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Standing Order for Pfizer COVID-19 Vaccine for Adolescents 12-15 Years of Age

Purpose
To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating individuals 12 to 15 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.

Procedure
1. Assess adults and Adolescents in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
    a. Must be 12 years and older
    b. Any minor authorized to receive this vaccine under this order, shall only receive such with the consent of a parent or guardian, or in compliance with Sections 431.056, 431.058, or 431.061, RSMo.
    c. Administer Pfizer-BioNTech COVID-19 vaccine intramuscularly as a series of two doses (0.3 mL each) 3 weeks (21 days) apart.
    d. If the recipient has received a previous dose of Pfizer-BioNTech COVID-19 vaccine, the second dose of the same brand should be administered.
    e. 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 adjuvant 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 reactogencity profile of the vaccines.
    f. A third dose of PfizerNBioTech vaccine may be administered to adolescents 12 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 due to active treatment for solid tumor and hematologic malignancies

- Immune compromised due to 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 "

2. Screen all adolescents for contraindication and precautions for the SARS-CoV-2 vaccine
    a. Contraindications
        i. Under 12 years of age
        ii. Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.
        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. 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)

        iii. Polysorbate allergy is a precaution to Pfizer-BioNTech COVID-19 vaccine administration (potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

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

vi. Delay vaccination if an adolescent has history of MIS-C until 90 days have passed from the MIS-C diagnosis

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:
            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
            3. 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/144414/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 the vaccine
    a. Choose the correct needle length and gauge for an intramuscular injection

Age of child or adolescent	**needle length/gauge**	**injection site**	**dose /route**
children 12 - 15 years of age	5/8" – 1" 23 gauge needle	Deltoid Muscle of the arm	0.3ml/intramuscularly

a. Prepare the PfizerBioNTech COVID-19 vaccine

i. Identify which Pfizer-BioNTech vaccine you are using

Pfizer-BioNTech (purple cap) COVID-19 Vaccine	**Pfizer-BioNTech-Tris COVID-19 Vaccine (Gray cap) – DO NOT DILUTE**
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)	

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.

8. Administer

Type of Vaccine	Age group	Dose	Route	Instruction	Dose Schedule
PfizerBioNTech	Adolescents 12 – 15 years of age	0.3 ml	Intramuscular	Administer vaccine in deltoid muscle	Give dose # 2 21 days from dose # 1* Give dose #3 at least 28 days from dose #2

* Patients who do not receive the 2nd vaccination dose at 21 days should still receive that 2nd dose as soon as possible thereafter. Effectiveness of vaccination when the second dose is given beyond the 6 weeks interval from the first dose administration is unknown.

** For individuals in which a 3rd dose is recommended the same mRNA vaccine should be used. A person should not receive more than three mRNA vaccines. If the mRNA vaccine product give for the first two doses is not available or is unknown either mRNA vaccine product may be administered.

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

9. Document Vaccination
    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/EUA given, and VIS/EUA publication date.

    b. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic.

    c. Documentation of the vaccination in Missouri's immunization information system

10. Emergency medical protocol for management of anaphylactic reaction in children
    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 resolve.

    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.

First Line Treatment Epinephrine

Age group	**Range of weight**	**Epinephrine dose**	
		1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose: 0.05 mL	Epinephrine auto injector or prefilled syringe 0.3 mg)
12 years of age	77-99 lbs. or 35-45 kg.	0.35-0.4ml or	0.3mg/dose
13-15 years of age	100+lbs. or 46+ kg.	0.5ml or 0.5mg	

∗If weight known, then dose by weight is preferred, if unknown then dose by age is appropriate.

May use Diphenhydramine (Benadryl) as a second line treatment

Age group	**Range of weight**	**Diphenhydramine *(Benadryl)* dose** *50mg/ml intramuscularly*
12 years of age	57-99 lbs. or 26-45 kg.	25-50 mg/ dose
13-15 years of age	100+ lbs. or 46+ kg.	50 mg/dose (up to 50mg or 100 mg single dose) **

∗If weight known then dose by weight is preferred, if unknown then dose by age is appropriate.
** AAP. Red Book: 2018–2021, 31st ed. (p. 66). Diphenhydramine maximum single dose for children younger than age 12 years is 40 mg, for children age 12 years and older, 100 mg.

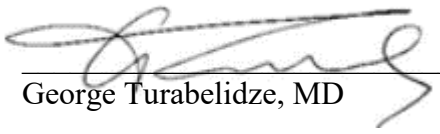
i. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.

ii. 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.

iii. 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.

iv. Notify the patient's primary care physician.

This order and procedure shall be effective on May 12, 2021 and shall remain in effect until rescinded or until June 30, 2022.



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