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August 29, 2022

Standing Order for the Novavax COVID-19 Vaccine

Purpose

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

Procedure

1) Assess adults in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria:
   a) Must be 12 years and older
   b) Must not have received a previous dose of SARS-CoV-2 authorized vaccine
   c) The vaccine is administered in a 2-dose series separated by 3-8 weeks
   d) The Novavax vaccine may be administered with other vaccines. Use a different arm for other vaccine 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) If a previously administered 1 dose of a COVID-19 vaccine product cannot be determined or is no longer available or contraindicated, administer Novavax COVID-19 vaccine at least 4-8 weeks after the first dose.
   f) If a person is moderately or severely immune compromised and has never received a COVID-19 vaccine administer 2 doses of the Novavax vaccine separated by 3 weeks.
   g) If a person is moderately or severely immune compromised and a previously received 1 dose of COVID-19 vaccine product that cannot be determined or is no longer available or contraindicated, administer the Novavax vaccine at least 4 weeks after the first dose.

2) Screen all adults for contraindications and precautions for the SARS-CoV-2 vaccine
   a) Contraindications
      i) Do not give the SARS-CoV-2 NOVAVAX vaccine to an individual who has experienced a serious reaction* (e.g., anaphylaxis) to a prior dose of NOVAVAX vaccine or to any of its components. For more information on vaccine components, refer to the manufactures insert https://www.fda.gov/media/159897/download

*Immediate allergic reaction to a vaccine or mediation is defined as any hypersensitivity-related signs or symptoms consistent with urticarial, angioedema, respiratory distress (wheezing, stridor), or anaphylaxis that occur within four hours following administration of vaccine or Interim Clinical Consideration for the use of Novavax COVID-19 vaccine currently authorized in the United States at https://www.fda.gov/media/159897/download

b) Precautions
   i) Moderate or severe acute illness with or without fever
   ii) Severe allergic reaction to polysorbate (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG**) Monitor patient for at least 30 minutes following vaccination.
   iii) Severe allergic reaction (e.g. Anaphylaxis) to a medication** that is injectable. Monitor patient for at least 30 minutes following vaccination.
c) 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)
d) Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
e) 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
f) If the person has a history of myocarditis or pericarditis:
   i) If history is prior to COVID-19 vaccination, may receive Novavax COVID-19 Vaccine, after the episode of myocarditis or pericarditis has completely resolved
   ii) If myocarditis or pericarditis occurred after the first dose of an mRNA or Novavax COVID-19 vaccine, generally experts advise no additional doses of any COVID-19 vaccine. Administration of the second dose of an mRNA or Novavax COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis.

**Providers may consider deferring vaccination with the Novavax COVID-19 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 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 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

d) Routine testing for pregnancy or COVID-19 antibody testing is not recommended prior to vaccination.

4) 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/159898/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.

5) Prepare
a) The Novavax COVID-19 Vaccine is supplied in a multiple-dose vial.
i) A multi-dose vial containing a maximum of 10 doses.
ii) Concentration is 50mcg/0.5mL
b) 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
Male or Female adults	22-25	1 ½"	Intramuscular vasteous lateralis

c) Prepare the vaccine
i) Remove vaccine vial from the refrigerator
ii) Document the date and time of first puncture on the vial label
iii) Gently swirl vial for 20 seconds
iv) Clean the top of the vial off with alcohol prep pad and withdraw 0.5mL of the vaccine
v) Gently swirl vial for 20 seconds between each dose withdrawn
vi) Discard any remaining vial after 6 hours or if you are not able to withdraw 0.5mL

If at any time the vial fluid is discolored or has particulate matter after gently swirling do not administer and discard the vial. Each vial should contain at least 10 doses, discard vial if any

remaining fluid is not a full dose or discard vial 6 hours after first puncture- whichever comes first. **DO NOT FREEZE THIS VACCINE**

6) Administer

Type of Vaccine	Age Group	Dose	Route	Instructions
Novavax	12 years and older	5 µg rS and 50 µg of Matrix-M™ adjuvant/0.5mL	Intramuscular	dose 1 and dose 2 separated by 3 to 8 weeks
Novavax	12 years and older who are moderately to severely immune compromised	5 µg rS and 50 µg of Matrix-M™ adjuvant/0.5mL	Intramuscular	dose 1 and dose 2 separated by 3 weeks

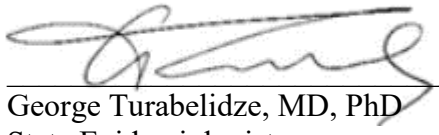
All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose. More information on interim clinical guidelines of the Novavax vaccine can be found at Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

7) 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

8) 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 August 29, 2022 and shall remain in effect until rescinded or until December 31, 2022.



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