USF Health
Standing Order for Pfizer SARS-CoV-2 Vaccine

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

Policy
- Under these standing orders, qualified LPN's, Certified Medical Assistants, RNs, pharmacists and other healthcare professionals acting on behalf of USF Health or at their direction, where allowed by Florida statute, may vaccinate patients who meet any of the criteria below.
- 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.

Procedure

1. Assess patients in need of vaccination against the SARS-CoV-2 virus based on the following criteria
    a. Must be 16 years and older
    b. If the recipient has received a previous dose of Pfizer 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 the second dose was given as early as 17 days after the first dose, then do not restart the series.

2. Screen all patients for contraindications and precautions for the SARS-CoV-2 vaccine
    a. Contraindications
        i. Under 16 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 minutes 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. In situations of limited vaccine supply, vaccination of persons previously infected with COVID-19 can begin 60-90 days after their recovery.
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 once they have considered the following criteria and discussed risks/benefits with their health care provider
        i. Level of COVID-19 community transmission (risk of acquisition)
        ii. Personal risk of contracting COVID-19 (by occupation or other activities)
        iii. Risks of COVID-19 to her and potential risks to the fetus
        iv. Efficacy of the vaccine
        v. Known side effects of the vaccine
        vi. Current lack of data about the vaccine during pregnancy

    b. Lactating (breastfeeding) is not a current contraindication to the vaccine

    c. Immunocompromised or altered immunocompetence
        i. Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies
            1. Data not currently available to establish safety and efficacy of vaccine in these groups
        ii. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
        iii. Individuals should be counseled on the following criteria:
            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 COVID-19 Antibody testing is not recommended prior to vaccination.

5. Provide to Patient
    a. Provide the Emergency Use Authorization (EUA) Fact Sheet
        i. Provide all patients (or in the case of minors or incapacitated patients 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/media/144638/download

    b. Provide the Vaccine Information Statement (VIS)
        i. Provide all patients (or in the case of minors or incapacitated patients, 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/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. Prepare the Pfizer BioNTech 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. Bring vial to room temperature before diluting (about 30-minutes). Vial must be diluted or used within two hours ,or must be discarded
        iii. Gently invert the vaccine vial 10 times prior to dilution but do not shake
        iv. Using aseptic technique, remove vial cap on vaccine and wipe with alcohol prep pad and repeat the same for vial of diluent (0.9% sodium chloride). Do not use any other diluent for this vaccine. Use diluent from ancillary kit.
        v. Remove 1.8 ml of 0.9% sodium chloride from the 2mL vial and inject into vaccine vial. To equalize pressure before removing needle, draw in 1.8mL of air from the vaccine vial.,
        vi. Once diluted, gently invert the vaccine vial 10 times, but do not shake

vii. Document date and time the vaccine was diluted on the Pfizer BioNTech vaccine vial.
viii. Discard opened vial after 6 hours or after all doses have been removed (whichever comes first) in approved receptacles
ix. Using aseptic technique, wipe rubber stopper of Pfizer BioNTech vaccine vial with alcohol prep pad and withdraw 0.3ml of vaccine (one dose). Repeat this process for each additional dose, to a maximum of five.
x. Any remaining vaccine that does not equal a full 0.3 dose should **not** be pooled with remainder from other vials to obtain a full 0.3ml dose

7. Administration

Type of Vaccine	Age group	Dose	Route	Instruction	Dose Schedule
Pfizer	Patients 16+	0.3mL	Intramuscular	Administer vaccine in deltoid muscle	Give dose # 2 at least 21 days from dose # 1

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.
   b. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic. Give card to recipient at time of vaccination.
   c. Documentation of the vaccination in EPIC within 24 hours following vaccination.
   d. All required reportable adverse events should be entered into VAERS database according to federal requirements for VFC program.
   e. Encourage all patients to download V-SAFE CDC app to register for adverse event surveillance. This will track adverse events daily for the first 7 days and weekly for 6 weeks.

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 & level of alertness. Vital signs (heart rate, BP, respirations and pulse oximetry should be taken every 5 minutes.) Patient should be positioned supine, and not be allowed to stand. Elevate legs.

i. First-line treatment of a reaction is to administer Epinephrine auto-injector (0.3ml) IM in VASTUS LATERALIS/Outer Thigh
ii. For hives or itching, you may also administer diphenhydramine (orally or intramuscular with a standard dose of 25-50mg.)
iii. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
iv. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 15 minutes for up to 3 doses depending on patient's response.
v. 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.
vi. Notify the patient's primary care physician.

10. Encourage patients to follow-up with their primary care provider if they experience any new symptoms/side effects, have sustained side effects beyond 48-72 hours, or develop COVID-19 symptoms after vaccination. Providers are required to report the following that occur after mRNA COVID-19 vaccination under Emergency Use Authorization:
    a. Vaccine administration errors
    b. Serious Adverse Events
    c. Cases of Multisystem Inflammatory Syndrome
    d. Cases of COVID-19 that result in hospitalization or death
    e. Reporting is encouraged for any clinically significant event, even if it is uncertain whether the vaccine caused the event.
    f. Report through https://vaers.hhs.gov or by calling 1-800-822-7967

This policy and procedure shall remain in effect for all USF Health patients from the date signed until rescinded.

Signature: _____ Effective Date: _____

Asa Oxner, MD	ME119829		
Title (Name)	License Number	Signature	Date