Interim Clinical Considerations Update for Pediatric COVID-19 Vaccines

Elisha Hall, PhD Clinical Guidelines Lead

Advisory Committee on Immunization Practices Meeting 6/18/2022



cdc.gov/coronavirus



Outline

- Pediatric vaccination schedule
- Formulation and dosage
- Administration
- Patient counseling

Interim Clinical Considerations

- Interim Clinical Considerations for Use of COVID19 Vaccines Currently Approved or Authorized in the United States: <u>https://www.cdc.gov/vaccines/covid-</u> <u>19/clinical-considerations/interim-</u> <u>considerations-us.html</u>
- FAQs for the Interim Clinical Considerations: <u>https://www.cdc.gov/vaccines/covid-</u> <u>19/clinical-considerations/faq.html</u>
- At-A-Glance COVID19 Vaccination Schedule:

https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-scheduleat-a-glance-508.pdf



Clinical Resources

 US COVID-19 Vaccine Product Information: <u>https://www.cdc.gov/vaccin</u> <u>es/covid-19/info-by-</u> <u>product/index.html</u>

accines & Immunizations				
DC > COVID-19 Vaccination			Ø	🖸 🗊 🍪
COVID-19 Vaccination Product Info by U.S. Vaccine -	U.S. COVID-19 Va	accine Produ	ct Information	
Pfizer-BioNTech Vaccines + Moderna Vaccine	Find a suite of information and ma storage and handling, safety, and r	terials that are needed for e eporting.	each specific COVID-19 vaccine that cover ac	lministration,
Janssen/J&J Vaccine EUA	Pfizer-BioNTech	Moderna	Janssen/J&J	
EUI FAQs for Healthcare Professionals + Interim Clinical Considerations + Clinical Care + Provider Requirements and + Support	Interim COVID-1 Immunization Sc for Ages 5+ Find guidance for COV vaccination schedules age and medical condi	9 chedule 1D-19 based on tition.	Prevaccination Screening For COVID-19 Prevaccination Guidelines Download a prevaccination checklist in languages. Arabic , Dari , Finglish , French (C Haitian Creole , Korean , Pashto (Portugal , Simplified Chinese , Sp. Ukrainian , Vietnamese	multiple anada) ≅ , , <u>Portuguese</u> anish ≅ ,

Resources for Vaccine Recipient Education

- Recipient Education: <u>https://www.cdc.gov/vaccines</u> /covid-19/hcp/index.html
- COVID-19 Vaccination for Children:

https://www.cdc.gov/vaccines

<u>/covid-</u>

19/planning/children.html





www.cdc.gov/covid-19/children-teens.html

COVID-19 Pediatric Vaccination Schedule



COVID-19 Vaccine Pediatric Age Groups

- Moderna COVID-19 Vaccine
 - Ages 6 months through 5 years
- Pfizer-BioNTech COVID-19 Vaccine
 - Ages 6 months through 4 years
- "Through" means "up to and including" and is denoted by an en dash (–).

Pediatric Schedule: Moderna COVID-19 Vaccine

People who are **<u>NOT</u>** moderately or severely immunocompromised



People who ARE moderately or severely immunocompromised



Pediatric Schedule: Pfizer-BioNTech COVID-19 Vaccine

People who are **<u>NOT</u>** moderately or severely immunocompromised



People who ARE moderately or severely immunocompromised



Pediatric Schedule: People Who Are <u>NOT</u> Moderately or Severely Immunocompromised



Pediatric Schedule: People Who <u>ARE</u> Moderately or Severely Immunocompromised



Considerations for Extended Interval Between Dose 1 & 2



Considerations for Extended Interval Between Dose 1 & 2



- Reduced myocarditis risk
- Adolescent and young adult males
- Optimize vaccine effectiveness

- Immunocompromised
- High risk for severe disease
- Household members with high risk for severe disease
- High COVID-19 community levels

Considerations for Extended Interval Between Dose 1 & 2



- Immunocompromised
- High risk for severe disease
- Household members with high risk for severe disease
- High COVID-19 community levels

- Reduced myocarditis risk
- Adolescent and young adult males
- Optimize vaccine effectiveness

Formulations



Vaccine Dosage

- Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age <u>on the day of vaccination</u>, regardless of their size or weight.
- If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.

Pfizer-BioNTech COVID-19 Vaccine Formulations

	Formulation for ages 6 months– 4 years	Formulation for ages 5–11 years	Formulation for ages 12 years and older
Authorized for ages	6 months-4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes-2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Formulations

	Formulation for ages 6 months– 4 years	Formulation for ages 5–11 years	Formulation for ages 12 years and older
Authorized for ages	6 months–4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes–2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Formulations

	Formulation for ages 6 months– 4 years	Formulation for ages 5–11 years	Formulation for ages 12 years and older
Authorized for ages	6 months–4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes-2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Formulation for Ages 6 Months–4 Years



Vial label states Age 2y to <5y but can be used in children ages 6 months-4 years.

Moderna COVID-19 Vaccine Formulations

	6 months –5 years	12 years and older
Authorized for ages	6 months–5 years	12 years and older
Vial cap color	Dark blue	Red
Label border color	Magenta	Light blue
Dose (mRNA concentration)	25 mcg	100 mcg
Injection volume volume	0.25 mL	0.5 mL
Dilution required	No	No
Doses per vial	10	Maximum of 11

Formulation for ages Formulation for ages

Moderna COVID-19 Vaccine Formulations

	Formulation for ages 6 months – 5 years	Formulation for ages 12 years and older
Authorized for ages	6 months–5 years	12 years and older
Vial cap color	Dark blue	Red
Label border color	Magenta	Light blue
Dose (mRNA concentration)	25 mcg	100 mcg
Injection volume volume	0.25 mL	0.5 mL
Dilution required	Νο	No
Doses per vial	10	Maximum of 11

Moderna COVID-19 Vaccine Formulations

	Formulation for ages 6 months –5 years	Formulation for ages 12 years and older	
Authorized for ages	6 months–5 years	12 years and older	
Vial cap color	Dark blue	Red	
Label border color	Magenta	Light blue	
Dose (mRNA concentration)	25 mcg	100 mcg	
Injection volume volume	0.25 mL	0.5 mL	
Dilution required	No	No	
Doses per vial	10	Maximum of 11	

Moderna COVID-19 Vaccine Formulation for Ages 6 Months Through 5 Years



Interchangeability

- COVID-19 vaccines are not interchangeable.
- The same mRNA vaccine product should be used for all doses of the primary series.
- In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, either age-appropriate available mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series.

Vaccine Administration



Coadministration

- COVID-19 vaccines may be administered without regard to timing of other vaccines.
- Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.
- Data assessing the outcomes of simultaneous administration of COVID-19 vaccines with other vaccines are limited currently.

Coadministration

- In accordance with <u>general best practices</u>, routine administration of all ageappropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the healthcare visit.
- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers and parents/guardians may consider:
 - Whether a child is behind or at risk of becoming behind
 - Likelihood of the child returning for another vaccination
 - Their risk of vaccine-preventable diseases
 - The reactogenicity profile of the vaccines

Coadministration

Best practices for multiple injections include:

- Label each syringe
- Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible
- Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs

Vaccination Coverage 2020-2021 School Year

- Vaccination coverage among kindergartners nationwide was lower during the 2020-21 school year compared with 2019–20 school year
 - 94% for MMR, DTaP, and varicella vaccines, a level just under the Healthy People target of 95%
 - Coverage for all three vaccines decreased in a majority of states
 - Nonexempt undervaccinated students often attend school while in a grace period or are provisionally enrolled; in many states, these policies were expanded either formally or informally during the 2020–21 school year

Comparison of Monthly VFC Provider Orders for All Non-Flu Vaccine Components through May by Fiscal Year



Adverse Events and Patient Counseling



Patient and Parent/Guardian Counseling: Side Effects

- Children may experience fewer side effects than adolescents or young adults.
- Local side effects
 - Pain, swelling, and redness at the injection site,
 - Axillary or inguinal lymphadenopathy
- Systemic side effects
 - Fever, fatigue, headache, chills, myalgia, arthralgia
 - Irritability, crying, sleepiness, loss of appetite in infants and younger children

Febrile Seizures

- Febrile seizures were rare in COVID-19 vaccine clinical trials for young children.
 - The impact of coadministration with COVID-19 vaccines on risk of febrile seizures has not been specifically studied.
- Febrile seizures are not uncommon generally and can occur in infants and young children with any condition that causes a fever, including COVID-19.
 - Nearly all children who have a febrile seizure recover quickly and do not have any permanent neurological damage.
- CDC will closely monitor for febrile seizures following COVID-19 vaccination in young children.

Acknowledgements

- Mary Chamberland
- Lauren Daniel
- Megan Freedman
- Susan Goldstein
- Jarrad Hogg
- Lauren Hughes

- Sarah Meyer
- Valerie Morelli
- Sara Oliver
- Evelyn Twentyman
- JoEllen Wolicki
- ACIP WG Team



For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



Children Who Turn From Age 4 to 5 years Between Any Dose in the Primary Series May Receive...

 Scenario 1: A 2-dose primary series using the formulation for people ages 5–11 years (orange cap)



Children Who Turn From Age 4 to 5 years Between Any Dose in the Primary Series May Receive...

Scenario 2: A 3-dose primary series initiated with the formulation for ages 6 months–4 years. Dose 2 and 3 may be with: the formulation for ages 6 months–4 years or the formulation for ages 6–11 years.



Mixed Series For Children Ages 6 months–4 Years

 Children ages 6 months—4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should receive a third dose of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose primary series.

Mixed Series For Children Ages 6 months-4 Years

Scenario 1:



Mixed Series For Children Ages 6 months-4 Years

Scenario 2:



Administration

Age	Needle gauge	Needle length	Injection Site
6 months through 2 years	22- to 25-gauge needle	1-inch (25mm) needle [*]	Vastus lateralis in the anterolateral thigh
3 years and older	22- to 25-gauge needle	5/8- to 1-inch (25mm) needle [†]	Deltoid muscle

*Use a 5/8 to 1-inch (16 to 5 mm) if using the deltoid muscle. A 5/8 nch needle may be used only if the skin is stretched tighty and the subcutaneous tissue is not bunched.

† Use a 4 to 1.25-inch (25-32 mm) needle if administering vaccine in the vastus lateralis muscle in the anterolateral thigh

- Intramuscular (IM) Injection Infants 11 months of age and younger: <u>https://www.cdc.gov/vaccines/hcp/admin/downloads/IM -Injection-Infants-508.pdf</u>
- Intramuscular (IM) Injection Children 1 through 2 years of age: <u>https://www.cdc.gov/vaccines/hcp/admin/downloads/IM -Injection-1-2-Years508.pdf</u>
- Intramuscular (IM) Injection Children 3 through 6 years of age: <u>https://www.cdc.gov/vaccines/hcp/admin/downloads/IM -Injection-3-6-Years.pdf</u>

COVID-19 Vaccine Administration Errors

Err	or	Rec	commended Action
•	If the incorrect formulation is administered, resulting in a higher -than -authorized dose	•	Do <u>NOT</u> repeat dose. [†] ‡
•	If the incorrect formulation is administered, resulting in a lower -than -authorized dose	•	Repeat dose immediately (no minimum interval) with the age-appropriate formulation. Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, especially in males ages 12–39. ^{†‡}

[†]If the administration error resulted in a higher-than-authorized vaccine dose, in general a subsequent dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the subsequent dose, this dose might be delayed, but this decision should be assessed on a case-by-case basis.

[‡]If the dosing is in accordance with the FDA EUA, it is not considered an error and VAERS reporting is not indicated.