Protocol for Coronavirus 19 Vaccines
(Pfizer-BioNTech, Moderna, Novavax)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a dose of updated 2023–2024 Pfizer or Moderna Coronavirus 19 (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.[1-4] Novavax monovalent vaccine may be used as a first booster in an adult patient only if an FDA-authorized mRNA bivalent booster is not accessible or clinically appropriate, or the patient elects to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine.[5]

B. COVID-19 vaccine may be administered concomitantly with other vaccines. There is no need to separate COVID-19 vaccine from other vaccinations by 2 weeks.

3. Vaccine Schedule[1-3]

A. Any immunocompetent person ≥7 years of age who has received at least 1 dose of updated 2023–2024 COVID-19 vaccine is currently up-to-date.[6]

B. Any immunocompetent unvaccinated person ≥7 years of age may be brought up-to-date with a single dose of updated 2023–2024 COVID-19 vaccine.[6]

C. The PREP Act currently allows pharmacists to administer COVID-19 vaccines to persons aged 3-18 years old until 12/31/24.[2] Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.

Preferred Vaccines

PFIZER[1,3]

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 3 mcg, IM (yellow cap and border). ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
Unvaccinated children 3-4 years of age*		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	3-4 years of age (<5 years)	
2		3 weeks
3		8 weeks

*Not withstanding 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 3-4 years of age previously vaccinated with Pfizer vaccine, any formulation ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 dose	2 doses 2023-2024 Pfizer	3 weeks after last dose
2 or more doses	1 dose 2023-2024 Pfizer	8 weeks after last dose

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 10 mcg, IM (blue cap and border) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
Children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years of age	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 updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Pfizer 2023-2024 mRNA vaccine (COMIRNATY®) Dose and Route – 0.3-mL, 30 mcg, IM (gray cap and border or pre-filled syringe)[3]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**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)

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

MODERNA[2,4]

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border)[2]		
Unvaccinated children 3-4 years of age **For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.**		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	6 months-4 years (<5 years)	
2*		28 days

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Immunocompromised children may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

Children 3-4 years previously vaccinated with Moderna COVID-19 vaccine, any formulation[2] ***<u>For Informational Purposes Only</u>- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
Received	**Needs Now**	**Minimum Spacing**
1 dose	1 dose 2023-2024 Moderna (0.25mL, dark blue cap and green border)	4 weeks after last dose*
2 or more doses	1 dose 2023-2024 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 updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border) ***<u>For Informational Purposes Only</u>- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
Unvaccinated children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years (<12 years)	

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 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 Moderna COVID-19 vaccine, any formulation ***<u>For Informational Purposes Only</u>- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
Received	**Needs Now**	**Minimum Spacing**
1 or more doses	1 dose 2023-2024 Moderna* (0.25mL, dark blue cap and 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 updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 mRNA vaccine (SPIKEVAX®) Dose and Route – 0.5-mL, 50 mcg, IM (dark blue cap and border)[4]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**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)

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

Alternate vaccine not preferred.

NOVAVAX[5]

Novavax, adjuvanted vaccine Dose and Route –0.5-mL, 5 mcg, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥12 years	
2		21 days
Booster*	≥18 years	6 months

*For use only in individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, or in individuals 18 years of age and older who elect to receive a Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine. This dose is not authorized to follow any prior booster dose.[7]

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Cap/Label Color**
Preferred Vaccines				
Pfizer 2023-2024 formulation[1]	mRNA	0.9 mL, 3 dose vial 0.3 mL, single dose vial	3-4 years 5-11 years	Yellow Cap Blue Cap
Pfizer COMIRNATY®[3] 2023-2024 formulation	mRNA	0.3 mL, single dose vial 0.3 mL, prefilled syringe	≥ 12 years	Gray Cap
Moderna 2023-2024 formulation[2]	mRNA	0.25 mL, single dose vial	3-11 years	Blue Cap/Green Label
Moderna SPIKEVAX® 2023-2024 formulation[4]	mRNA	2.5 mL, 5 dose vial 0.5 mL, single dose vial 0.5 mL, prefilled syringe	≥ 12 years	Blue Cap/Blue Label
Non_Preferred Vaccines				
NVX-CoV2373[3] (NOVAVAX®)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years ≥ 18 years (booster)	Royal Blue Cap

5. Recommendations for Use[1-7]

A. An updated, 2023–24 mRNA COVID-19 vaccine dose should be offered to all persons aged ≥ 7 years. For adults and children ≥12 years of age, a protein subunit (Novavax) vaccine may be used.

B. For a primary series, COVID-19 vaccines are not routinely interchangeable. When multiple doses are indicated (i.e. 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.

C. Doses for adults and immunocompromised persons ≥7 years of age may be any authorized product.

D. Though not preferred, Novavax vaccine is currently approved as a two-dose primary series and as a first booster dose in certain circumstances, regardless of immunocompetency status. Persons who complete the Novavax series may receive a 2023-24 mRNA dose at least 2 months after their final dose of Novavax. Alternatively, Novavax may be administered as a first booster dose 6 months after completion of a primary series for individuals 18 and older for whom an FDA-authorized mRNA 2023–2024 vaccine is not accessible or clinically appropriate, or who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive an mRNA COVID-19 vaccine. A Novavax booster dose is not authorized to follow any prior booster dose.[5]

E. Children ≤11 years of age with immune compromise require a 3-dose primary series. All three doses should be the same vaccine brand. At least one dose should be of the 2023–24 COVID-19 vaccine.[1,2]

F. 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.[7]

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

H. 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 Chimeric antigen receptor (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/mm3, 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.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-5]

Vaccine	Contains
Pfizer 2023-2024 formulation[1] (yellow cap and border)[1]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N itetradecylacetamide, 0.01 mg 1,2-distearoyl-snglycero-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 2023-2024 formulation[1] (blue cap and border)	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane6,1-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 COMIRNATY® 2023-2024 formulation[3] (gray cap and border)	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-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 2023-2024 formulation[2] (dark blue cap and 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 SPIKEVAX® 2023-2024 formulation[4] (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.
NVA-CoV2373 (NOVAVAX®)[5]	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[7]

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[7]

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. Patients with a known community or outpatient setting COVID-19 exposure should wait until the end of their quarantine period before seeking vaccination to avoid potentially exposing healthcare personnel.

D. Patients who have been exposed to COVID-19 living in congregate settings, including long-term care, homeless shelters, or correctional institutions, where exposure or transmission can occur repeatedly over a long period of time may be vaccinated without completing a quarantine period.

E. 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.

F. 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.

G. 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.

H. Persons who are trying to become pregnant do not need to avoid pregnancy after receiving COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.

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

J. Children 3 years 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 the 2023–2024 COVID-19 mRNA vaccines. Doses for adults and immunocompromised persons ≥5 years of age may be any authorized product.

9. Side Effects and Adverse Reactions

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

Pfizer[1,3] and Moderna[2,4] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 93%
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Up to 16%
Lymphadenopathy*	Up to 20%
Serious adverse events	Uncommon, up to 1% (similar to placebo group)
Novavax[5] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 82%
Systemic events (fatigue, muscle pain, headache, nausea)	Very common, up to 62%
Fever	Uncommon, up to 6%

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10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. For Pfizer vaccine only: thaw, if needed. The yellow cap formulation requires reconstitution; the blue and gray cap formulations are ready to administer.[1,3]

C. For Moderna vaccine only: thaw vaccine prior to administration.[2,4]

Vaccine	Temp	Storage Issues	Notes
Pfizer[1,3]	-90° to -60° C (-130° to -76° F)	Vaccine may be stored until the expiration date.	
	2° to 8° C (36° to 46° F)	**Adolescent/adult bivalent formulation (blue or gray cap):** store in the refrigerator for up to 10 weeks	
		Pediatric formulation (yellow cap): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
	Ambient temperatures	**Adolescent/adult bivalent formulation (blue or gray cap):** vaccine may be held at room temperature for up to 12 hours	Any unused vaccine should be discarded.
		Pediatric bivalent formulations (yellow cap): once mixed, vaccine may be held at room temperature for up to 12 hours	
Moderna[2,4]	-50° to -15° C (-58° to 5° F)	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 (36° to 46° F)	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vials of vaccine is viable for up to 24 hours at room temperature	
Novavax[5]	2°– 8°C (36° to 46° F)	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at www.novavaxcovidvaccine.com enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C (36° to 77° F) for use within 6 hours. Discard the vial 6 hours after first puncture. Do not freeze. Protect vaccine from light.

11. References

1. Pfizer-BioNTech COVID-19 Vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet, 11 Sep 2023. Available at: https://www.fda.gov/media/167211/download. Accessed 14 Sep 2023.
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4. Moderna Spikevax, 2023–2024 formulation. Package insert, 11 Sep 2023. Available at: https://www.fda.gov/media/155675/download. Accessed 14 Sep 2023.
5. Novavax, Inc. Full emergency use authorization (EUA) prescribing information, 28 Mar 2023. Available at: https://www.fda.gov/media/159897/download. Accessed 14 Sep 2023.
6. Wallace M. Evidence to Recommendations Framework: 2023–2024 (Monovalent, XBB Containing) COVID-19 Vaccine. PowerPoint presentation, 12 Sep 2023. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf. Accessed 14 Sep 2023.
7. Interim clinical considerations for use of COVID-19 vaccines in the United States, May 12, 2023. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html. Accessed 14 Sep 2023.

12. Appendix

A. COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, May 2023: https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf