May 7, 2023

StandingOrder for **Moderna** COVID-19 Vaccine Administration for

**Children Ages 6-11 years**

**Purpose**

To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating individuals 6-11 years of age 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 listed in Attachment A to this Order, that is not expressly authorized to vaccinate by the declaration of the Secretary of the Department of Health and Human Services, is authorized to administer a COVID-19 vaccine, if such individual complies with the requirements enumerated Attachment A.

**Procedure**

1. Assess children in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria:
   1. Must be 6 to 11 years of age
   2. If the child has never received a previous dose of any SARS-CoV-2 vaccine, administer
   3. The Moderna 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.
   4. **For children WHO ARE NOT moderately to severely immunocompromised,** refer to administration schedule and instructions in table 5A below
   5. For **children WHO ARE moderately to severely IMMUNOCOMPROMISED**, refer to administration schedule and instructions table 5B below.

1. Screen all children for contraindication and precautions for the SARS-CoV-2 vaccine
   1. Contraindications
      1. Under 6 years of age or over 11 years of age
      2. 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
      3. 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)\*\*
      4. Child has already received at least one (1) dose of an mRNA SARS-CoV-2 Bivalent, vaccine.

# \*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)

* 1. Precautions
     1. Moderate or severe acute illness with or without a fever
     2. Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any vaccine\*\*\* (not including Moderna Vaccine)
        + Action
          1. Assess the risk of vaccination
          2. Observe patient for 30 minutes following vaccination
     3. Polysorbate allergy is a precaution to Moderna COVID-19 vaccine(due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
     4. Severe allergic reaction (e.g. anaphylaxis) to a medication\*\*\* that is injectable
        + Action
          1. Assess the risk of vaccination
          2. Observe patient for 30 minutes following vaccination
     5. 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)
     6. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
     7. People who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications>). If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, considerations for subsequent vaccination may include:
  + The myocarditis or pericarditis was considered unrelated to the mRNA Covid-19 vaccination, especially if the myocarditis or pericarditis occurred more than 3 weeks after the most recent doses of COVID-19 vaccine
  + Increased personal risk of severe acute COVID-19 disease
  + Increased level of COVID-19 community transmission and personal risk of infection
    1. People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person’s clinical team.
    2. 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>

1. Provide
   1. Provide the Emergency Use Authorization (EUA) Fact Sheet
      1. 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/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>
   2. Provide the Vaccine Information Statement (VIS)
      1. 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](http://www.immunize.org)
2. Prepare
   1. The Moderna COVID-19 Vaccine is supplied in a multiple-dose vial
      * A multiple-dose vial containing a maximum of 5 doses
      * Concentration is 50mcg/0.5mL
   2. Choose the correct needle length and gauge for an intramuscular injection

|  |  |  |
| --- | --- | --- |
| **Age of child or adolescent** | **needle length/gauge** | **injection site** |
| Children 6-11 years of age | 5/8” – 1” 23 gauge needle | Deltoid Muscle |
| Children 6-11 years of age | 1” to 1 ¼” 22-25 gauge needle | Vastus Lateralis |

* 1. Prepare the Moderna COVID-19 vaccine
     + Ensure that the vial is for 6 through 11 years of age (50mcg/0.5mL)
     + Thaw the vaccine vial if frozen for 1 hour at room temperature or for 2 hours and 30 minutes in a refrigerator
     + Once thawed remove the cap of the Moderna vaccine
     + Let vial sit at room temperature for 15 minutes before administering
     + Document date and time the vaccine was opened on the Moderna vaccine vial
     + Clean top of Moderna vaccine vial with alcohol prep pad and withdraw:
       - 1. 0.5mL
         2. Bivalent booster 0.25mL
     + Gently swirl the vial between each dose withdrawn
     + Discard open vial after 12 hours or after all doses have been removed (Whichever comes first)

1. Administer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 5A: Children who ARE NOT moderately to severely immunocompromised** | | | | |
| **Type of vaccine** | **Age group** | **Dose** | **Instruction** | **Vaccination History /Dose schedule** |
| Moderna COVID-19 Vaccine **Bivalent** (Original and Omicron BA.4/BA.5)  **Vial with Dark Blue Cap with Gray Label Border** | 6 – 11  years of age | **0.25ml** | Administer vaccine intramuscularly in deltoid muscle/Vastus lateralis | Unvaccinated children should receive one (1) dose  Children who have had 1 or more doses of monovalent mRNA vaccine should receive 1 dose at least 8 weeks after the last monovalent dose |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 5B: Children who ARE moderately to severely IMMUNOCOMPROMISED** | | | | |
| **Type of vaccine** | **Age group** | **Dose** | **Instruction** | **Vaccination History /Dose schedule** |
| Moderna COVID-19 Vaccine **Bivalent** (Original and Omicron BA.4/BA.5)  **Vial with Dark Blue Cap with Gray Label Border** | 6 – 11  years of age | **0.25ml** | Administer vaccine intramuscularly in Deltoid  /Vastus lateralis | **Unvaccinated children** should receive 3 doses.   * Dose 1 and 2 are 4 weeks apart * Dose 2 and 3 are at least 4 weeks apart   **Children who have received 1 dose of mRNA Moderna COVID-19 monovalent vaccine** should receive 2 doses.   * Dose 1 at least 4 weeks from the last monovalent dose * Dose 1 and 2 are 4 weeks apart   **Children with 2 previous doses of mRNA/Moderna COVID-19 monovalent vaccine** should receive 1 dose   * After at least 4 weeks after the last monovalent dose   **Children with 3 previous doses of mRNA/ Moderna COVID-19 monovalent vaccine** should receive 1 dose   * After at least 8 weeks after the last monovalent dose   **Children with 3 previous doses of Moderna COVID-19 monovalent vaccine** **and 1 dose of bivalent mRNA vaccine** may receive an additional dose of bivalent vaccine   * After at least 8 weeks from the last dose * (This dose is optional and dependent on personal preference and/or health circumstances). |

For the most recent updated clinical guidelines visit <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

1. Document
   1. 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.
   2. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic.
   3. Documentation of the vaccination in Missouri’s immunization information system
2. Emergency medical protocol for management of anaphylactic reaction in children
   1. 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.
   2. 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 0.15mcg, 0.3 mg) |
| 5—7 years of age | 40-56 lbs. or 18-25.5 kg. | 0.2-0.25 ml (or mg) | 0.15 mg/dose |
| 8–10 years | 57–76 lbs. or 26–34.5  kg | 0.25–0.3 mL (or mg) | 0.15 mg or 0.3 mg/dose |
| 11-12 years of age | 77-99lbs. or 35-45 kg | 0.35–0.4 mL (or mg) | 0.3 mg/dose |

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

\*Rounded weight at the 50th percentile for each age range

May use Diphenhydramine (Benadryl) as a second line treatment

|  |  |  |
| --- | --- | --- |
| **Age group** | **Range of weight** | **Diphenhydramine *(Benadryl)* dose**  *50mg/ml intramuscularly* |
| 5-7 years of age | 40–56 lbs. or 18–25.5 kg | 20–25 mg/dose \* |
| 8- 12 years of age | 57-99 lbs. or 26-45 kg. | 25-50 mg/ dose |

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

\*Rounded weight at the 50th percentile for each age range

\*\*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.

* + 1. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
    2. If EMS has not arrive and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on patient’s response.
    3. 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.
    4. Notify the patient’s primary care physician.

This order and procedure shall be effective on DATE and shall remain in effect until rescinded or until DATE.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

xxxxx

Chief Medical Officer

VACCINE ADMINISTRATION RESOURCE LINKS

Moderna label for 6-11

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-children-updated-label-iinfo-508.pdf>

Moderna Products

<https://www.fda.gov/media/159306/download>

At a Glance Schedule

<https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf>

Vaccine Needle Length and Gauge chart

<https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf>

Age transition and Moderna COVID-19 vaccine guidelines

<https://www.cdc.gov/vaccines/covid-19/downloads/Moderna-Child-Age-Transition-508.pdf>

Frequently Asked Questions by Health Care providers

<https://www.cdc.gov/vaccines/covid-19/hcp/faq.html>

**Attachment A**

**to Standing Order for Moderna COVID-19**

**Vaccine Administration for Children 6-11 Years of Age**

* The 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 or physician assistant student working under the license and direction of a licensed physician may administer this vaccine.
* The order authorizes any Registered Professional Nurse or Licensed Practical Nurse who is licensed by the Missouri Board of Nursing or has a privilege to practice in the State of Missouri from another compact state to administer this vaccine. After receiving documented training nursing students and medical assistants (MA) working under the direction of a licensed nurse may administer this vaccine.
* The order authorizes Advanced Emergency Medical Technicians, Emergency Medical Technician-Paramedics, Emergency Medical Technician-Basics and Emergency Medical Responders to administer this vaccine, whose authorized scope of practice includes administering immunizations via the intramuscular route
* The order authorizes licensed pharmacist, intern pharmacists and pharmacy technicians with the supervision of a Missouri licensed pharmacist to administer this vaccine, provided the pharmacist, intern pharmacist or pharmacy technician has:

1. Documentation of completing 20 hours of practical training on immunizations approved by the Accreditation Council for Pharmacy Education (ACPE) this training must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines; and
2. Complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.

* The order authorizes any of the following individuals to administer this vaccine, provided that such individual held a license, certification, or could have otherwise lawfully administered this vaccine under this order within the last five years. If such individual held a license or certification, such must have been active with no disciplinary action nor under an investigation prior to the date it went inactive, expired or lapsed and must not have been revoked by the licensing authority, in an alternative to discipline program, surrendered while under suspension, surrendered following an arrest, and the individual cannot be on the List of Excluded Individuals/Entities maintained by the Office of the Inspector General. Prior to administering the vaccine, such individual shall: (1) complete the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules <https://www2.cdc.gov/vaccines/ed/covid19/>; (2) document their identification and prior license, certification, or experience that would have allowed such individual to lawfully administer this vaccine under this order within the last five years; and (3) certify that the individual does not have any condition or impairment which in any way affects their ability to administer the vaccine in a competent and safe manner, including but not limited to: (a) a mental, emotional, nervous or sexual disorder; (b) an alcohol or substance abuse disorder; or (c) a physical disease or condition. Such individual shall initially be under the observation of a currently practicing Missouri licensed or certified healthcare professional adequately experienced in vaccination, who shall review the submitted documentation, initially observe, and confirm the competency of such individual to prepare and administer the vaccine.

If such currently practicing Missouri licensed or certified healthcare professional, who is observing the individual, is unable to confirm the competency of such individual, such individual will not be permitted to administer a vaccine.

* + licensed physician;
  + assistant physician;
  + physician’s assistant;
  + Advanced Practice Registered Nurse;
  + Registered Professional Nurse or Licensed Practical Nurse who is licensed by the Missouri Board of Nursing or has a privilege to practice in the State of Missouri from another compact state to administer this vaccine;
  + Advanced Emergency Medical Technicians, Emergency Medical Technician-Paramedics, Emergency Medical Technician-Basics and Emergency Medical Responders, whose authorized scope of practice includes administering immunizations via the intramuscular route;
  + licensed pharmacist;
  + pharmacy technicians with the supervision of a Missouri licensed pharmacist to administer this vaccine, provided the pharmacist, intern pharmacist or pharmacy technician has:
  1. Documentation of completing 20 hours of practical training on immunizations approved by the Accreditation Council for Pharmacy Education (ACPE) this training must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines; and
  2. Completed a minimum of two hours of ACPE- approved, immunization-related continuing pharmacy education during each state licensing period.
* The order authorizes any healthcare provider who is licensed or certified in any state to prescribe, dispense, and/or administer a vaccine, to administer this vaccine. Such individual shall alert the relevant licensing body within the State of Missouri of their intention to administer a COVID-19 vaccine in Missouri and provide their professional credentials to such licensing body.
* Any individual authorized to administer this vaccine under the order shall be certified to provide cardiopulmonary resuscitation, or in the case of a medical student or former healthcare provider without current certification to administer cardiopulmonary resuscitation, such individual may only administer the vaccine in the presence of someone with current certification to administer cardiopulmonary resuscitation
* Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event of an acute anaphylactic reaction following administration of the vaccine.