Model Standing Order

COVID-19 Vaccine (Pfizer-BioNTech, Moderna, Johnson and Johnson)	
Last Reviewed	2 March 2021
Last Revised	2 March 2021
This order expires	31 December 2021

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1. What's new

Addition of Johnson & Johnson COVID-19 vaccine.

New vaccines are being authorized for use in the United States by the U.S. Food and Drug Administration (FDA) in response to the worldwide coronavirus pandemic. These vaccines have strict storage and handling requirements. See section 10.

2. Oregon immunization model standing order

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine.

B. Screen client for contraindications.

C. Provide an Emergency Use Authorization Fact Sheet for Recipients and Caregivers, and answer any questions.

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 dose of COVID-19 vaccine, verify that staff are using the same vaccine brand that was administered for the first dose.

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]

Amy Henninger/s/ 3/15/21

Health Officer Signature Date

Health Officer Signature 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	16 years	
2		21 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
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	

4. Licensed COVID-19 vaccine

Product Name	Vaccine Components	Presentation	Acceptable age range	Thimerosal
BNT162b2 (Pfizer/BioNTech)[3]	mRNA	2.0-mL, 5-dose vial	≥16 years	No
mRNA-1273 (Moderna)[8]	mRNA	5.0-mL, 10-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 should be offered in accordance with the ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines and Oregon-specific prioritization.

ACIP Prioritization Group[2]	Includes	Oregon-Specific Guidance

1A	Health care workers	https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le3527A.pdf
1B	Frontline essential workers and persons over 65 years of age	
1C	Essential workers and persons 16–64 years of age with high-risk conditions	

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 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 from 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.

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 vaccination should be separated from administration of other vaccines by 2 weeks.

F. 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.

G. 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.

H. Adolescents 16–17 years of age who are part of a part of a group that is recommended to receive COVID-19 vaccine may receive Pfizer vaccine, with appropriate consent.

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

J. 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]	-80° to -60° C	Vaccine should be opened and inspected within 24 hours.	
	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 120 hours (5 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]	-25° to -15° C	Vaccine is viable for 6 months in freezer conditions.	Once vial stopper has been punctured, all doses must be used within 6 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 12 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.

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 standing order is available at: standing orders

Electronic copy of this pharmacy protocol is available at: protocols

13. Appendix A[11]

Triage of persons presenting for COVID-19 vaccination:

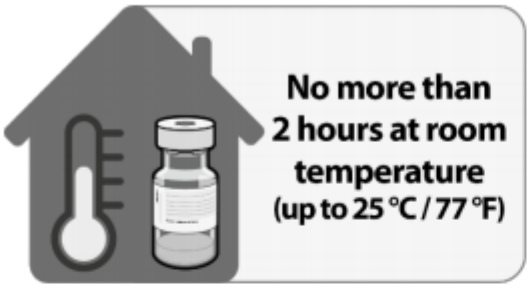
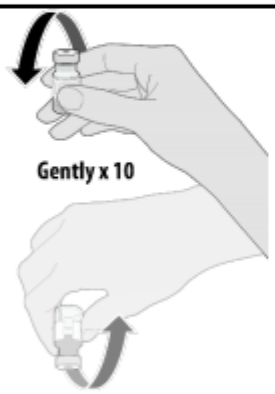
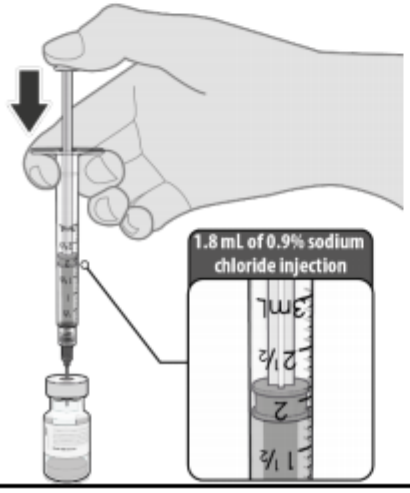
Contraindications and precautions for COVID-19 vaccines

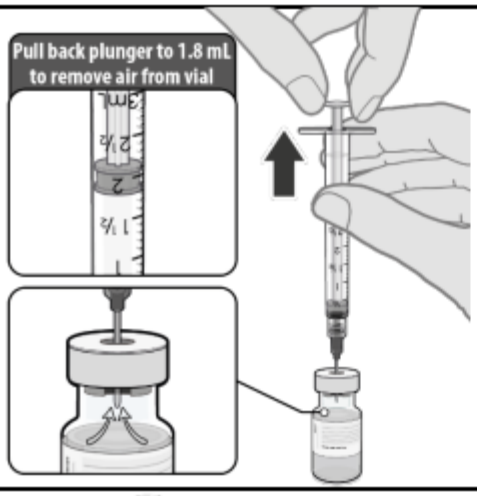
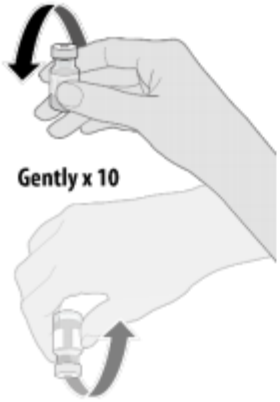
CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Among persons without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa# Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Among persons 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: • 30-minute observation period: persons with history of anaphylaxis (due to any cause) • 15-minute observation period: all other persons

† See Appendix C for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).
* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.
‡Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.
#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

14. Appendix B[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.

15. Appendix C[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.
- 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. 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 0.5mL. • 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 6 hours. Do not refreeze.

16. Appendix D[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.