Revised Standing Order for Pfizer SARS-CoV-2 Vaccine

Purpose

To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating adults and adolescents 16 years of age and older in the state of Missouri who meet the criteria established by the Advisory Committee on Immunization Practices (ACIP).

Policy

- This standing order authorizes any licensed physician, assistant physician, physician's assistant, or Advanced Practice Registered Nurse to prescribe and administer this vaccine. Additionally any medical student working under the license and direction of a licensed physician may administer this vaccine.

- This standing order authorizes any Registered Professional Nurse or Licensed Practical Nurse who is licensed by the Missouri State Board of Nursing or has a privilege to practice in the State of Missouri from another compact state to administer one of these vaccines. After receiving documented training, the designee of any aforementioned RN or LPN such as Medical Assistants (MA), Advanced Emergency Medical Technicians, Emergency Medical Technician-Paramedics, and nursing students (working under the license and direction of a licensed nurse) may administer this vaccine.

- Have a current certification in basic cardiopulmonary resuscitation

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine

- Additionally, under this standing order, licensed pharmacists and intern pharmacists and pharmacy technicians with the supervision of a Missouri Licensed pharmacist may administer this vaccine, provided the pharmacist, intern pharmacist or pharmacy technician has:

    a. Documentation of completing 20 hours of a practical training program on immunizations approved by the Accreditation Council for Pharmacy Education (ACPE) this training which must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines

    b. Completed a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period

Procedure

1. Assess adults in need of vaccination against the SARS-CoV-2 virus based on the following criteria
    a. Must be 16 years and older

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2. Screen all adults for contraindications and precautions for the SARS-CoV-2 vaccine
    a. Contraindications
        i. Under16 years of age

        ii. Do not give SARS-CoV-2 vaccine to an individual who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of SARS-CoV-2 vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert: www.immunize.org/packageinserts

    b. Precautions
        1. Moderate or severe acute illness with or without a fever

        2. Allergies:
            a. History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech)
            b. History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication
        3. Actions
            a. Risk assessment
            b. Potential deferral of vaccination
            c. Observe patient for 30 minute after vaccination

        ii. There is no information on co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines. The Pfizer-BioNTech COVID-19 should be spaced at least 14 days from any other vaccine.

        iii. Delay vaccination in individuals (community or outpatient setting) who have a known SARS-CoV-2 exposure until quarantine period has ended, unless individual resides in congregate healthcare settings or residents of other congregate settings (e.g., correctional facilities, homeless shelters)

        iv. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation

        v. Delay vaccination if the individual has had passive antibody therapy for COVID-19 until 90 days have passed from completion of said therapy.

3. Special Populations for which special counseling and a 15 minute observation period is recommended
    a. Pregnant females are recommended for vaccine depending on
        i. Level of COVID-19 community transmission (risk of acquisition)
        ii. Personal risk of contracting COVID-19 (by occupation or other activities)
        iii. The risks of COVID-19 to her and potential risks to the fetus
        iv. The efficacy of the vaccine
        v. The known side effects of the vaccine
        vi. The lack of data about the vaccine during pregnancy
    b. Breastfeeding not a contraindication

c. Immunocompromised persons
   i. Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies
   ii. Data not currently available to establish safety and efficacy of vaccine in these groups
   iii. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
   iv. Individuals should be counseled about:
      1. Unknown vaccine safety and efficacy profiles in immunocompromised persons
      2. Need to continue to follow all current guidance to protect themselves against COVID-19

4. Routine testing for pregnancy or Antibody testing is not recommended prior to vaccination.

5. Provide
   a. Provide the Emergency Use Authorization (EUA) Fact Sheet
      i. Provide all patients (or in the case of minors or incapacitated adults their legal representative) with a copy of the Emergency Authorization Fact Sheet. Provide non-English speaking patients with a copy of the EUA fact sheet in the native language if one is available and desired; these can be found at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine

   b. Provide the Vaccine Information Statement (VIS)
      i. Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis.

6. Prepare
   a. Choose the correct needle length and gauge for an intramuscular injection

Gender and Weight of patient	Needle Gauge	Needle Length	Injection Site
Female or Male less than 130 pounds	22-25	5/8" – 1"	Intramuscular Deltoid
Female or Male 130- 152 pounds	22-25	1"	Intramuscular Deltoid
Female 153- 200 pounds	22-25	1"-1 ½"	Intramuscular Deltoid
Male 153-260 pounds	22-25	1"-1 ½"	Intramuscular Deltoid
Female 200 + pounds	22-25	1 ½"	Intramuscular Deltoid
Male 260 + pounds	22-25	1 ½"	Intramuscular Deltoid

   b. Pfizer mRNA SARS-CoV-2 vaccine
      i. Thaw the vaccine vial if frozen for 30 minutes at room temperature or for 3 hours in a refrigerator

ii. Once thawed remove the cap of the Pfizer vaccine and inject 1.8 ml of 0.9% sodium chloride that comes in the ancillary kit of the vaccine
iii. Gently invert the vaccine vial 10 times
iv. Document date and time the vaccine was diluted on the Pfizer vaccine vial
v. Clean top of Pfizer vaccine vial with alcohol prep pad and with draw 0.3ml of vaccine
vi. Discard open vial after 6 hours or after all full 0.3ml doses, even if greater than 5, have been removed (Whichever comes first)
vii. Any remaining vaccine that does not equal a full 0.3 dose should not be pooled with other remaining vaccine to obtain a full 0.3ml dose

7. Administer

Type of Vaccine	Age group	Dose	Route	Instruction	Dose Schedule
Pfizer	Adults 18+	0.3ml	Intramuscular	Administer vaccine in deltoid muscle	Give dose # 2 at least 21 days from dose # 1
Pfizer	Adolescents 16- 17 years of age	0.3 ml			

Patients who do not receive the 2nd vaccination dose at 21 days should still receive that 2nd dose as soon as possible thereafter

All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose.

8. Document
   a. Consent Form: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.

   b. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic and supply to recipient at time of vaccination.

   c. Documentation of the vaccination in Missouri's immunization information system-ShowMeVax within 24-48 hours following vaccination.

9. Emergency Protocols
   a. If a patient experiences itching and swelling confined to the injection site where the vaccination was given, apply a cold compress to the injection site. Observe patient closely for the development of generalized symptoms until symptoms subside.

   b. If symptoms are generalized (generalized itching, redness, urticaria (hives); or include angioedema (swelling of the lips, face, or throat); shortness of breath; shock; or

abdominal cramping; call 911 and notify the patient's physician. Notifications 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 (heart rate, respirations and Blood Pressure, pulse ox) should be taken every 5 minutes.

i. First-line treatment of an anaphylactic reaction is to administer Epinephrine 1:1000 dilution intramuscularly adult dose 0.3ml to 0.5ml with maximum dose of 0.5ml; or
ii. To administer Epinephrine auto-injector (0.3ml)
iii. For hives or itching, you may also administer diphenhydramine (orally or intramuscular with a standard dose of 25-50mg.) or hydroxyzine (standard oral dose is 25mg -100mg or 0.5-1.0 mg/kg.
iv. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
v. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on patient's response.
vi. Record the patient's reaction to the vaccine (e.g., hives, anaphylaxis), all vital signs, and medications administered to the patient, including time dosage, response, and the name of the medical personnel who administered the medication and other relevant clinical information. Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.
vii. Notify the patient's primary care physician.

This order and procedure shall be effective on December 23, 2020 and shall remain in effect until rescinded or until December 31, 2021.

Randall W. Williams, MD, FACOG,
Director Missouri Department of Health and Senior Services

December 23, 2020
Date