Immunization Pharmacy Protocol

COVID-19 Vaccine (Pfizer-BioNTech, Moderna, Johnson and Johnson)	
Last Reviewed	3 September 2021
Last Revised	3 September 2021
This order expires	31 December 2021

Table of contents

1. What's new

Added definition of advanced HIV to section 5.

Added third dose of mRNA vaccine for persons who are moderately to severely immunocompromised.

Added instruction to report all doses of COVID-19 vaccine to ALERT IIS within 72 hours.

2. Oregon immunization pharmacy 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 an Emergency Use Authorization 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 be present. For more information, see appendix G.

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 and mix vaccine prior to administration.[4] See Appendix B.

H. For Moderna vaccine only, thaw vaccine prior to administration.[8] See Appendix C.

I. Administer a 0.3-mL dose of Pfizer COVID-19 vaccine,[3] a 0.5-mL dose of Moderna COVID-19 vaccine,[7] or a 0.5-mL dose of Johnson & Johnson COVID-19 vaccine[10] according to ACIP recommendations, priority group and vaccine package insert.

J. COVID-19 vaccines are not interchangeable.[6] If patient is due for a second or third[14] dose of COVID-19 vaccine, verify that staff are using the same vaccine brand that was administered for the first and second doses.

K. COVID-19 vaccine appears to be highly reactogenic.[6] Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12–24 hours.

L. 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.

M. 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.[6]

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

Immunizing Pharmacist Date

3. Vaccine schedule for COVID-19 Vaccine

Dose and Route: Pfizer mRNA vaccine 0.3-mL, 30 µg, IM[3]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	12 years	
2		21 days
3*		28 days
Dose and Route: Moderna mRNA vaccine 0.5-mL, 100-µg, IM[8]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	18 years	
2		28 days
3*		28 days
Dose and Route: Johnson & Johnson Ad26 vaccine 0.5-mL, 5×10^{10} viral particles, IM[10]		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	18 years	

*Only for certain moderately to severely immunocompromised patients. See Section 5.[14]

4. Licensed COVID-19 vaccine

Product Name	Vaccine Components	Presentation	Acceptable age range	Thimerosal
BNT162b2 (Pfizer/BioNTech)[3]	mRNA	2.0-mL, 6-dose vial	≥12 years	No

mRNA-1273 (Moderna)[8]	mRNA	5.0-mL, 10-dose vial or 15-dose vial	≥18 years	No
Ad26.COV2.S (Johnson & Johnson)[10]	recombinant adenovirus type 26	2.5-mL, 5-dose vial	≥18 years	No

5. Recommendations for use

The 1- or 2-dose series of a COVID-19 vaccine should be offered to all persons aged 18 years and older. Additionally, Pfizer COVID-19 vaccine should be offered to all persons aged 12 years through 17 years of age.

Moderate to severely immunocompromised persons should be offered a third dose of either Pfizer or Moderna COVID-19 vaccine, depending on the brand received previously. There is currently no indication for additional doses of Johnson and Johnson vaccine.[14]

Conditions causing moderate to severe immunodeficiency include:[14]

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR*-T-cell or hematopoietic stem cell transplant (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

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

immunomodulatory.

6. Contraindications[6]

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

Vaccine	Vaccine Excipient Summary
BNT162b2 (Pfizer/BioNTech)[3]	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 0.2 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.
mRNA-1273 (Moderna)[8]	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.
Ad26.COV2.S (Johnson & Johnson)[10]	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[6]

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 Johnson & Johnson 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.[11]

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 Johnson & Johnson 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 Johnson & Johnson 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. Most cases of thrombosis with thrombocytopenia (TTS) reported following the Johnson & Johnson COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal.

8. Other considerations[6]

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 should defer vaccination for 90 days after initial infection to avoid potential immune interference.

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.[13]

F. CDC recommends that Pfizer vaccine for adolescents aged 12–17 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.[13]

G. While OHA does not recommend intentional delays between doses of mRNA vaccination series, there is no need to repeat the dose or to restart the series in individuals who receive the second dose of their mRNA series more than 42 days after the first. There is no need to report this dosing interval discrepancy to VAERS.

H. There are currently few data on the safety of COVID-19 vaccines in pregnant or lactating people. Experts believe that mRNA vaccines and Ad26.COV2.S vaccine are unlikely to pose a risk to the pregnant person or the fetus. However, the potential risks of COVID-19 vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people. If pregnant or lactating persons are part of a group that is recommended to receive vaccination, they may choose to be vaccinated.

I. 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.

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

K. Immunocompromised persons may receive COVID-19 vaccination if they have no contraindications to vaccinations. However, they should be counseled about the unknown safety profile and effectiveness in this population.

9. Side effects and adverse reactions

Adverse Event (Pfizer[5] and Moderna[7])	Frequency
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 85%
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Uncommon, up to 16%
Lymphadenopathy	Uncommon, up to 20%
Serious adverse events	Rare, up to 1% (similar to placebo group)
Adverse Event (Johnson & Johnson[10])	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Common, up to 50%
Systemic events (fatigue, headache, muscle ache, joint pain)	Common, up to 55%

Fever	Uncommon, up to 13%
Serious adverse events	Rare, up to 2.3% (slightly higher than placebo group)

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[4, 12]	-80° to -60° C	Vaccine should be opened and inspected within 24 hours.	
	-25° to -15° C	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 5 days.
	2° to 8° C	Once shipper is opened, vaccine must be re-iced with dry ice pellets. Before mixing, the vaccine may be stored in the refrigerator for up to 1 month (31 days).	
	Ambient temperatures	Once mixed, vaccine may be held at room temperature for up to 6 hours.	Any unused vaccine should be discarded.

Moderna[8]	-50° to -15° C	Vaccine is viable for 6 months in freezer conditions.	Once vial stopper has been punctured, all doses must be used within 12 hours.
	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.	
Johnson & Johnson	2° to 8° C	Vaccine is viable under refrigeration for several months.	Once vial stopper has been punctured, refrigerate remaining doses for use within 6 hours. At room temperature, remaining doses must be used within 2 hours. Protect vaccine from light.
	Ambient temperatures	Unpunctured vials of vaccine viable for up to 12 hours at room temperature.	

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[6]
A. Vaccine administration errors B. Serious adverse events C. Multisystem Inflammatory Syndrome D. Cases of COVID-19 resulting in hospitalization or death

12. References

1. Pfizer. Briefing Document for Vaccine and Related Biological Products Advisory Committee. 10 December 2020. Available at www.fda.gov/media/144246/download. Accessed 2 March 2021.
2. Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' interim recommendation for allocating initial supplies of COVID-19 vaccine. MMWR 2020; 69:1857–9. Available at www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm. Accessed 2 March 2021.
3. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' interim recommendations for use of Pfizer-BioNTech COVID-19 vaccine. MMWR 2020; 69(50): 1922–4. Available at www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm. Accessed 2 March 2021.
4. Pfizer-BioNTech COVID-19 Vaccine. Full emergency use authorization (EUA) prescribing information, 2020, available at: www.fda.gov/media/144413/download. Accessed 2 March 2021.
5. Local reactions, systemic reactions, adverse events, and serious adverse events: Pfizer-BioNTech COVID-19 Vaccine. Available at www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html. Accessed 2 March 2021.
6. Interim clinical considerations for use of mRNA COVID-19 vaccine. Available at www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Accessed 2 March 2021.
7. Moderna. Meeting Presentation for Vaccine and Related Biological Products Advisory Committee. Available at www.fda.gov/media/144452/download. Accessed 2 March 2021.
8. Moderna. Full emergency use authorization (EUA) prescribing information, 2020, available at: https://www.fda.gov/media/144637/download. Accessed 2 March 2021.
9. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' interim recommendations for use of Moderna COVID-19 vaccine. MMWR 2021;69(5152): 1653–6. Available at www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w. Accessed 2 March 2021.
10. Janssen Biotech, Inc. Briefing Document for Vaccine and Related Biological Products Advisory Committee. 26 February 2021. Available at:

www.fda.gov/media/146217/download. Accessed 2 March 2021.

11. McNeil J. Clinical Considerations for Use of COVID-19 Vaccines. 1 March 2021. Available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html Accessed 2 March 2021.
12. Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf. Accessed 29 March 2021.
13. Woodworth K. Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccination in Adolescents. 12 May 2021. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/05-COVID-Woodworth-508.pdf. Accessed 12 May 2021.
14. Goswami ND. Clinical Considerations for Use of an Additional mRNA COVID-19 V accine Dose After a Primary mRNA COVID-19 Vaccine Series for Immunocompromised People. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/03-COVID-Goswami-508.pdf. Accessed 16 August 2021.

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[11]

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

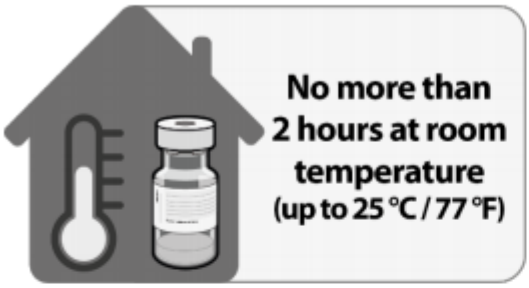
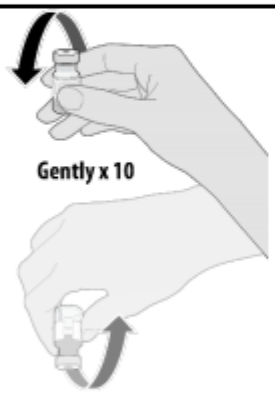
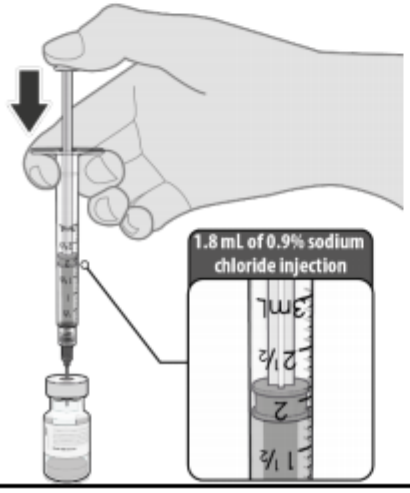
14. Appendix B

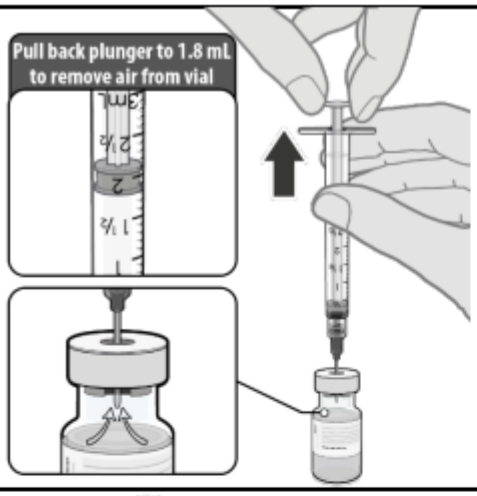
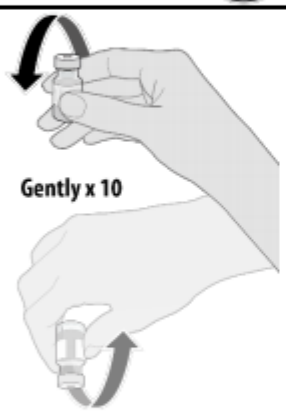
In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine (including the second dose of an mRNA COVID-19 vaccine). The 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[8]

Directions for thawing and mixing Pfizer vaccine.

<table>
<tr><th colspan="2">THAWING PRIOR TO DILUTION</th></tr>
<tr><td> 
</td><td>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).
○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
• Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.</td></tr>
<tr><td> 
</td><td>• Before dilution invert vaccine vial gently 10 times.
• Do not shake.
• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
• Do not use if liquid is discolored or if other particles are observed.</td></tr>
<tr><th colspan="2">DILUTION</th></tr>
<tr><td> 
</td><td>• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
• Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
• Cleanse the vaccine vial stopper with a single-use antiseptic swab.
• Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.</td></tr>
</table>

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

16. Appendix D[8]

For intramuscular injection only.

Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes (10-dose vial) or 3 hours (15-dose vial).
- After thawing, let vial stand at room temperature for 15 minutes before administering. Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour (10-dose vial) or 1 hour and 30 minutes (15-dose vial). After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5 mL. • After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

17. Appendix E[10]

- The Johnson & Johnson COVID-19 vaccine is a refrigerated suspension that does not need to be thawed or reconstituted.
- Protect from light.
- The Johnson & Johnson is a colorless to slightly yellow, clear to very opalescent sterile vaccine containing a replication-incompetent recombinant adenovirus type 26 (Ad26) vector.
- Each 2.5-mL multi-dose vial contains 5, 0.5-mL doses containing $5x10^{10}$ adenovirus particles expressing the SARS-CoV-2 spike protein in a stabilized conformation.

- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake.
- Administer a single, 0.5-mL dose intramuscularly.
- Unpunctured vials may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours. After the first dose has been withdrawn, the vial should be held between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. The vial should be discarded if the vaccine is not used within these times.

18. Appendix F

- Incompletely vaccinated persons who received their first vaccine dose outside of Oregon should complete the series with the same vaccine brand, if available.
- If there is no record of the first dose (of an mRNA vaccine) and the patient cannot remember the brand, either Pfizer or Moderna may be given 28 days after the first dose.
- Incompletely vaccinated persons vaccinated outside the United States with Pfizer or Moderna vaccine should complete the series with a second dose of the same vaccine brand.
- Incompletely vaccinated persons vaccinated outside the United States with a vaccine not authorized for use in the U.S. should complete the series with a single dose of Johnson and Johnson vaccine.
    - Sputnik (Gam-COVID-vac) – give 1 dose of Johnson and Johnson vaccine at least **21 days** after the previous dose.
    - CoronaVac (Sinovac) - give 1 dose of Johnson and Johnson vaccine at least **28 days** after the previous dose.
    - AstraZeneca (Covishield) - give 1 dose of Johnson and Johnson vaccine at least **28 days** after the previous dose.
- Incompletely vaccinated persons may opt to restart a vaccine series with 1 dose of Johnson and Johnson vaccine or 2 doses of either Pfizer or Moderna vaccine.
- In addition to the above, persons who have received a complete series with a WHO non-authorized vaccine series (see attached list for WHO EUL status),

may choose to restart vaccination with an FDA-authorized vaccination series.

19. Appendix G

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).