Northwestern Medicine

Protocol

Title: **Clinical Support Staff Ordering and Administering COVID-19 Vaccines**	Page **1 of 5**	Protocol # Version: **2.0**
Department: **Northwestern Medicine**	Revision of: 1/22/2021	Effective Date: **04/28/2022**
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SCOPE: Applies to entities indicated below as well as their subsidiaries and affiliates

☐ **NM – Northwestern Memorial Hospital**	☐ **NM – Lake Forest Hospital**
☐ **NM – Northwestern Medical Group**	☐ **NM – Central DuPage Hospital**
☐ **NM – Regional Medical Group**	☐ **NM – Delnor Hospital**
☐ **NM – Kishwaukee Hospital**	☐ **NM – Valley West Hospital**
☐ **NM – Marianjoy Rehabilitation**	☐ **NM – Marianjoy Medical Group**
☐ **NM – System Functions / NMHC Employees**	☐ **NM – Home Health & Hospice**
☐ **NM – Huntley /** ☐ **NM – McHenry /** ☐ **NM – Woodstock Hospitals**	
☒ **NM – Other** ****See "Scope / Areas / Persons Affected" section below****	

I. PURPOSE:

To provide physician-approved guidelines, based on the Centers for Disease Control and Prevention and the National Center for Immunization and Respiratory Disease recommendations, to allow clinical support staff (RN, RPh, LPN, CMA) to administer COVID-19 vaccines to patients that meet the defined criteria.

II. SCOPE / AREAS / PERSONS AFFECTED:

All NM sites that administer COVID-19 vaccinations approved or authorized for use by the FDA.

III. GENERAL INFORMATION/SPECIAL INSTRUCTIONS:

Under this procedure, clinical support staff (RN, LPN, MA), may screen for, order, sign, and administer COVID-19 vaccinations for adults who meet the criteria below:

A. Required vaccine-specific screening questions in Epic and EUA information, if applicable, will be reviewed with all patients prior to proceeding to B.

B. All patients presenting for a COVID-19 vaccination will be screened for contraindications and precautions (See appendix pertaining to vaccine to be administered)

1. If there are no contraindications, the clinical support staff may administer the COVID-19 vaccination according to this NM system-approved procedure.

IV. PROCEDURE:

A. For screening and administering Pfizer-BioNTech COVID-19 Vaccine, see **Appendix A**
B. For screening and administering Moderna COVID-19 Vaccine, see **Appendix B**
C. For screening and administering Janssen COVID-19 Vaccine see **Appendix C**
D. For guidance in the medical management of vaccine reactions, see **Appendix D**
E. For a listing of vaccine components see **Appendix E**

APPENDIX A – PFIZER-BIONTECH COVID-19 VACCINE

Pfizer-BioNTech COVID-19 Vaccine Procedure

Assessment

Assess persons 5 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

- For those **without** moderate to severe immunocompromise:
  - This vaccine is administered in a 2-dose series. Separate doses by at least 21 days.
    - An 8-week interval may be preferred for some people 12 years and older (eg, males ages 12 to 39 years).
    - A shorter interval of 3 weeks is recommended for adults 65 years and older, people who are moderately to severely immunocompromised, and for patients at higher risk of severe disease.
  - Incomplete Primary Series: Patients who are unvaccinated or have received 1 prior mRNA COVID-19 vaccine are eligible to receive Pfizer-BioNTech COVID-19 Vaccine. If the recipient has received 1 previous dose, the second dose of the same brand should be administered.
  - Previously Completed Primary Series: Patients **12 years and older** who have completed a primary series of any COVID-19 Vaccine (2 doses for mRNA COVID-19 vaccine or 1 dose of Janssen COVID-19 vaccine) are eligible for a single booster dose with the Pfizer-BioNTech COVID-19 Vaccine. The booster dose may be homologous or heterologous (ie, mix-and-match) to the COVID-19 Vaccine(s) provided for the primary series. Patients 50 years and older are eligible for a second booster dose at least 4 months after the first booster dose.
    - mRNA COVID-19 vaccine Primary Series: first booster dose should be given at least 5 months after primary series completion
    - Janssen COVID-19 Vaccine Primary Series: first booster dose should be given at least 2 months after the single primary series dose.

- For those **with** moderate to severe immunocompromise:
  - This vaccine is administered in a 3-dose series. Separate the second dose after at least 21 days and the third dose after at least 28 days. A shorter interval of 3 weeks is recommended for people who are moderately to severely immunocompromised.
  - Incomplete Primary Series: Patients who are unvaccinated or have received 1 or 2 prior mRNA COVID-19 vaccines are eligible to receive Pfizer-BioNTech COVID-19 Vaccine. If the recipient has received 1 or 2 previous doses, the subsequent dose(s) should be administered using the same brand of COVID-19 vaccine.
  - Previously Completed Primary Series: Patients **12 years and older** who have completed a primary series of any COVID-19 Vaccine (3 doses for mRNA COVID-19 vaccine or 1 dose of Janssen COVID-19 vaccine) are eligible for a single booster dose with the Pfizer-BioNTech COVID-19 Vaccine. The booster dose may be homologous or heterologous (ie, mix-and-match) to the COVID-19 Vaccine(s) provided for the primary series. Patients with moderate to severe immunocompromise are eligible for a second booster dose at least 4 months after the first booster dose.
    - mRNA COVID-19 vaccine Primary Series: first booster dose should be given at least 3 months after primary series completion
    - Janssen COVID-19 Vaccine Primary Series: first booster dose should be given at least 2 months after the single primary series dose

Screen for Contraindications and Precautions

- Contraindications:
  - Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
  - Immediate allergic reaction± of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]. See Table 1 of vaccine components on page 3.
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
- Precautions:
  - History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
  - Moderate to severe acute illness

- History of myocarditis or pericarditis following a dose of an mRNA COVID-19 vaccine
- History of multisystem inflammatory syndrome
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.

Prepare to Administer Vaccine

- Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination as per procedure in Epic.

Manage Medical Emergencies

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
  - 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
  - 15 minutes: All other persons
- See **Appendix D** for information regarding managing vaccine reactions.
- Submit report of vaccine reactions to VAERS and as specified within the EUA.

APPENDIX B – MODERNA COVID-19 VACCINE

Moderna COVID-19 Vaccine Procedure

Assessment

Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- For those **without** moderate to severe immunocompromise:
  - This vaccine is administered in a 2-dose series. Separate doses by at least 28 days.
    - An 8-week interval may be preferred for some people 18 years and older (eg, males ages 18 to 39 years).
    - A shorter interval of 4 weeks is recommended for adults 65 years and older, people who are moderately to severely immunocompromised, and for patients at higher risk of severe disease.
  - Incomplete Primary Series: Patients who are unvaccinated or have received 1 prior mRNA COVID-19 vaccine are eligible to receive Pfizer-BioNTech COVID-19 Vaccine. If the recipient has received 1 previous dose, the second dose of the same brand should be administered.
  - Previously Completed Primary Series: Patients **18 years and older** who have completed a primary series of any COVID-19 Vaccine (2 doses for mRNA COVID-19 vaccine or 1 dose of Janssen COVID-19 vaccine) are eligible for a single booster dose with the Moderna COVID-19 Vaccine. The booster dose may be homologous or heterologous (ie, mix-and-match) to the COVID-19 Vaccine(s) provided for the primary series. Patients 50 years and older are eligible for a second booster dose at least 4 months after the first booster dose.
    - mRNA COVID-19 vaccine Primary Series: first booster dose should be given at least 5 months after primary series completion
    - Janssen COVID-19 Vaccine Primary Series: first booster dose should be given at least 2 months after the single primary series dose.

- For those **with** moderate to severe immunocompromise:
  - This vaccine is administered in a 3-dose series. Separate doses by at least 28 days. A shorter interval of 4 weeks is recommended for people who are moderately to severely immunocompromised.
  - Incomplete Primary Series: Patients who are unvaccinated or have received 1 or 2 prior mRNA COVID-19 vaccines are eligible to receive Moderna COVID-19 Vaccine. If the recipient has received 1 or 2 previous doses, the subsequent dose(s) should be administered using the same brand of COVID-19 vaccine.
  - Previously Completed Primary Series: Patients **18 years and older** who have completed a primary series of any COVID-19 Vaccine (3 doses for mRNA COVID-19 vaccine or 1 dose of Janssen COVID-19 vaccine) are eligible for a single booster dose with the Moderna COVID-19 Vaccine. The booster dose may be homologous or heterologous (ie, mix-and-match) to the COVID-19 Vaccine(s) provided for the primary series. Patients with moderate to severe immunocompromise are eligible for a second booster dose at least 4 months after the first booster dose.
    - mRNA COVID-19 vaccine Primary Series: first booster dose should be given at least 3 months after primary series completion
    - Janssen COVID-19 Vaccine Primary Series: first booster dose should be given at least 2 months after the single primary series dose

Screen for Contraindications and Precautions

- Contraindications:
  - Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
  - Immediate allergic reaction± of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]. See Table 1 of vaccine components on page 3.
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
- Precautions:
  - History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
  - Moderate to severe acute illness
  - History of myocarditis or pericarditis following a dose of an mRNA COVID-19 vaccine

- History of multisystem inflammatory syndrome
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.

Prepare to Administer Vaccine

- Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection. No reconstitution is required.
- Document vaccination as per procedure in Epic.

Manage Medical Emergencies

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
  - 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
  - 15 minutes: All other persons
- See **Appendix D** for information regarding managing vaccine reactions.
- Submit report of vaccine reactions to VAERS and as specified within the EUA.

APPENDIX C – JANSSEN COVID-19 VACCINE (Johnson & Johnson)

Janssen (Johnson & Johnson) COVID-19 Vaccine Procedure

Assessment

Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:

- **Note:** An mRNA COVID-19 vaccine series is preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination for all patient populations. Offering the Janssen COVID-19 is preferred over no vaccine.
- For those **without** moderate to severe immunocompromise:
  - This vaccine is administered as a single-dose series in patients who are previously unvaccinated.
  - A booster dose may be provided at least 2 months after the first dose
  - For patients who received Janssen COVID-19 Vaccine as their primary series and first booster dose, a mRNA COVID-19 vaccine may be given at least 4 months after the booster dose; these patients should not receive another dose of the Janssen COVID-19 Vaccine.
- For those **with** moderate to severe immunocompromise:
  - A single primary Janssen vaccine dose may be provided, followed by a second dose using an mRNA COVID-19 vaccine at least 4 weeks later.
  - For patients who received Janssen COVID-19 Vaccine followed by an mRNA COVID-19 vaccine as their primary series, an mRNA COVID-19 vaccine may be given at least 4 months after the primary series completion; these patients should not receive another dose of the Janssen COVID-19 Vaccine.
  - Patients with moderate to severe immunocompromise are eligible for a second booster dose of an mRNA COVID-19 vaccine at least 4 months after the first booster dose.

Screen for Contraindications and Precautions

- Contraindications:
  - Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
  - Immediate allergic reaction± of any severity to a component the vaccine. See Appendix E for vaccine components.
  - Thrombosis with thrombocytopenia syndrome following a previous Janssen COVID-19 Vaccine (or other adenovirus vector-based COVID-19 vaccine)
  - History of immune-mediated syndrome characterized by thrombosis and thrombocytopenia (eg, heparin-induced thrombocytopenia)
  - Guillain-Barre syndrome within 6 weeks after a prior Janssen COVID-19 vaccine
- Precautions:
  - History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies). This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polysorbate or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
  - People with a contraindication to an mRNA COVID-19 vaccine have a precaution to the Janssen COVID-19 Vaccine (consult with allergist).
  - Moderate to severe acute illness
  - History of multisystem inflammatory syndrome
  - Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
  - History of Guillain-Barre syndrome

Prepare to Administer Vaccine

- Administer 0.5 mL Janssen COVID-19 Vaccine by intramuscular (IM) injection. No reconstitution is required.
- Document vaccination as per procedure in Epic.

Manage Medical Emergencies

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
  - 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
  - 15 minutes: All other persons
- See **Appendix D** for information regarding managing vaccine reactions.
- Submit report of vaccine reactions to VAERS and as specified within the EUA.

APPENDIX D – MEDICAL MANAGEMENT OF VACCINE REACTIONS IN ADULTS

Source - Medical Management of Vaccine Reactions in Adults in a Community Setting (immunize.org)

- Administering any medication, including vaccines, has the potential to cause an adverse reaction.
- To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination.
- When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.
- Vaccine providers should know how to recognize allergic reactions, including anaphylaxis.
- Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

Medical Management of Vaccine Reactions in Adults Procedure

The table below describes steps to take if an adverse reaction occurs following vaccination.

Reaction	Signs & Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright, presyncope, and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Patient feels "faint" (e.g., light-headed, dizzy, weak, nauseated, or has visual disturbance)	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to patient's face and neck. Keep them under close observation until full recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Loss of consciousness Check to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse, dizziness, tachycardia, hypotension.	See the emergency medical protocol on the next page for detailed steps to follow in treating anaphylaxis.

Medical Management of Vaccine Reactions in Adults Procedure, continued

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the hospital emergency medical response team if onsite or emergency medical system (EMS; e.g., call 911) if offsite. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
3. DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
    a. First-line treatment: Epinephrine is the first-line treatment for anaphylaxis, and there is no known equivalent substitute. Use epinephrine in a 1.0 mg/mL aqueous solution (1:1000 dilution). Administer a 0.3 mg dose IM using a premeasured or prefilled syringe or an autoinjector in the mid-outer thigh. If using another epinephrine formulation, the recommended dose is 0.01 mg/kg, ranging for adults from 0.3 mg to maximum dose of 0.5 mg. Administer IM, preferably in the mid-outer thigh. Epinephrine dose may be repeated 2 additional times every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.
    b. Optional treatment: H1 antihistamines relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving diphenhydramine (e.g., Benadryl) for relief of itching and hives. Administer orally 1–2 mg/kg every 4–6 hours, up to a maximum single dose of 100 mg.*
4. Monitor the patient closely until the hospital emergency medical response team or EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
5. Document the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information in Epic.
6. Patients treated for allergic reaction/anaphylaxis with epinephrine and/or diphenhydramine must be taken to the Emergency Department or transported by EMS for further evaluation and treatment.
7. Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

Suggested Medications for Managing Anaphylaxis in a Community Immunization Setting

FIRST-LINE MEDICATION

- Epinephrine 1.0 mg/mL aqueous solution (1:1000 dilution) in prefilled autoinjector or prefilled syringe (0.3 mg), prepackaged syringes, vials, or ampules. At least three epinephrine doses should be available onsite.

OPTIONAL MEDICATIONS: H1 ANTIHISTAMINES

These relieve itching and hives only; they DO NOT relieve upper or lower airway obstruction, hypotension, or shock.

- Diphenhydramine (e.g., Benadryl) oral, 12.5 mg/5 mL liquid, 25 or 50 mg tablets

Additional emergency supplies you may need

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") if needed for epinephrine
- Alcohol wipes
- Tourniquet Applied on the extremity above the injection site to slow systemic absorption of antigen and anaphylactic mediators
- Stethoscope
- Blood pressure measuring device with adult-sized and extra-large cuffs
- Tongue depressors
- Light with extra batteries (for examination of the mouth and throat)
- A timing device, such as wristwatch, for checking pulse
- Cell phone or access to onsite phone

APPENDIX E – Vaccine Components

The following is a list of ingredients for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 Vaccines reported in the prescribing information for each vaccine.*

Description	Pfizer-BioNTech (mRNA) For people ages 5-11 years (orange cap) and ≥12 years (gray cap) formulations	Pfizer-BioNTech (mRNA) For people ages ≥12 years (purple cap) formulation	Moderna (mRNA) For people ages ≥18 years	Janssen (viral vector) For people ages ≥18 years
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 • 5–11 years (orange cap): 10 µg • 12 years and older (gray cap): 30 µg	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 (30 µg)	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG:1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102:heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

* None of the vaccines contain eggs, gelatin, latex, or preservatives. All COVID-19 vaccines are free from metals such as iron, nickel, cobalt, lithium, rare earth alloys or any manufactured products such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors.

V. APPROVAL:

Owner / Author	
Other Reviewer(s)	
Committee(s)	NM System P&T Committee
Approver(s)	David Cooke, MD, Chair NM System P&T Committee