FIELD GUIDANCE #17 APPENDIX B: CHILDREN WHO RECEIVED COVID-19 VACCINE OUTSIDE THE UNITED STATES

(First issued November 19, 2021, revised January 28, 2022)

Pediatric and adolescent COVID-19 vaccination in other countries is becoming more common, and children entering ORR care might report or have documentation of a COVID-19 vaccine received outside of the United States. ORR care providers must follow the guidance below to determine if a child who reports (or has documentation of) receipt of a COVID-19 vaccine outside of the United States should receive Pfizer-BioNTech COVID-19 vaccine while in ORR care.

For other non-COVID-19 childhood vaccines, ORR does not count verbal report of prior vaccination towards the routine immunization schedule. Only valid, documented vaccines count toward the immunization schedule. This is in line with CDC's guidance on evaluating vaccination records for arriving refugees. ORR currently recommends a different approach for COVID-19 vaccines received outside of the United States, and verbal report of prior COVID-19 vaccination must be considered when determining whether a child should receive Pfizer-BioNTech COVID-19 vaccine while in ORR care. Care providers must ensure that vaccination records in a child's possession are reviewed by a healthcare provider to verify the number and type of COVID-19 vaccine doses the child might have received outside of the United States. This approach may change based on the accumulation of evidence and experience with COVID-19 vaccines.

This guidance was developed in consultation with CDC for the UC Program, and balances the known benefits of COVID-19 vaccination with the hypothetical risk of excess mRNA COVID-19 vaccination when an individual's COVID-19 vaccination history is unknown or vaccination records are not available. ORR care providers must refer to the scenarios below and to the "Children who received COVID-19 vaccine outside the United States — Quick Reference" guide on pages 4–5 to determine if a child should receive Pfizer-BioNTech COVID-19 vaccine while in ORR care. Care providers should consult with the Division of Health for Unaccompanied Children (DHUC) at DCSMedical@acf.hhs.gov for reported or documented vaccination histories that fall outside of these scenarios. Recommendations may be updated as more information becomes available or when additional vaccines are authorized by the U.S. Food and Drug Administration (FDA) or listed for emergency use by the World Health Organization (WHO).

COVID-19 vaccines administered <u>prior to and during</u> a child's admission to ORR care must be documented in the UC Portal. Refer to the "COVID-19 Vaccine-Related Portal Documentation Guidelines" (revised November 8, 2021) for detailed instructions on how to document COVID-19 vaccination. All COVID-19 Vaccination Record cards (for doses administered outside the United States and those administered while the child was in ORR care) must be included in the child's Transfer or Discharge Packet at the time of transfer/unification.

SCENARIO 1. Children (ages 5–17 years) who report that they received NO PRIOR COVID-19 vaccine doses or DO NOT KNOW whether they received any prior COVID-19 vaccine doses:

Administer Pfizer-BioNTech COVID-19 vaccine according to Field Guidance #17 (FG#17). The first
vaccine dose should be administered at the earliest opportunity (e.g., at the IME or MHA), and
the second dose should be administered 21 days later, if the child is still in ORR care at that
time. The age-appropriate Pfizer-BioNTech COVID-19 vaccine formulation must be used

COVID-19 Vaccination of Unaccompanied Children (UC) in ORR Care

- (pediatric formulation for children ages 5–11 years [orange vial cap]; adult/adolescent formulation for children ages 12–17 years [purple or gray vial cap]).
- Under Scenario 1, children ages 12–17 years should receive a Pfizer-BioNTech COVID-19 booster shot at least 5 months after completing the primary Pfizer-BioNTech COVID-19 vaccine series.

SCENARIO 2. Children (ages 5–17 years) who report having received ONE, TWO, or an UNKNOWN NUMBER of PRIOR COVID-19 vaccine doses, with no knowledge of the vaccine manufacturer:

- Administer one single dose of Pfizer-BioNTech COVID-19 vaccine dose 28 days after the last vaccination date (if date is known or can be estimated). If the vaccination date is not known and it cannot be estimated, the single Pfizer-BioNTech COVID-19 vaccine dose should be administered 28 days after the child's ORR placement date. The age-appropriate Pfizer-BioNTech COVID-19 vaccine formulation must be used (pediatric formulation for children ages 5–11 years [orange vial cap]; adult/adolescent formulation for children ages 12–17 years [purple or gray vial cap]).
- Under Scenario 2, children ages 12–17 years should receive a Pfizer-BioNTech COVID-19 booster shot at least 5 months after receiving the single dose of Pfizer-BioNTech COVID-19 vaccine.

SCENARIO 3. Children (ages 5–17 years) who report having received (or have documentation of) an FDA-AUTHORIZED COVID-19 VACCINE (Pfizer-BioNTech, Moderna, or Janssen):

- SCENARIO 3A. For children who received ONE or an UNKNOWN NUMBER of an FDA-AUTHORIZED COVID-19 VACCINE (Pfizer-BioNTech, Moderna, or Janssen) doses, administer one single dose Pfizer-BioNTech COVID-19 vaccine. The age-appropriate Pfizer-BioNTech COVID-19 vaccine formulation must be used (pediatric formulation for children ages 5–11 years [orange vial cap]; adult/adolescent formulation for children ages 12–17 years [purple or gray vial cap]).
 - i. Pfizer-BioNTech COVID-19 vaccine: for children who received one or an unknown number of Pfizer-BioNTech COVID-19 vaccine doses, administer one single Pfizer-BioNTech COVID-19 vaccine dose 21 days after the last vaccination date (if date is known or can be estimated). If the vaccination date is not known and it cannot be estimated, the single Pfizer-BioNTech COVID-19 vaccine dose should be administered 21 days after the child's ORR placement date.
 - ii. Moderna COVID-19 vaccine: for children who received one or an unknown number of Moderna COVID-19 vaccine doses, administer one single Pfizer-BioNTech COVID-19 vaccine dose 28 days after the last vaccination date (if date is known or can be estimated). If the vaccination date is not known and it cannot be estimated, the single Pfizer-BioNTech COVID-19 vaccine dose should be administered 28 days after the child's ORR placement date.
 - iii. Janssen (Johnson and Johnson) COVID-19 vaccine: for children who received one or an unknown number of Janssen COVID-19 vaccine doses, administer a single Pfizer-BioNTech COVID-19 vaccine dose two (2) months after the Janssen administration date. If the vaccination date is not known and it cannot be estimated, the single Pfizer-BioNTech COVID-19 vaccine dose should be administered two months after the child's ORR placement date.
 - iv. **Pfizer-BioNTech COVID-19 Booster Shot:** under Scenarios 3A.i and 3A.ii, children ages 12–17 years who received two mRNA COVID-19 vaccines (2 Pfizer-BioNTech doses, or 1 Moderna does + 1 Pfizer-BioNTech dose) should receive a Pfizer-BioNTech COVID-19

<u>booster shot</u> at least 5 months after completing the primary COVID-19 vaccine series. No additional Pfizer-BioNTech COVID-19 vaccine doses are recommended at this time for children who received a Janssen COVID-19 vaccine followed by a single Pfizer-BioNTech COVID-19 vaccine at least two months later (Scenario 3A.iii).

- **SCENARIO 3B.** For children who received TWO doses of an FDA-AUTHORIZED COVID-19 VACCINE (Pfizer-BioNTech, Moderna, or Janssen):
 - For children ages 5–11 years who received TWO Pfizer-BioNTech or Moderna COVID-19 vaccine doses, no additional Pfizer-BioNTech COVID-19 vaccine doses should be administered at this time. The child is considered fully vaccinated two weeks after the last dose was received.
 - Under Scenario 3B, children ages 12–17 years who completed a primary COVID-19 vaccine series (Pfizer-BioNTech or Moderna) at least 5 months ago should receive a Pfizer-BioNTech COVID-19 booster shot.
 - The Janssen COVID-19 vaccine series is a single dose. However, if a child reports having received TWO Janssen COVID-19 vaccine doses, no Pfizer-BioNTech COVID-19 vaccine doses should be administered.

SCENARIO 4. Children (ages 5–17 years) who report having received (or have documentation of) a COVID-19 vaccine that is NOT authorized by FDA and is NOT listed for emergency use by WHO¹:

- Administer Pfizer-BioNTech COVID-19 vaccine according to FG#17. The first vaccine dose should be administered 28 days after the last COVID-19 vaccine received outside the United States, and the second dose should be administered 21 days later, if the child is still in ORR care at that time. If the vaccination date is not known and it cannot be estimated, the first Pfizer-BioNTech COVID-19 vaccine dose should be administered 28 days after the child's ORR placement date. The age-appropriate Pfizer-BioNTech COVID-19 vaccine formulation must be used (pediatric formulation for children ages 5–11 years [orange vial cap]; adult/adolescent formulation for children ages 12–17 years [purple or gray vial cap]).
- Under Scenario 4, children ages 12–17 years who complete the primary Pfizer-BioNTech COVID-19 vaccine series are considered fully vaccinated and are not recommended to receive a Pfizer-BioNTech COVID-19 booster shot at this time.

SCENARIO 5. Children (ages 5–17 years) who report having received (or have documentation of) a COVID-19 vaccine that is NOT <u>authorized by FDA</u> but IS <u>listed for emergency use by WHO</u>¹:

• SCENARIO 5A. For children who did not receive all recommended doses of a COVID-19 vaccine that is listed for emergency use by WHO, administer one single Pfizer-BioNTech COVID-19 vaccine dose 28 days after the last vaccine date (if date is known or can be estimated). according to FG#17. If the vaccination date is not known and it cannot be estimated, the single Pfizer-BioNTech COVID-19 vaccine dose should be administered 28 days after the child's ORR placement date. The age-appropriate Pfizer-BioNTech COVID-19 vaccine formulation must be used (pediatric formulation for children ages 5–11 years [orange vial cap]; adult/adolescent formulation for children ages 12–17 years [purple or gray vial cap]).

¹ As of January 28, 2022, AstraZeneca, Sinopharm BIBP, Sinovac-Coronavac, Bharat Biotech, and Novavax COVID-19 vaccines are listed for emergency use by the WHO; all are 2-dose vaccine series.

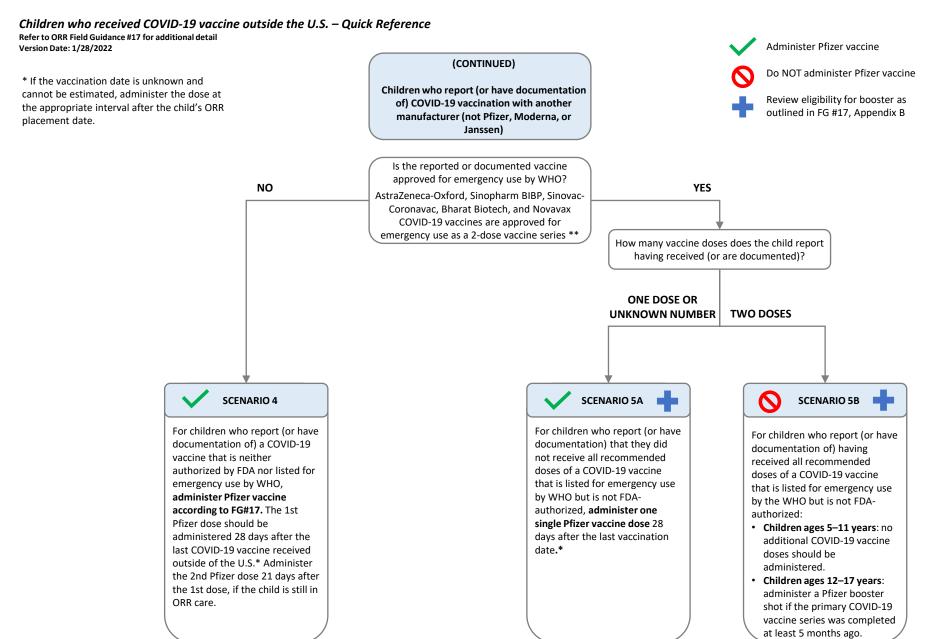
COVID-19 Vaccination of Unaccompanied Children (UC) in ORR Care

- Under Scenario 5A, children ages 12–17 years should receive a Pfizer-BioNTech COVID-19 booster shot at least 5 months after receiving the single dose of Pfizer-BioNTech COVID-19 vaccine.
- **SCENARIO 5B.** Children who report having received (or have documentation of) all recommended doses of a COVID-19 vaccine that is listed for emergency use by WHO:
 - For children ages 5–11 years who received all recommended doses of a COVID-19 vaccine that is listed for emergency use by WHO, no additional COVID-19 vaccine doses should be administered at this time. The child is considered fully vaccinated two weeks after the last dose was received.
 - Under Scenario 5B, children ages 12–17 years should receive a Pfizer-BioNTech COVID-19 booster shot at least 5 months after completing the primary COVID-19 vaccine series.

REFERENCES:

- 1. CDC: People who received COVID-19 vaccine outside the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us
- 2. CDC: Vaccine administration errors and deviations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-A
- 3. WHO: COVID-19 Regulation and Prequalification (click on "Status of COVID-19 Vaccines") https://www.who.int/teams/regulation-prequalification/eul/covid-19
- 4. CDC: COVID-19 Vaccine Booster Shots: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

Children who received COVID-19 vaccine outside the U.S. - Quick Reference Refer to ORR Field Guidance #17 Appendix B for additional detail Administer Pfizer vaccine Version Date: 1/28/2022 Do NOT administer Pfizer vaccine Did child arrive with COVID-19 vaccine record? * If the vaccination date is unknown and cannot be estimated, administer the dose at Review eligibility for booster as the appropriate interval after the child's ORR outlined in FG #17, Appendix B YES NO placement date. NO OR DON'T KNOW NO Does child report previous COVID-19 Is the COVID-19 vaccine manufacturer Pfizer. **GO TO NEXT PAGE** vaccination? Moderna, or Janssen? SCENARIO 1 YES YES YES Administer Pfizer vaccine according to FG#17 (1st dose at intake, 2nd dose 21 days later if child is still in ORR care). How many doses are documented or does the Does child know the vaccine manufacturer? child report having received? ONE DOSE OR TWO DOSES NO UNKNOWN NUMBER SCENARIO 3A **SCENARIO 2** SCENARIO 3B For children who report having For children who received one • For children ages 5-11 years received one dose, two doses, or an unknown number of an who received two doses of or an unknown number of FDA-authorized COVID-19 Pfizer or Moderna vaccine, no COVID-19 vaccine doses, with vaccine (Pfizer, Moderna, or additional doses should be unknown manufacturer, Janssen), administer one single administered. administer one single Pfizer Pfizer vaccine dose: • Children ages 12–17 years vaccine dose 28 days after the · Pfizer: administer 1 Pfizer who received two doses of last vaccination date.* vaccine dose 21 days after Pfizer or Moderna vaccine at the last vaccination date.* least 5 months ago should Moderna: administer 1 Pfizer receive a Pfizer booster shot. vaccine dose 28 days after · The Janssen vaccine series is the last vaccination date.* a single dose. However, if a · Janssen: administer 1 Pfizer child reports having received vaccine dose 2 months after two Janssen vaccine doses. the last vaccination date.* no Pfizer doses should be administered. Page 5 of 6



^{**} See CDC and WHO websites for updated information on vaccines that are listed for emergency use by WHO but are not FDA-authorized: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us https://www.who.int/teams/regulation-prequalification/eul/covid-19