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Standing Orders for Pfizer-BioNTech's COVID-19 Vaccine Administration to Persons 16 Years of Age and Older

Purpose

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

Policy

This standing order establishes administration parameters for any individual authorized to administer a COVID-19 vaccine by declaration of the Secretary of the Department of Health and Human Services, issued pursuant to the Public Readiness and Emergency Preparedness Act. Any healthcare provider who is authorized to administer a COVID-19 vaccine in Missouri under the March 18, 2021 DHSS Standing Orders, that is not expressly authorized to vaccinate by the declaration of the Secretary of the Department of Health and Human Services, is still authorized to administer a COVID-19 vaccine, if such individual complies with the requirements enumerated in the applicable March 18, 2021 Standing Order. All other provisions of the March 18, 2021 Standing Orders relating to administration of a COVID-19 vaccine are hereby terminated and this Order shall control.

Procedure

1. Assess adults and Adolescents in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
 - a. Must be 16 years and older
 - b. If the recipient has received a previous dose of Pfizer-BioNTech COVID-19 vaccine, the second dose of the same brand should be administered.
 - c. The vaccine is administered in a 2-dose series separated by at least 21 days however if dose was given as early as 17 days after the first dose, then do not repeat.
 - d. PfizerBioNTech COVID-19 vaccine may be administered with any other vaccines. Use a different arm for other vaccine administration. It is unknown whether reactogenicity is increased with co-administration, including with other vaccines known to be reactogenic such as adjuvanted vaccines. When deciding to co-administer with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines and the reactogenicity profile of the vaccines.
 - e. A third dose of Pfizer-BioNTech COVID-19 vaccine may be administered for certain individuals 16 years and older with moderate to a severe immune compromise due to a medical condition or recipe of immunosuppressive medication or treatments including but not limited to
 - Immune compromised due to undergone solid organ transplantation and taking immune suppressing medications

- Immune compromised active treatment for solid tumor and hematologic malignancies
 - Immune compromised receipt of CAR-T cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
 - Moderate to severe primary immunodeficiency (eg., DiGeorge, Wiskott-Aldrich Syndromes)
 - Immune compromised due to Advanced or untreated HIV infection
 - Immune compromised due to “Active treatment with high-dose corticosteroids or other drugs that may suppress immune response: high-dose corticosteroids (ie., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blocker or other biologic agents that are immunosuppressive or immunomodulatory”
- f. A Booster dose of Pfizer-BioNTech COVID-19 vaccine **should** be administered to the following groups at least 6 months after completing their Pfizer-BioNTech primary series (i.e., the first 2 doses of a COVID-19 vaccine):
- people aged 65 years and older
 - residents aged 16 years and older in long-term care settings
 - people aged 50–64 years with underlying medical conditions
(<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>)
- g. A Booster dose of Pfizer-BioNTech COVID-19 vaccine **may** be administered to the following groups, at least 6 months after completing their Pfizer-BioNTech primary series (i.e., the first 2 doses of a COVID-19 vaccine), based on their individual benefits and risks:
- people aged 16–49 years with underlying medical conditions
(<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>)
 - people aged 16–64 years at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting*
 - First responders (healthcare workers, firefighters, police, congregate care staff)
 - Education staff (teachers, support staff, daycare workers)
 - Food and agriculture workers
 - Manufacturing workers
 - Corrections workers
 - U.S. Postal Service workers
 - Public transit workers
 - Grocery store workers

2. Screen all adults and adolescents for contraindication and precautions for the SARS-CoV-2 vaccine

a. Contraindications

- i. Under 16 years of age
- ii. Do not give the 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 more information on vaccine components, refer to the manufactures' package insert <https://www.fda.gov/media/144413/download>
- iii. Do not give the SARS-CoV-2 vaccine to an individual who has had an immediate allergic reaction of any severity to a previous dose of any mRNA COVID-19 vaccine or any of its components (including polyethylene glycol (PEG)**

*Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticarial, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration of vaccine or Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>

** These individuals should not receive mRNA SARS-CoV-2 vaccine at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

b. Precautions

- i. Moderate or severe acute illness with or without a fever
- ii. Severe allergic reaction** (e.g., anaphylaxis) to a previous dose of any vaccine (not including Pfizer-BioNTech COVID-19 Vaccine)
 - Action
 - a. Assess the risk of vaccination
 - b. Observe patient for 30 minutes following vaccination
- iii. Polysorbate allergy is a precaution to Pfizer-BIONTech COVID-19 vaccine(due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
- iv. Severe allergic reaction ** (e.g. Anaphylaxis) to a medication that is injectable
 - Action
 - a. Assess the risk of vaccination
 - b. Observe patient for 30 minutes following vaccination

- v. Delay vaccination in individuals in community or outpatient settings who have a known SARS-CoV-2 exposure until quarantine period has ended, unless individual resides in congregate healthcare setting or resident of other congregate settings (e.g., correctional facilities, homeless shelter)
 - vi. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
 - vii. Delay vaccination if the individual has had passive antibody therapy for COVID-19 until 90 days have passed from completion of said therapy
 - viii. Delay vaccination if the individual has history of MIS-C or MIS-A until 90 days have passed from the MIS-C or MIS-A diagnosis
- ** Providers may consider deferring vaccination with the mRNA SARS-CoV-2 vaccine at this time until individual has been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available) depending on risk of exposure to SARS-CoV-2 or risk of severe disease or death due to COVID-19 for further guidance visit <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>

3. Special Populations for which special counseling 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 contraction COVID-19 to her and potential risks to the fetus
 - iii. The efficacy of the vaccine
 - iv. The known side effects of the vaccine
 - v. The lack of data about the vaccine during pregnancy
- b. Lactating (Breastfeeding) is not a contraindication to vaccination
- c. Immunocompromised
 - 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:
 - Unknown vaccine safety and efficacy profiles in immunocompromised persons
 - Need to continue to follow all current guidance to protect themselves against COVID-19

- Have individuals seeking a 3rd dose of the mRNA PfizerBioNTech COVID-19 vaccine complete the Additional mRNA COVID-19 Vaccine Dose Attestation statement
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 language if one is available and desired; these can be found at: <https://www.fda.gov/media/144413/download>
 - b. Provide the Vaccine Information Statement (VIS)
 - i. Provide all patients (or in the case of minors or incapacitated adults their 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
 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. Prepare the PfizerBioNTech COVID-19 vaccine

i. **Identify which PfizerBioNTech vaccine you are using**

Pfizer-BioNTech (purple cap) COVID-19 Vaccine	Pfizer-BioNTech-Tris COVID-19 Vaccine (Gray cap) – <u>DO NOT DILUTE</u>
Thaw the vaccine vial if frozen for 30 minutes at room temperature or for 3 hours in a refrigerator	Thaw the vaccine vial if frozen for 30 minutes at room temperature or for 3 hours in a refrigerator
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	Gently invert the vaccine vial 10 times.
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	Clean top of Pfizer vaccine vial with alcohol prep pad and with draw 0.3ml of vaccine
Gently invert the vaccine vial 10 times	Document date and time the vaccine vial was punctured on the Pfizer vaccine vial
Document date and time the vaccine was diluted on the Pfizer vaccine vial	Discard open vial after 12 hours or after all doses have been removed (Whichever comes first)
Clean top of Pfizer vaccine vial with alcohol prep pad and with draw 0.3ml of vaccine	
Discard open vial after 6 hours or after all doses have been removed (Whichever comes first)	

- ii. Due to production at the factory a 6th dose may be removed. However any remaining vaccine that does not equal a full 0.3ml 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 *2 dose series	Individuals 16+	0.3ml	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give dose #1 and #2 at least 21 days apart
Pfizer **3 dose series	Moderately to severely immune compromised individuals 16+	0.3ml	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give dose #1 and #2 at least 21 days apart #2 and #3 at least 28 days apart
**Pfizer Booster dose	Adults 16+	0.3ml	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give booster dose at least 6 months from the last dose in the series

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

**If the same vaccine that the person received previously is not available, a mixed series of mRNA COVID-19 or a dose of Janssen COVID-19 vaccine may be administered spaced appropriately apart according to the most recent clinical guidelines that can be found here <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html> .

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

8. Document

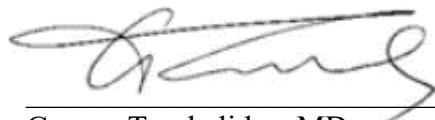
- a. Consent Form: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.
- b. Immunization Record Card: Record 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 10, 2021 and shall remain in effect until rescinded or until June 30, 2022.



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