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Information for Health Care Professionals about the Screening Checklist for Administration of the COVID-19 Vaccine for Children Ages 6 Months – 11 Years
Updated: December 20, 2022

Note: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

1. **Are you between the ages of 6 months and 11 years old?**
   If yes, determine the child's age. Below is a breakdown of the mRNA vaccines and doses currently authorized for this age group. Then proceed with screening question #3.
   - Pfizer 3 µg/0.2 mL formulation is approved for children 6 months through 4 years.
   - Pfizer 10 µg/0.2 mL formulation is approved for children 5 to 11 years old.
   - Moderna 25µg/0.25 mL formulation is approved for children 6 months to 5 years old.
   - Moderna 50µg/0.5mL formulation is approved for children 6 to 11 years old.

   The primary series should be completed with the same mRNA COVID-19 vaccine product. If a child who is 6 months through 4 years of age inadvertently receives a dose of Pfizer vaccine and a dose of Moderna vaccine, regardless of the order in which these doses were received, the child should receive a third dose of the age-appropriate mRNA vaccine (either Moderna or Pfizer). The third dose should be administered 8 weeks after the second dose. This would be considered an administration error and should be reported to VAERS. For more information regarding COVID-19 vaccine administration error, please consult the CDC's clinical considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c. For information regarding reporting to VAERS, please see information available here: https://vaers.hhs.gov/.

   The primary series FDA EUA authorization for children 6 months to 4 years receiving Pfizer vaccine was updated on December 8, 2022. If the patient is ages 6 months–4 years of age and is receiving the Pfizer vaccine for their primary series, doses 1 and 2 must be provided with the monovalent Pfizer vaccine, and dose 3 must be provided with the bivalent Pfizer vaccine. If dose 3 was not administered utilizing a bivalent vaccine after December 8, 2022, a VAERS report will need to be completed.

   If no, advise the parent or guardian that this patient is not currently eligible for the above mRNA COVID-19 vaccine formulations. Instead, if the patient is 12 years old or older, the patient may receive the Pfizer BioNTech Covid-19 adult formulation for children 12 years old or older (30 µg/ 0.3 mL) or the Moderna COVID-19 formulation for children 12 years old or older (100µg/ 0.5mL).

   There is no COVID-19 vaccine currently authorized for a child less than 6 months old.

   If a child transitions from a younger age group to an older age group, CDC recommends the child receive the age-appropriate vaccine dosage based on their age on the day of vaccination. FDA authorization allows for different dosing for certain age transitions as described below:
   - A child receiving the Pfizer COVID-19 vaccine who will turn from age 4 years to 5 years between any dose in the primary series is authorized to receive:
     - A 2-dose primary series using the Pfizer-BioNTech COVID-19 vaccine product authorized for children ages 5-11 years; OR
     - A 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 vaccine product

authorized for children ages 6 months-4 years. Each of doses 2 and 3 may be with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years, **or** the Pfizer-BioNTech COVID-19 vaccine product authorized for children ages 5-11 years.

- A child receiving the Moderna COVID-19 vaccine who will turn from age 5 to 6 years between any dose in the primary series is authorized to receive:
    - The Moderna product authorized for children ages 6 months through 5 years; OR
    - The Moderna product authorized for children ages 6-11 years.
- A child receiving the Moderna COVID-19 vaccine who will turn from age 11 to 12 years between any dose in the primary series is authorized to receive:
    - The Moderna product authorized for children ages 6-11 years; OR
    - The Moderna product authorized for children ages 12-17 years.
- If a child turns from 11 to 12 years of age in between their first and second dose in the primary regimen, they may receive, for either dose, either:
    - The Pfizer-BioNTech COVID-19 vaccine formulation for children aged 5–11 years (each 0.2 ml dose containing 10 µg in an orange cap vial); or
    - COMIRNATY or the Pfizer-BioNTech COVID-19 vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 µg in a purple cap vial). If they receive the 10 µg dose for their second dose instead of the 30 µg dose, this is not considered an error, VAERS reporting is not required, and the child is considered fully vaccinated. However, based on clinical judgment, a repeat dose of the 30µg adult formulation may be administered 21 days after the second pediatric formulation dose was administered.

2. **Are you feeling sick today?**
   If yes, refer to the vaccination site healthcare provider for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time. Ask the parent or guardian to return with the patient when symptoms improve.

3. **In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?**
    - If yes, advise the parent or guardian that the patient must return to isolation or quarantine and reschedule for after isolation/quarantine ends.
    - If the patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 72 hours or more, patient may be vaccinated.
    - If the patient has had a test in the last 10 days, ask for the result. If positive, send them home. If negative, they can proceed to vaccination. If the result is unsure or unknown, advise the patient toreturn once a negative test has been confirmed or 10 days have passed since a positive test.
    - Persons with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A) should consider delaying vaccination until they have recovered from their illness and for 90 days after the diagnosis of MIS-C or MIS-A. However, the parent or guardian can choose to have the patient vaccinated. For further information on counseling a parent or guardian with a child who has a history of MIS-C or MIS-A regarding COVID-19 vaccines, please see the Centers for Disease Control and Prevention's (CDC) section on MIS-C and MIS-A in their "Interim Clinical Considerationsfor Use of COVID-19 Vaccines Currently Authorized in the United States" available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

4. **Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? If yes, when did you receive the last dose?**
   If yes, notify them that they should defer future doses of Evusheld™ for at least 2 weeks after vaccination.

However, COVID-19 vaccination need not be delayed due to previous antibody therapy nor receipt of convalescent plasma.

5. **Have you ever had an immediate allergic reaction, such as hives, facial swelling, difficulty breathing, anaphylaxis to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?**
   If yes, then refer to the vaccination site healthcare provider for assessment of allergic reaction. Review the ingredient lists at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#Appendix-C.

   Contraindications to COVID-19 vaccine:
   - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine.
   - Known diagnosed allergy to a component of the COVID-19 vaccine.
   - People with a contraindication to one of the mRNA COVID-19 vaccines should not receive a dose ofthe Pfizer or Moderna COVID-19 vaccine.

   Precautions to COVID-19 vaccine: (Refer to your organization's protocol to see whether individuals with a precaution to vaccination warrant further evaluation.)
   - Immediate (onset within 4 hours after vaccination), but non-severe, allergic reaction after a previous dose of COVID-19 vaccine
   - Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies excluding subcutaneous immunotherapy for allergies).
   - Individuals with a contraindication to one type of COVID-19 vaccine, or a component of a COVID-19 vaccine may have a precaution to the other.
     - Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination, and vaccination of these individuals should only be undertaken in an appropriate clinical setting under the supervision of a healthcare providerexperienced in the management of severe allergic reactions.
     - Note: These individuals should not be administered COVID-19 vaccine at State-operated vaccination sites.
     - For mRNA COVID-19 vaccines, for history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine, a subsequent dose of COVID-19 vaccine should generally be avoided (there is a separate question on the screening and consent form regarding myocarditis and pericarditis – question #9).

   For patients who are determined eligible for COVID-19 vaccination after assessment of allergy history, a 30-minute post-vaccination observation period is needed for the following:
   - Patients with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy.
   - Patients with a contraindication to any type of COVID-19 vaccine (e.g., mRNA or Janssen viral vector).
   - Patients with a history of anaphylaxis due to any cause.

6. **Do you have cancer, leukemia, HIV/AIDS, or any other condition that weakens the immune system?**
   If yes, ask the parent or guardian if they would like to have a discussion with the vaccination site healthcareprovider about what is known and not yet known about COVID-19 vaccine for immunocompromised people. You can tell the parent or guardian that the patient may have a less strong

immune response to thevaccine but may still get vaccinated. Patient may be vaccinated if the parent or guardian chooses to, and they are not required to go to medical evaluation.

7. **Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?**
   If yes, ask the parent or guardian if they would like to have a discussion with the vaccination site healthcareprovider about what is known and not yet known about COVID-19 vaccine for immunosuppressed people. You can tell the parent or guardian that they may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if the parent or guardian chooses to, and they are not required to go to medical evaluation.

8. **Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner?**
   If yes, refer to parent or guardian to their health care provider to assess the patient's bleeding risk and thrombosis history. Persons with a history of Thrombosis with Thrombocytopenia Syndrome (TTS) following receipt of Janssen COVID-19 vaccine or of any other immune-mediated thrombosis and thrombocytopenia, such as Heparin-Induced Thrombocytopenia (HIT) within the past 90 days should be offered an mRNA COVID-19 vaccine (i.e., Pfizer vaccine). If a person with a bleeding disorder or taking a blood thinner is cleared for vaccination, then administer vaccine using a 23-gauge or smaller caliber needle and apply firm pressure on the site of vaccination, without rubbing, for at least 2 minutes after vaccination. TTS after a dose of Janssen COVID-19 vaccine is a contraindication to further doses of Janssen COVID-19 vaccine.

9. **Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)?**
   If yes:
   - Evaluate if this history was in relation to a dose of mRNA vaccine. If it was not, then the patient can receive any U.S. Food and Drug Administration (FDA) authorized COVID-19 vaccine after complete resolution of a myocarditis or pericarditis episode.
   - Until additional safety data are available, experts advise that 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. If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until at least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). Decisions to proceed with vaccination should include conversations with the patient, parent/legal representative, and the clinical team, including a cardiologist. Considerations for vaccination may include:
     - The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent COVID-19 vaccine.
     - Personal risk of severe acute COVID-19 disease (e.g., age, underlying conditions).
     - Level of COVID-19 community transmission and personal risk of infection.
     - Timing of immunomodulatory therapeutics; ACIP's general best practice guidelines for immunization can be consulted for more information.
   - The CDC advises that an increased interval of 8 weeks between the 2 doses of the primary series may decrease the risk of myocarditis. However, the 3 week interval should be used for the following people:
     - Immunocompromised people
     - High risk for severe disease
     - Household members with high risk for severe disease
     - High COVID-19 community levels

- For the full CDC interim clinical considerations regarding a history of myocarditis and/or pericarditis,please see the CDC's COVID-19 Vaccines Currently Authorized in the United States and Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults.

10. **Do you have a history of MIS-C (Multisystem Inflammatory Syndrome in Children)?**
    Experts consider the benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness following COVID-19 vaccination for those who meet the following criteria:
    - Clinical recovery has been achieved, including return to normal cardiac function
    - It has been at least 90 days after the diagnosis of MIS-C

    COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and do not meet both criteria, at the discretion of their clinical care team (see consultation for decisions about COVID-19 vaccination). Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to certain medical conditions, may also be considered.

    Decisions about administration of subsequent COVID-19 vaccine doses in people who develop MIS-C **after** COVID-19 vaccination depend on timing of MIS in relation to vaccination, clinical recovery, and epidemiologic considerations.

    For the complete consideration for vaccination of children with a history of MIS-C, and those who develop MIS-C after COVID-19 vaccination, please refer to the CDC's clinical considerations available here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-misc-misa.

11. **Have you received a previous dose of the Pfizer, Moderna or Janssen COVID-19 vaccine?**
    If yes, verify current age. If the Pfizer vaccine is to be administered, children 6 months through 4 years should receive a total of 3 doses for their primary series, 2 doses of monovalent Pfizer vaccine and 1 dose of bivalent Pfizer vaccine, and children 5-11 should receive 2 doses for their primary series. If the Moderna vaccine is to be administered, children 6 months –5 years should receive 2 doses for their primary series and children 6 –11 should receive 2 doses for their primary series.

    If the patient is 12 years old or older, please counsel the parent or guardian on current guidelines to provide a Pfizer COVID-19 vaccine adult formulation (30 µg) or the Moderna COVID-19 formulation for children 12 years old or older (100µg/ 0.5mL). The Janssen vaccines are only authorized for those 18 years or older.

12. **Are you between 5–11 years of age and received 2 doses of the Pfizer or Moderna vaccine with the second dose being at least 2 months ago, or are you between the ages of 6 months–4 years old and received 2 doses of the Moderna vaccine with the second dose being at least 2 months ago?**
    - Children 5–6 years of age who received Pfizer for their primary may only receive Pfizer for a bivalent booster.
    - Children 5-6 years of age who received Moderna as a primary may receive either Pfizer or Moderna. For patients 6–11 years of age, administer either a Pfizer or Moderna bivalent booster as long as 2 months has passed since their second dose. For children 6 months–4 years of age who received Moderna for their primary series, administer a Moderna only bivalent booster as long as 2 months has passed since their second dose.
    - Children 6 months–4 years of age who received Moderna for a primary series are not eligible for a

Pfizer booster and must only receive a Moderna booster.

- Children ages 6 months–4 years of age who received Pfizer for their primary series currently are not eligible for another dose of vaccine.

13. **Have you received a previous dose of a COVID-19 vaccine recognized by the WHO but NOT by the FDA (AstraZeneca - VAXZEVRIA, Sinovac - CORONAVAC, Serum Institute of India - COVISHIELD, Sinopharm / BIBP, Covaxin, Serum Institute of India – NUVAXOVID, or CanSino Biologics – Convidecia)?**
    - If yes, identify if the patient has received a complete or partial series of the vaccine. If the patient received a complete series (e.g., 2 doses), determine if they received a bivalent mRNA booster dose containing the original strain and the Omicron BA.4/BA.5 variant or Omicron BA.1 variant.
    - If a patient received a partial series of a World Health Organization (WHO) authorized COVID-19 vaccine that is not currently authorized for use in the U.S. by the FDA, the CDC does NOT consider these persons to be fully vaccinated. They should be offered a single dose of the age-appropriate COVID-19 vaccine of either Pfizer, Moderna or Novavax to complete the primary series (i.e., Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 6 months-11 years). They would then be eligible for a bivalent mRNA booster dose 2 months after completion of the primary series.
    - If the patient received either a partial series or complete series of a COVID-19 vaccine that is not authorized for use by either the WHO or the FDA, the CDC does NOT consider these persons to be fully vaccinated. They should be offered a two-dose series of the age-appropriate COVID-19 vaccine (i.e., Pfizer-BioNTech COVID-19 vaccine formulation for children ages 6 months-11 years). They would then be eligible for a bivalent mRNA booster dose 2 months after completion of the primary series.
    - If the patient received a complete series of a COVID-19 vaccine authorized by WHO but not FDA approved or authorized and have not yet received a bivalent mRNA COVID-19 vaccine, they are eligible to receive a bivalent mRNA COVID-19 vaccine at least 2 months after their most recent dose.

*** Anyone answering "Unknown" to any screening question should be referred to the medical director or responsible healthcare provider at the POD or clinic to further assess their answer to that question (e.g., the person might not have understood the question and the healthcare provider could explain it further).**