Immunization Protocol

COVID-19 Vaccine (Pfizer-BioNTech, Moderna, Novavax)	
Last Reviewed	4 March 2024
Last Revised	4 March 2024
This order expires	31 March 2025

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1. What's new

As of February 28, 2024, the ACIP recommends that all people ages 65 and older receive one additional dose of any 2023–2024 season COVID-19 vaccine at least 4 months following the previous dose of 2023–2024 season COVID-19 vaccine.

2. Oregon immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine. If ALERT IIS is unavailable, use available documentation and patient statement.

B. Screen client for contraindications and precautions.

C. Provide a Vaccine Information Fact Sheet for Recipients and Caregivers, and answer any questions. Adolescents aged 15–17 years may consent for their own vaccinations and do not need a parent to consent or to be present.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for IM injection.

F. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the vastus lateralis or deltoid muscle and use proper IM administration technique.

G. For Pfizer vaccine only: thaw, if needed. The yellow cap formulation requires reconstitution; the gray and blue cap formulations are ready to administer.[1,5]

H. For Moderna vaccine only: thaw, if needed, prior to administration.[2]

I. Administer a dose of 2023–2024 season Pfizer, Moderna, or Novavax COVID-19 vaccine according to ACIP recommendations and the vaccine package insert. See section 3 for vaccine volume and spacing based on age and vaccine formulation.

J. COVID-19 vaccines appear to be more reactogenic than most.[4] Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12–24 hours.

K. Anaphylaxis has been reported after COVID-19 vaccination. Vaccinator must be prepared to respond to a severe allergic reaction. See Section 6 for a list of excipients.

L. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Patients with a history of severe allergic reactions should be asked to remain for 30 minutes.[4]

M. Report all administered COVID-19 doses to ALERT IIS within 72 hours of administration.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for COVID-19 Vaccines

PFIZER[1,5]

Dose and Route: Pfizer 2023–2024 pediatric mRNA vaccine 0.3 mL, 3 µg, IM (yellow cap and border)			
Unvaccinated children 6 months through 4 years			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	6 months	through 4 years* (<5 years)	
2			3 weeks
3			8 weeks

*Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 Vaccine, supplied in vials with yellow caps and borders.[1]

Children 6 months through 4 years of age previously vaccinated with Pfizer vaccine, any formulation		
Doses Received Previously	**Dose(s) Needed Now**	**Minimum Spacing**
1 dose	2 doses 2023–24 Pfizer	3 weeks after last dose.
2 or more doses	1 dose 2023–24 Pfizer	8 weeks after last dose

Dose and Route: Pfizer 2023–2024 pediatric mRNA vaccine 0.3 mL, 10 µg, IM (blue cap and border)			
Children 5–11 years of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1*	5 years	11 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised children ≤11 years of age should receive a **3-dose vaccine series**. At least one dose should be the 2023–2024 season COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Dose and Route: Pfizer 2023–2024 mRNA vaccine (COMIRNATY®), 0.3 mL, 30 µg, IM (gray cap and border or prefilled syringe)[4,5]		
Children ≥12 years of age and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1*	12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)
Booster	65 years	4 months following the previous dose of any 2023–2024 season COVID-19 vaccine

*Immunocompromised persons need an initial series of 3 homologous doses that may be followed by additional doses at the discretion of the healthcare provider based on individual patient circumstances.

MODERNA[2,6]

Dose and Route: Moderna 2023–2024 mRNA vaccine 0.25 mL, 25 µg, IM (dark blue cap, green border)			
Unvaccinated children 6 months through 4 years of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	6 months	through 4 years (<5 years)	
2*			4 weeks

* Immunocompromised children ≤11 years of age should receive a **3-dose vaccine series**. At least one dose should be the 2023–2024 season COVID-19 vaccine. Immunocompromised children may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

Children 6 months through 4 years of age previously vaccinated with Moderna vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 dose, any formulation	1 dose 2023–24 Moderna (0.25 mL, dark blue cap, green border)	4 weeks after last dose*
2 or more doses, any formulation	1 dose 2023–24 Moderna (0.25 mL, dark blue cap, green border)	8 weeks after last dose*

*Immunocompromised children ≤11 years of age should receive a **3-dose vaccine series**. At least one dose should be the 2023–2024 season COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Dose and Route: Moderna 2023–2024 mRNA vaccine 0.25 mL, 25 µg, IM (dark blue cap, green border)			
Unvaccinated children 5–11 years of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1*	5 years	11 years (<12 years)	

*Immunocompromised children ≤11 years of age should receive a **3-dose vaccine series**. At least one dose should be the 2023–2024 season COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children 5–11 years of age previously vaccinated with any COVID-19 vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 or more doses, any formulation	1 dose 2023–24 Moderna* (0.25 mL, dark blue cap, green border)	8 weeks after last dose

*Immunocompromised children ≤11 years of age should receive a **3-dose vaccine series**. At least one dose should be the 2023–2024 season COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Dose and Route: Moderna 2023–2024 mRNA vaccine (Spikevax®), 0.5 mL, 50 µg, IM (dark blue cap and border)[4,6]		
Children ≥12 years of age and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1*	12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)
Booster	65 years	4 months following the previous dose of any 2023–2024 season COVID-19 vaccine

* Immunocompromised persons need an initial series of 3 homologous doses that may be followed by additional doses at the discretion of the healthcare provider based on individual patient circumstances.

NOVAVAX[3,4]

Dose and Route: Novavax, adjuvanted 2023–2024 vaccine, 0.5 mL, 5 µg, IM (dark blue cap, light blue on label)		
Unvaccinated children ≥12 and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	12 years	
2		3 weeks*
Booster†	65 years	4 months

*Minimum spacing is 3 weeks, but a longer spacing of up to 8 weeks may be used to reduce the risk of myocarditis.
†Patients 65 and older who need initial vaccination and prefer Novavax should complete a 2-dose Novavax series before administration of the booster dose. If the patient has previously been vaccinated with one dose of a 2023—2024 season mRNA COVID-19 vaccine, the patient should receive one booster dose with any 2023–2024 season COVID-19 vaccine (Moderna, Novavax, Pfizer).

Children ≥12 years of age and adults previously vaccinated with COVID-19 vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 or more doses (any original monovalent or bivalent COVID-19 vaccine)	1 dose 2023–2024 Novavax*	8 weeks after last dose

*Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

4. Licensed COVID-19 vaccines

Product Name	Vaccine Components	Presentation	Acceptable age range	
Preferred vaccines				
Pfizer 2023–2024 formulation[1,5]	mRNA	0.9-mL, 3-dose vial	6 months – 4 years	
		0.3-mL, single-dose vial	5–11 years	
		0.3-mL, single-dose vial	≥12 years	
		0.3-mL, prefilled syringe		
Moderna 2023–2024 formulation[2,6]	mRNA	0.25-mL, single-dose vial	6 months – 11 years	
		2.5-mL, 5-dose vial	≥12 years	
		0.5-mL, single-dose vial		
		0.5-mL, prefilled syringe		
Novavax 2023–2024 formulation[3]	Protein subunit	2.5-mL, 5-dose vial	≥12 years	

5. Recommendations for use[1-7]

A. A 2023–2024 season mRNA COVID-19 vaccine dose should be offered to all persons aged 6 months and older. Children 6 months through 4 years of age should complete a multi-dose initial series (2 doses of Moderna vaccine or 3 doses of Pfizer vaccine) with at least one dose of 2023–2024 COVID-19 mRNA vaccine. For adults and children ≥12 years of age, a protein subunit (Novavax) vaccine may be used.

B. All people ages 65 and older should receive one additional dose of any 2023–2024 season COVID-19 vaccine at least 4 months following the previous dose of 2023–2024 season COVID-19 vaccine. For initial vaccination with Novavax COVID-19 vaccine, the 2-dose series should be completed before administration of the booster dose.

C. Covid-19 vaccines are not interchangeable. When multiple doses are indicated (e.g., in unvaccinated children), the same vaccine brand should be used. In exceptional situations in which an mRNA vaccine series was begun, but the particular product administered for previous doses is not available, the other mRNA Covid-19 vaccine may be administered to complete the primary vaccine series.

D. 2023–2024 Novavax vaccine is currently approved as a two-dose series in unvaccinated persons ≥12 years of age. Persons ≥12 years who have received 1 or more doses of any original monovalent or bivalent COVID-19 vaccine may receive one 2023–2024 Novavax vaccine dose at least 2 months after their last COVID-19 vaccine dose. [3]

E. Children ≤11 years of age with immune compromise require a 3-dose primary series. All three doses should be the same (mRNA) vaccine brand. At least one dose should be of the 2023–2024 COVID-19 vaccine.[1,2]

F. Moderately or severely immunocompromised persons ≥12 years of age should receive either 3 doses of homologous (i.e., from the same manufacturer) mRNA COVID-19 vaccine, at least one dose of which should be a 2023–2024 COVID-19 vaccine, or 2 doses of Novavax, 1 of which should be the 2023–2024 formulation.

G. For all persons with immune compromise, additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.[4]

H. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.

I. Conditions causing moderate to severe immunodeficiency include:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR*-T-cell or hematopoietic cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day)
- alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Chimeric antigen receptor. Added to a patient's T lymphocytes so that they recognize and attack cancer cells.

6. Contraindications

Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Vaccine Excipient Summary
Pfizer 2023–24 formulation[1] [yellow cap and border]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide, 0.01 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.02 mg cholesterol), 9.4 mg sucrose, 0.02 mg tromethamine, and 0.12 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.88 mg sodium chloride per dose.
Pfizer 2023–24 formulation[1] [blue cap and border]	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 31 mg

	sucrose, 0.06 mg tromethamine, and 0.4 mg tromethamine hydrochloride.
Pfizer 2023–24 formulation[5] [gray cap and border]	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.
Moderna 2023–24 formulation[2] [dark blue cap with green border]	Total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.
Moderna 2023–24 formulation[2,6] [dark blue cap and border]	Total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.
Novavax 2023-24 formulation[3] [dark blue cap and light blue on label]	Cholesterol, phosphatidylcholine, potassium dihydrogen phosphate (3.85 µg), potassium chloride (2.25 µg), disodium hydrogen phosphate dihydrate (14.7 µg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.766 mg) and polysorbate 80 (0.050 mg). The Matrix-M adjuvant is composed of Fraction-A (42.5 µg) and Fraction-C (7.5 µg) of saponin extracts from the soapbark tree, *Quillaja saponaria* Molina. The pH is adjusted with sodium hydroxide or hydrochloric acid.

7. Warnings and precautions[4]

A. History of severe allergic reaction (e.g. anaphylaxis) to any other vaccine or injectable therapy (e.g. intravenous, intramuscular or subcutaneous).

B. Persons who have a contraindication to additional doses of mRNA COVID-19 vaccines are considered to have a precaution to the Novavax vaccine. A single dose may be given in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist.

This additional dose could be considered after a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. See Appendix A for additional information.

C. Moderate or severe acute illness.

8. Other considerations[4]

A. Patients with known COVID-19 infection should wait until their symptoms have resolved and criteria have been met to discontinue isolation. Persons who have a history of COVID-19 disease should be vaccinated if otherwise indicated. If desired, persons with acute COVID-19 may wait up to 90 days to receive vaccination, as reinfection within 90 days is uncommon. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

B. Patients who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.

C. COVID-19 vaccine may be administered concomitantly with other vaccines.

D. CDC recommends that vaccine for children aged 5–17 years of age with history of Multisystem Inflammatory Syndrome of Children (MIS-C) be delayed for 90 days after their diagnosis of MIS-C. Providers should inform patients that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.

E. COVID-19 vaccination is recommended for all people of childbearing age, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.

F. Persons with underlying medical conditions who have no contraindications may receive COVID-19 vaccine.

9. Side effects and adverse reactions

Adverse Event (Pfizer[1,5] and Moderna[2,6])	Frequency
Injection site events (pain at the injection site, redness, swelling)	Up to 93%
Systemic events (fatigue, headache, muscle ache, joint pain)	Up to 77%
Fever	Up to 16%
Lymphadenopathy*	Up to 20%
Serious adverse events	Up to 1% (similar to placebo group)
Adverse Event (Novavax[3])	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Up to 81%
Systemic events (fatigue, muscle pain, headache, nausea)	Up to 70%

Fever	Up to 23%

*Lymph node swelling in the underarm is more common after the booster dose than after the initial series.

10. Storage and handling

For COVID-19 vaccines only, all clinics and pharmacies with vaccine storage and handling concerns should contact the manufacturer directly.

Vaccine	Temp	Storage Issues	Notes
Pfizer[1,5]	-90° to -60° C	Vaccine may be stored until the expiration date.	.
	2° to 8° C	**Adolescent/adult formulation in prefilled glass syringes**: Store only in the refrigerator. Use through the expiration date on the carton.	**Glass syringes – DO NOT FREEZE**
		Adolescent/adult formulation in prefilled plastic syringes: Store in the refrigerator for up to 10 weeks.	
		Adolescent/adult formulation (blue or gray cap) single-dose vials: store in the refrigerator for up to 10 weeks.	
		Pediatric formulation (yellow caps) multi-dose vials: before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
	Ambient temperatures	**Adolescent/adult formulation (blue or gray cap) single-dose vials**: vaccine may be held at room temperature for up to 12 hours.	Any unused vaccine should be discarded.
		Pediatric formulations (yellow cap) multi-dose vials: once mixed, vaccine may be held at room temperature for up to 12 hours.	

Moderna[2,6]	-50° to -15° C	Vaccine is viable until the expiration date.	For multi-dose vials, once stopper has been punctured, all doses must be used within 12 hours Do not refreeze once thawed. Protect vaccine from light.
	2° to 8° C	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vaccine vials and syringes are viable for up to 24 hours at room temperature.	
Novavax[3]	2° to 8° C	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number using the QR code on the carton or at www.novavaxcovidvaccine.com: enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C for use within 12 hours. Discard the vial 12 hours after first puncture. Do not freeze. Protect vaccine from light. Gently swirl before drawing up a dose. Do not shake. Do not pool excess vaccine from multiple vials.

11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Adverse events that must be reported under the Emergency Use Authorization
A. Vaccine administration errors, whether or not associated with an adverse event B. Serious adverse events, irrespective of attribution to vaccination C. Multisystem Inflammatory Syndrome D. Cases of COVID-19 resulting in hospitalization or death

12. References

1. Pfizer-BioNTech COVID-19 Vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet, 8 Dec 2023. Available at: www.fda.gov/media/167211/download. Accessed 4 March 2024.
2. Moderna COVID-19 vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet and prescribing information, 1 Nov 2023. Available at www.fda.gov/media/167208/download. Accessed 4 March 2024.
3. Novavax, Inc. Full emergency use authorization (EUA) prescribing information, 03 Oct 2023. Available at www.fda.gov/media/159897/download. Accessed 4 March 2024.
4. Interim clinical considerations for use of COVID-19 vaccines in the United States, March 1, 2024. Available at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. Accessed 4 March 2024.
5. Pfizer-BioNTech Comirnaty, 2023–2024 formulation. Package insert, September 2023. Available at www.fda.gov/media/151707/download. Accessed 4 March 2024.
6. Moderna Spikevax, 2023–2024 formulation. Package insert, 11 Sep 2023. Available at: www.fda.gov/media/155675/download. Accessed 4 March 2024.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: immunization protocols