series dose*****





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
- Observe all recipients **after** vaccination for an immediate adverse reaction:
 - **30** minutes for persons with
 - History of an **immediate allergic reaction** of **any severity** to a vaccine or injectable therapy
 - History of **anaphylaxis** due to any cause
 - **15** minutes for all other persons

Adverse Events

- Serious adverse events after COVID-19 vaccination are **rare** but may occur.
 - **Anaphylaxis** after COVID-19 vaccination is rare and has occurred in approximately 2 to 5 people per million vaccinated in the United States.
 - **Thrombosis with thrombocytopenia syndrome (TTS)** after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare (48 confirmed reports out of 15.5 million doses given in the United States).
 - **Guillain-Barré Syndrome (GBS)** CDC and FDA are monitoring reports (224 preliminary reports out of 15.5 million doses given in the United State).
 - **Myocarditis and pericarditis** after mRNA COVID-19 vaccination are rare. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older.
 - **Death:** A review of available clinical information, including death certificates, autopsy, and medical records, has not established a causal link to COVID-19 vaccines. Recent reports indicate a plausible causal relationship between the J&J COVID-19 Vaccine and TTS which has caused deaths.



Vaccine Adverse Event Reporting System (VAERS)

- VAERS is a national early warning system to detect possible safety problems in U.S.-licensed vaccines.
- VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination.
- Anyone can report an adverse event to VAERS.
- Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.
- VAERS is not designed to determine if a vaccine caused a health problem but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.
- **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.**

V-SAFE

- **V-safe** is a smartphone-based tool that uses text messaging and web surveys to give personalized health check-ins after receipt of a COVID-19 vaccine.
- Information gathered through V-safe helps CDC monitor the safety of COVID-19 vaccines in near real time.
- During the first week after receiving the first dose of COVID 19 vaccine, v-safe will send a text message each day to ask how the patient is doing. Then v-safe will send check-in messages once a week for up to 6 weeks.
- The questions v-safe asks take less than 5 minutes to answer.
- Patients will receive check-ins at 3, 6, and 12 months after the final dose of vaccine.
- vsafe.cdc.gov



Questions?





Resource links

- [COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals \(cdc.gov\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
- <http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>
- [Healthcare Providers for 12 years of age and older, purple cap \(must dilute\) \(fda.gov\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)
- [Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary \(cdc.gov\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)
- [Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)
- <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>
- [Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers \(fda.gov\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)



- <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine>
- [Janssen COVID-19 Vaccine - EUA Fact Sheet for Healthcare Providers Administering Vaccine \(janssenlabels.com\)](#)
- <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>
- [VAERS - Report an Adverse Event \(hhs.gov\)](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)- for persons vaccinated outside the US
- [Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children \(MIS-C\) | CDC](#)
- [You Call The Shots: Temperature Log when Transporting Vaccine at Refrigerated Temperatures-March 4, 2021 \(cdc.gov\)](#)
- [CDC-HHS-COVID-19 Vaccine Administration Errors and Deviations](#)





Contact Information

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LAST MINUTE QUESTIONS & HOUSEKEEPING ITEM REVIEW

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