Immunization Pharmacy Protocol

COVID-19 Vaccine (Pfizer-BioNTech, Moderna, Janssen [Johnson & Johnson])	
Last Reviewed	21 June 2022
Last Revised	21 June 2022
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1. What's new

The FDA has approved an EUA for Moderna vaccine in children ages 3 years through 5 years and an EUA for Pfizer vaccine in children ages 3 years through 4 years. The ACIP now recommends the COVID vaccine series for all children over 3 years of age and all adults.

The ACIP recommends a booster dose of Pfizer vaccine for children 5 through 11 years of age at least 5 months after the previous dose. Immunocompromised children can receive the booster at least 3 months after the previous dose.

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. People aged 15–17 years may consent for their own vaccinations and do not need a parent to consent or to be present. For more information, see appendix D.

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 purple-, orange[5]- and maroon cap[7] formulations require reconstitution; the gray formulation is ready to administer.[1,7]

   For Moderna vaccine only: thaw vaccine prior to administration.[3]

H. Administer a dose of Pfizer[1,5] or Moderna[3] 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.

I. Janssen vaccine may be used in an adult patient only if there is a contraindication to an mRNA vaccine; or if the recipient refuses an mRNA vaccine, after a discussion of the risks and benefits of the Janssen vaccine.[4]

J. Persons who are immunocompromised and were vaccinated with an mRNA vaccine should receive a three-dose primary series of the same vaccine brand. A different brand of vaccine may be used if the same brand is unknown or unavailable.[2]

K. Persons who are immunocompromised and who received Janssen vaccine should receive an additional dose of Pfizer or Moderna vaccine. If they received one Janssen dose, give a mRNA vaccine ≥28 days after the first dose. If they received two Janssen doses, give a mRNA vaccine ≥2 months after the second Janssen dose. For more specific information, see appendix E.

L. COVID-19 vaccines appear to be more reactogenic than most.[2] Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12–24 hours.

M. 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.

N. 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.[2]

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

Pharmacist Signature Date

3. Vaccine schedule for COVID-19 Vaccines

Preferred vaccines[2]

Dose and Route: Pfizer Pediatric mRNA vaccine 0.2 mL, 3 µg, IM[5]			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	3 years	through 4 years (<5 yrs)	
2			21 days
3			8 weeks

Dose and Route: Moderna Pediatric mRNA vaccine 0.25 mL, 25 µg, IM			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	3 years	through 5 years (<6 yrs)	
2			28 days
3*	3 years for certain* immunocompromised patients	through 5 years* (<6 yrs)	At least 28 days

*Only for certain patients who are moderately to severely immunocompromised. See Section 5.

Dose and Route: Pfizer Pediatric mRNA vaccine 0.2 mL, 10 µg, IM[5]			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	5 years	11 years	
2		12 years*	21 days
3		12 years*†	28 days
Booster[6]		12 years*	5 months after primary dose 2 or 3 months after primary dose 3

*Children who turn 12 years of age between the first and second doses may receive either the pediatric or the adolescent/adult formulation.[2]

†Only for certain patients who are moderately to severely immunocompromised. See Section 5.

Dose and Route: Pfizer mRNA vaccine 0.3 mL, 30 µg, IM[1]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	12 years	
2		21 days
3*		28 days
Booster # 1[2]		5 months after primary dose 2 or 3 months after primary dose 3
Booster #2[2]	12 years for certain* immunocompromised patients; 50 years for healthy adults	4 months after booster dose #1

*Only for certain patients who are moderately to severely immunocompromised. See Section 5.[2]

Dose and Route: Moderna mRNA vaccine 0.5 mL, 100 µg, IM[3]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	18 years	
2		28 days
3*		28 days
Booster Dose and Route: Moderna mRNA vaccine 0.25 mL, 50 µg, IM[3]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
Booster #1[2]	18 years	5 months after primary dose 2 or 3 months after primary dose 3

Booster #2[2]	18 years for certain* immunocompromised patients; 50 years for healthy adults	4 months after booster dose #1

*Only for certain patients who are moderately to severely immunocompromised. See Section 5.[2]

Not a preferred vaccine. Use only after risk/benefit discussion with patient[4]

Dose and Route: Janssen Ad26 vaccine¶ 0.5 mL, 5×10^{10} viral particles, IM[4]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	18 years	
2*†[20]		28 days
Booster #1		2 months after primary dose 1 or 2
Booster #2		A dose of a mRNA vaccine may be given at least 4 months after booster dose #1.

¶ For use only in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine.[4]

*Only for certain patients who are moderately to severely immunocompromised. See Section 5.[2]

†An mRNA vaccine should be used for this dose.

4. Licensed COVID-19 vaccines

Product Name	Vaccine Components	Presentation	Acceptable age range	Thimerosal
Preferred vaccines				
BNT162b2† (Pfizer/BioNTech)	mRNA	2.2-mL, 10-dose vial	6 months - 4years	No
mRNA-1273 (Moderna)	mRNA	2.5-mL, 10-dose vial	6 months – 5 years	No
BNT162b2 (Pfizer/BioNTech)	mRNA	2.6-mL, 10-dose vial[5]	5–11 years	No
		2.25-mL, 6-dose vial[1]	≥12 years	
mRNA-1273 (Moderna)[3]	mRNA	5.0-mL, 10-dose vial or 14-dose* vial	≥18 years	No

Use only after risk/benefit discussion with patient				
Ad26.COV2.S (Janssen)[4]	recombinant adenovirus type 26	2.5-mL, 5-dose vial	≥18 years	No

*Moderna vial stoppers may not be punctured more than 20 times. Any remaining doses must be discarded.

†The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years". Vials with either printed age range can be used for individuals 6 months through 4 years of age.[9]

5. Recommendations for use[2]

A. A mRNA COVID-19 vaccine series should be offered to all persons aged 3 years and older.

B. Covid-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series. Only in exceptional situations in which the mRNA vaccine product administered for previous doses is not available, either age-appropriate available mRNA Covid-19 vaccine may be administered to complete the primary vaccine series.[9]

C. Children should receive age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size and weight. If a person moves from a younger age group to an older age group during the primary series or between primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.[9]

D. Children 3 years through 5 years who received the two-dose primary series of Moderna and are moderately to severely immunocompromised should be offered a third dose of Moderna COVID-19 vaccine ≥28 days after their previous dose. This dose is considered an additional primary dose, not a booster dose. Pfizer is recommended as a three-dose series for this age group regardless of immunocompetency status.[9]

E. For healthy patients 12–64 years of age and especially for males ages 12–39 years of age, an 8-week interval may be optimal to balance disease protection and vaccine risk. Adults ≥65 years of age, patients who are immunocompromised, and others who need rapid protection should continue to be vaccinated using the minimum interval.

F. All persons over 5 years of age who are moderate to severely immunocompromised should be offered an additional dose of either Pfizer or Moderna COVID-19 vaccine ≥28 days after their previous dose. This dose is

considered an additional primary series dose, not a booster dose. The additional dose should be the same brand as previously received, if possible, except for patients who received Janssen. An mRNA vaccine should be used for these patients, see appendix E for more information. Only Pfizer COVID-19 vaccine may be used for children 5–17 years of age.

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.

G. Children who turn 12 years of age after their first dose of Pfizer vaccine may be given either the pediatric formulation (orange cap) or adolescent/adult formulation (purple cap) of Pfizer for the second dose.

H. People 5–17 years of age who completed a Pfizer vaccine series are encouraged to receive a booster dose of Pfizer vaccine ≥5 months after their last dose.[6] For patients who are immunocompromised, the booster may be offered 3 months after completion of the primary series.

I. Persons ≥18 years of age who completed a Moderna mRNA primary vaccine series ≥5 months ago should receive a booster dose. For patients who are immunocompromised, the interval may be shortened to 3 months.

J. Persons ≥50 years of age, and certain immunocompromised persons 12–49 years of age, should receive a second booster dose of mRNA vaccine at least 4

months after their previous booster dose. In children 12–17 years of age, only Pfizer vaccine may be used.

K. Persons who are ≥18 years of age and received the Janssen vaccine ≥2 months ago should receive a mRNA booster dose.

L. Persons ≥18 years of age who received primary and booster doses of Janssen vaccine may be offered a second booster dose of a mRNA vaccine ≥4 months after their previous Janssen booster dose.

M. Some persons vaccinated as part of a clinical trial or vaccinated outside of the United States may be eligible for a booster dose of a mRNA vaccine. See Appendix C for more information.

N. Persons ≥5 years of age who are immunocompromised and were vaccinated outside the U.S. may receive an additional primary dose mRNA COVID-19 vaccine ≥28 days after their previous dose. Only Pfizer may be used in children <18 years of age.

O. Recipients of HCT, CAR-T-cell, or other B-cell depleting therapies who received doses of COVID-19 vaccine prior to or during treatment should be revaccinated for doses received before or during treatment.

P. Based on clinical judgement, revaccination may also be considered once immune competence is regained for people who received COVID-19 vaccine doses during chemotherapy or radiation treatment.

Q. An additional primary dose of an mRNA COVID-19 vaccine (if revaccinated with a 2-dose mRNA COVID-19 vaccine primary series) is recommended as part of revaccination for persons who continue to have moderate or severe immune compromise. The additional primary dose of an mRNA COVID-19 vaccine should be administered at least 28 days after the second dose. A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.

6. Contraindications[4]

Do not administer the Janssen COVID-19 vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccines (e.g., AstraZeneca's COVID-19 vaccine which is not authorized or approved in the United States).[4]

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

Vaccine	Vaccine Excipient Summary
BNT162b2 (Pfizer/BioNTech)[1]	Lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene

[purple cap]	glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose. Vaccine contains no preservative. Stopper is not made with natural rubber latex.
BNT162b2 (Pfizer/BioNTech) [gray cap]	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.
BNT162b2 (Pfizer/BioNTech) [orange cap]	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), 10.3 mg sucrose, 0.02 mg tromethamine, and 0.13 mg tromethamine hydrochloride.
BNT162b2 (Pfizer/BioNTech) [maroon cap]	Lipids (0.04 mg ((4hydroxybutyl)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), 3.2 mg sucrose, 0.006 mg tromethamine, and 0.04 mg tromethamine hydrochloride
mRNA-1273 (Moderna)[3] [red cap and dark blue cap with purple border on label]	A total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose. Vaccine contains no preservative. Stopper is not made with natural rubber latex.
mRNA-1273 (Moderna)[3]	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]),

[dark blue cap with magenta border on label]	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
Ad26.COV2.S (Janssen)[4]	Citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate 80, sodium chloride, sodium hydroxide, and hydrochloric acid.

7. Warnings and precautions[2]

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 Janssen Ad26.COV2.S 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. Patients who receive this dose should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series. See Appendix A for additional information.

C. Moderate or severe acute illness.

D. Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. Cases of thrombosis with thrombocytopenia (TTS) reported following administration of the Janssen COVID-19 vaccine have been reported in males and females, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30–49 years; overall, approximately 15% of TTS cases have been fatal.

8. Other considerations[2]

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. 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.

F. CDC recommends that Pfizer 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.

9. Side effects and adverse reactions

Adverse Event (Pfizer[1] and Moderna[3])	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 (Janssen[4])	**Frequency**

Injection site events (pain at the injection site, redness, swelling)	Up to 50%
Systemic events (fatigue, headache, muscle ache, joint pain)	Up to 55%
Fever	Up to 13%
Serious adverse events	Up to 2.3% (slightly higher than placebo group)

*Lymph node swelling in the underarm is more common after the booster dose than after the initial series.[2]

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 is viable for 12 months from manufacture date.	Regardless of storage condition, Pfizer vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.[7]
	-25° to -15° C **Adolescent/adult formulation only (purple cap)**	Before mixing, vaccine may be kept for up to 2 weeks.	Vials stored in the freezer may be moved to ultra-cold storage once. The 2-week timeframe is suspended once vials are placed in ultra-cold storage. Vials stored in the freezer may be stored in the refrigerator for an additional 31 days.
	2° to 8° C	**Adolescent/adult formulation (purple cap)**: before mixing, the vaccine may be stored in the refrigerator for up to 1 month (31 days).	

		Adolescent/adult formulation (gray cap): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks	
		Pediatric formulations (orange and maroon caps): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
	Ambient temperatures	**Adolescent/adult formulation (purple cap)**: once mixed, vaccine may be held at room temperature for up to 6 hours.	
		Pediatric formulations (orange and maroon caps) or Adolescent/adult formulation (gray cap): once mixed, vaccine may be held at room temperature for up to 12 hours.	Any unused vaccine should be discarded.
Moderna[3]	-50° to -15° C	Vaccine is viable until the expiration date.	Once vial 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 vials of vaccine viable for up to 24 hours at room temperature.	
Janssen[4]	2° to 8° C	Vaccine is viable until the expiration date.	Once vial stopper has been punctured,

	Ambient temperatures	Unpunctured vials of vaccine viable for up to 12 hours at room temperature.	refrigerate remaining doses for use within 6 hours. At room temperature, remaining doses must be used within 2 hours. Protect vaccine from light.

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, 12 years of age and older. Emergency use authorization (EUA) fact sheet and prescribing information, 17 Jun 2022, available at: www.fda.gov/media/153713/download. Accessed 19 Jun 2022.
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3. Moderna. Package insert. January 2022. Available at: www.fda.gov/media/155675/download. Accessed 19 Jun 2022 .
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available at: www.fda.gov/media/153714/download. Accessed 19 Jun 2022.
6. Centers for Disease Control and Prevention. CDC Strengthens Recommendations and Expands Eligibility for COVID-19 Booster Shots. Available at: www.cdc.gov/media/releases/2022/s0519-covid-booster-acip.html.Accessed 19 Jun 2022.
7. Pfizer-BioNTech COVID-19 Vaccine, 6 months through 4 years of age, Emergency use authorization (EUA) fact sheet and prescribing information, 17 June 2022, available at www.fda.gov/media/159312/download. Accessed 18 June 2022.
8. Moderna COVID-19 Vaccine, 6 months through 5 years of age, Emergency use authorization (EUA) fact sheet and prescribing information, 17 June 2022, available at: www.fda.gov/media/159307/download. Accessed 18 June 2022.
9. Hall, Elisha. Interim Clinical Considerations Update for Pediatric Covid-19 Vaccines. Presented at June 18, 2022, Advisory Committee on Immunization Practices (ACIP) meeting and available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/04-COVID-Hall-508.pdf. Accessed 18 June 2022.

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

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

13. Appendix A[1]

Triage of persons presenting for COVID-19 vaccination:

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	**Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	**Among people without a contraindication or precaution, a history of:** • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

14. Appendix B

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine (including the second dose of an mRNA COVID-19 vaccine). The following table of signs and symptoms is meant to serve as a resource but might not be exhaustive, and patients might not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, might have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; might have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine and clinical management recommendations			
If vaccinated with mRNA COVID-19 vaccine as first dose, recommended to receive second mRNA	No	Yes	Yes

15. Appendix C[2]

People vaccinated outside the United States

People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine:

- If they received all the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series, they are considered fully vaccinated.
- If they received the first dose of a 2-dose mRNA COVID-19 vaccine series, they do not need to restart the vaccine series in the United States. They should receive the second dose as close to the recommended time as possible and are considered fully vaccinated upon completion of the 2-dose primary series. This also applies to people who were vaccinated in countries where only a single mRNA dose is administered; they are not considered fully vaccinated in the United States until after completion of the 2-dose series.
- People who are moderately or severely immunocompromised and were vaccinated with a 2-dose mRNA COVID-19 vaccine primary series or a single dose of Janssen vaccine should receive an additional primary dose of an mRNA vaccine ≥28 days after the previous dose.

People who completed all the recommended doses of an WHO-EUL COVID-19 vaccine not approved or authorized by FDA, or people who completed a mix and match series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines:

- Are considered fully vaccinated.
- Under the EUI, people aged ≥5 years who are moderately or severely immunocompromised should receive an additional primary dose of an mRNA vaccine at least 28 days after receiving the second vaccine dose of their primary series. Only Pfizer-BioNTech COVID-19 vaccine may be used in children <18 years of age.
- Under the EUI, people aged ≥12 years (including people who are moderately or severely immunocompromised who received an additional primary dose) are eligible to receive a single booster dose of mRNA COVID-19 vaccine at least 5 months after completing their primary series. The interval may be shortened to 3 months for people who are immunocompromised.

People who received only the first dose of a multidose WHO-EUL COVID-19 primary series that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO:

- Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, with a minimum interval of at least 28 days since

receipt of the last dose of a non-FDA-approved/authorized vaccine. mRNA vaccines are preferred.

- After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated, and are not recommended to receive an additional primary or booster dose at this time.

People vaccinated as part of a clinical trial in the United States

Participants in clinical trials within or outside the United States who received all of the recommended "active" (not placebo) primary series doses of a WHO-EUL COVID-19 vaccine that is not FDA-approved or FDA-authorized or a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy (i.e., Novavax COVID-19 vaccine, Moderna COVID-19 vaccine in children aged 6-17 years):

- Are considered fully vaccinated.
- Unless they have received or plan to receive an additional dose through a clinical trial, under EUI, people who are moderately or severely immunocompromised clinical trial participants aged ≥5 years should receive an additional primary dose of a mRNA COVID-19 vaccine at least 28 days after receiving the second vaccine dose of their primary series. Only Pfizer-BioNTech COVID-19 vaccine may be used in children <18 years of age.
- Unless they have received or plan to receive a booster dose through a clinical trial, under EUI, clinical trial participants aged ≥12 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of mRNA COVID-19 vaccine at least 5 months after completing their primary series. The interval may be reduced to 3 months for people who are immunocompromised. Only Pfizer-BioNTech COVID-19 vaccine may be used in children <18 years of age.
- If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider.

Clinical trial participants who did not receive all of the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.

16. Appendix D

Minor Consent

- Under Oregon law (ORS 109.640) minors 15 and older have the legal authority to consent to medical treatment, including vaccinations, provided by a physician, physician assistant, naturopath, nurse practitioner, dentist or optometrist, or other professionals operating under the license of, or at the direction of, these providers. Parent or guardian consent cannot be required. OAR 333-003-5000. A sample consent form for minors age 12 to 14 can be found under Forms at https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Pages/COVIDvaccine.aspx.
- Most locations where COVID-19 vaccinations are provided have oversight by a medical provider on this list and therefore minors 15 and older can consent to vaccination. ***OHA prohibits a provider listed above, or anyone operating under the license of or at the direction of these providers, from requiring parental consent for a minor 15 or older, if that minor is exercising their right to consent to vaccination.*** A provider may, but is not required to, inform a parent or guardian about the vaccination (ORS 109.650).

17. Appendix E

Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

COVID-19 Vaccination History	And	Then	Next Dose Due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a 2nd dose of mRNA vaccine ≥28 days after the 1st dose. • Pfizer: 0.3 mL, or • Moderna: 0.5 mL	Administer a booster dose ≥2 months after the 2nd dose. • Pfizer: 0.3 mL, or • Moderna: 0.25 mL, or • Janssen: 0.5 mL*
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna: 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen and 1 booster dose of Pfizer or Moderna+ COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna: 0.5mL	
	1 dose of Janssen and 1 full dose of Pfizer or Moderna+ COVID-19 Vaccine	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna: 0.25mL, or • Janssen: 0.5mL*	

*mRNA vaccines are preferred.

+Doses of Moderna received prior to 02/07/2022 should be considered to have been the booster dosage (0.25 mL: 50 mcg).