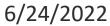
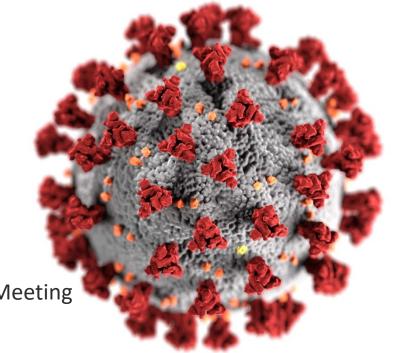
Interim Clinical Considerations Update: Moderna COVID-19 Vaccine for Children Ages 6–17

Elisha Hall, PhD
Clinical Guidelines Lead

Advisory Committee on Immunization Practices Meeting







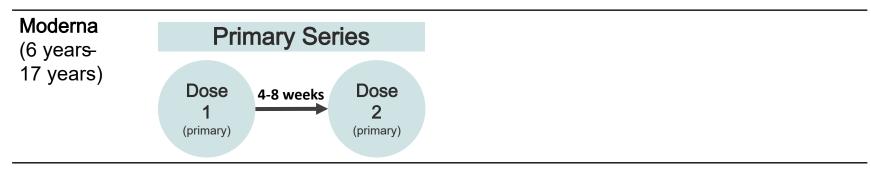
cdc.gov/coronavirus

COVID-19 Pediatric Vaccination Schedule

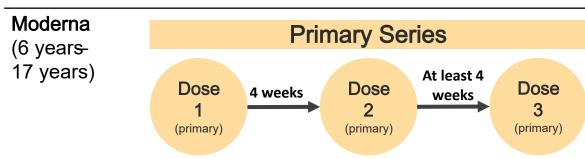


Pediatric Schedule: Moderna COVID-19 Vaccine

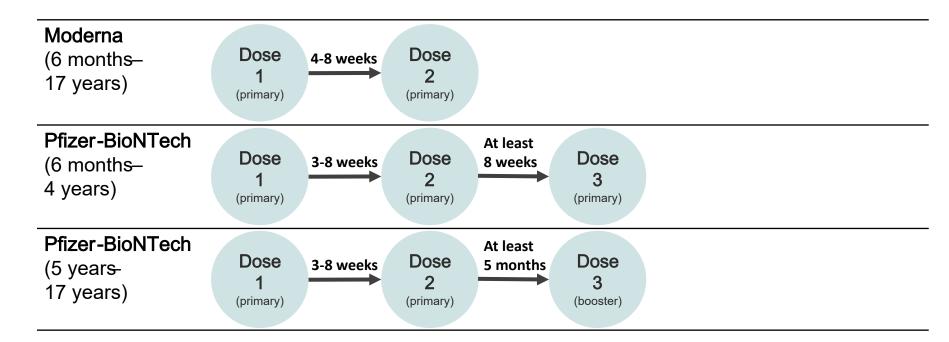
People who are **NOT** moderately or severely immunocompromised



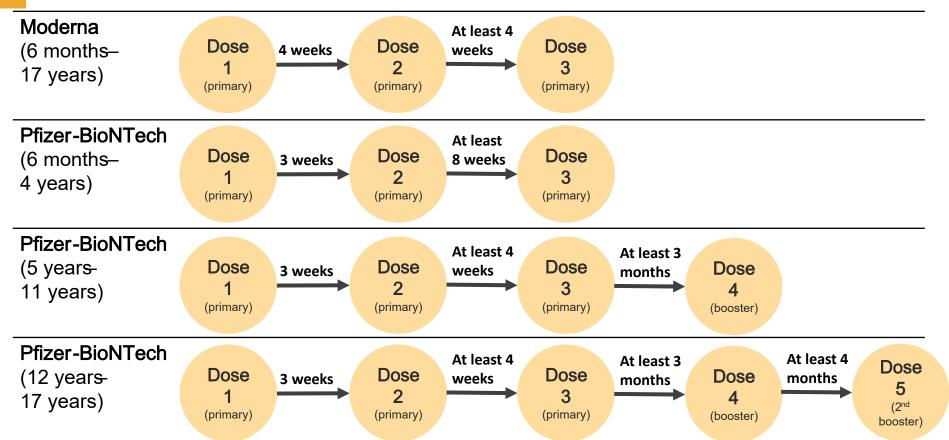
People who **ARE** moderately or severely immunocompromised



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



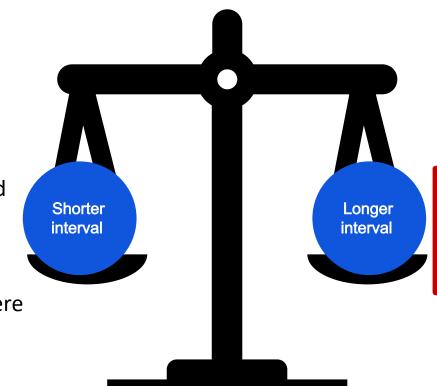
Pediatric Schedule: People Who <u>ARE</u> Moderately or Severely Immunocompromised



Considerations for Extended Interval Between Dose 1 & 2



- 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

Products

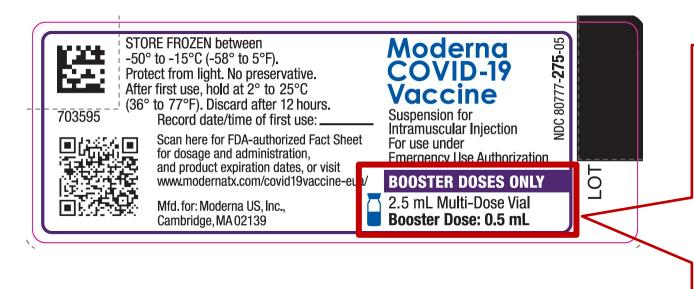


Authorized Age group	6 months –5 years (primary series)	• 6–11 years (primary series) • 18 years and older (booster doses)	• 12 years and older (primary series) • 18 years and older (booster doses)
Vial cap color	Dark blue	Dark blue	Red
Label border color	Magenta	Purple	Light blue
Dose (mRNA concentration)	25 mcg	50 mcg	100 mcg
Injection volume volume	0.25 mL	0.5 mL	0.5 mL(primary, age 12+); 0.25mL(booster, age 18+)
Dilution required	No	No	No
Doses per vial	10	5	Maximum of 11

Authorized Age group	6 months –5 years (primary series)	• 6–11 years (primary series) • 18 years and older (booster doses)	• 12 years and older (primary series) • 18 years and older (booster doses)
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Dilution required	No	No	No
Doses per vial	10	5	Maximum of 11

Moderna COVID-19 Vaccine Product for Ages 6–11 Years



Labeled for "BOOSTEF DOSES ONLY" but is authorized for:

- Primary doses in children ages 6–11 years
- Booster doses in adults ages 18 years and older

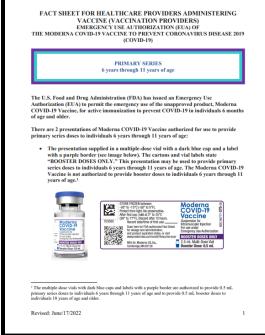
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Vial cap color	Dark blue	Dark blue	Red
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Dose (mRNA concentration)	25 mcg	50 mcg	100 mcg
Injection volume volume	0.25 mL	0.5 mL	0.5 mL(primary, age 12+); 0.25mL(booster, age 18+)
Dilution required	No	No	No
Doses per vial	10	5	Maximum of 11

FDA Resources

Wall chart:

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

MODERNA COVID-19 VACCINE PRESENTATIONS				
Age Group	6 months through 5 years (<i>Primary Series</i>)	6 years through 11 years (Primary Series) Currently unavailable (Use the vial with dark blue cap and a label with a purple border)	6 years through 11 years (Primary Series) 18 years and older (Booster Dose)	12 years and older (<i>Primary Series</i>) 18 years and older (<i>Booster Dose</i>)
Vial Cap Color	Dark Blue	Dark Blue	Dark Blue	Red
Vial Label Border Color	MAGENTA	TEAL	PURPLE	LIGHT BLUE
Vial Image	Moderno COVID-19 Voccine Vocci	Moderna COVID-19 VOCCINE To the state of the	Moderns Voccine Working to the state of the	Moderna Working Workin
Primary Dose Volume	0.25 mL	0.5 mL	0.5 mL	0.5 mL
Booster Dose Volume	None	None	0.5 mL	0.25 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	www.modernatx.com/ covid19vaccine-eua	www.modernatx.com/ covid19vaccine-eua	www.modernatx.com/	www.modernatx.com/ covid19vaccine-eua



ntation is included in the Description section of the respective Full EUA

concentrations of some of the ingredients differ between the two presentations. nise refers to individuals who have undergone solid organ transplantation, or who it are considered to have an equivalent level of immunocompromise.

used for a booster dose for individuals 18 years of age and older. The Moderna

nultiple-dose vials with dark blue caps and labels with a purple border and the

plied in multiple-dose vials with red caps and labels with a light blue border

R HEALTHCARE PROVIDERS ADMINISTERING

CINE (VACCINATION PROVIDERS)

RGENCY USE AUTHORIZATION (EUA) OF ID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019

nary Series Doses for 12 Years and Older Sooster Doses for 18 Years and Older1

SERIES AND BOOSTER DOSE PRESENTATION

Administration (FDA) has issued an Emergency Use ermit the emergency use of the unapproved product, MODERNA

or active immunization to prevent COVID-19 in individuals 6

only to Moderna COVID-19 Vaccine supplied in a multiple-dose

to individuals 18 years of age and older who have completed

on with another authorized or approved COVID-19 vaccine. The

lose to individuals 50 years of age and older who have received a

of any authorized or approved COVID-19 vaccine; and dose to individuals 18 years of age and older with certain kinds of ise and who have received a first booster dose of any authorized or a COVID-19 Vaccine supplied in multiple-dose vials with dark blue caps and

the heterologous booster dose is the same as that authorized for a

label with a light blue border which is authorized for use to

y series to individuals 12 years of age and older; ries dose to individuals 12 years of age and older with certain e to individuals 18 years of age and older who have completed a ith Moderna COVID-19 Vaccine or SPIKEVAX (COVID-19

vaccine used for primary vaccination;

(COVID-19)

Fact Sheet for Healthcare Providers

6 Through 11 Years:

https://www.fda.gov/media/159308/download

12 Years and Older:

https://www.fda.gov/media/157233/download

CDC Resources

- Clinical considerations:

 https://www.cdc.gov/vaccines/covid 19/clinical-considerations/interim considerations-us.html
- Self-paced training module: https://www2.cdc.gov/vaccines/ed/covid19/ moderna/index.asp
- Job aids: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
 - At-a-glance job aid for each manufacturer
 - Prep and admin summary
- Promotion through webinars, calls, and partners



Moderna COVID-19 Vaccine At-A-Glance

Blue cap: 6 Months through 5 Years of Age Red cap: 18 years of age and older

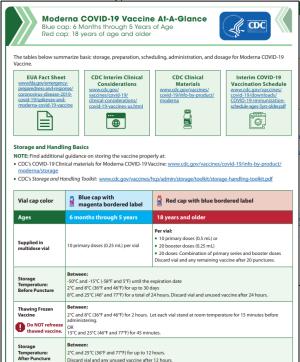


Preparation and Administration Basics

NOTE: Find additional guidance on properly preparing and administering the vaccine at:

- CDC's COVID-19 Clinical materials for Moderna COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/
- CDC's Vaccine administration library: www.cdc.gov/vaccines/hcp/admin/resource-library.html

Preparation and Administration



06/20/2022 05331571.8

Route	Needle gauge and length	Site
IM injection	22–25 gauge, 1"	6 months – 2 years of age: Vastus lateralis muscle in the anterolateral thigh
		3 - 5 years of age: Deltoid muscle in the upper arm [†]
IM injection	22–25 gauge, 1 – 1½*	Deltoid muscle in the upper arm [†]

9 vaccine based on age and immune status. For

/covid-19/info-by-product/moderna/

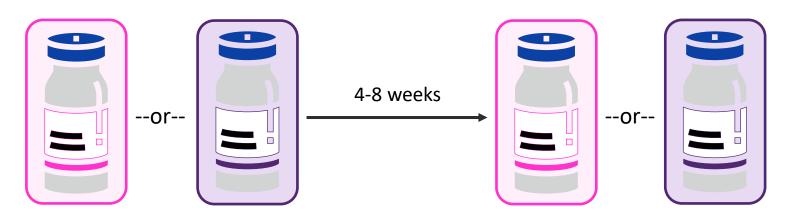


Vaccine Dosage

- Children should receive the age-appropriate vaccine product and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.
- If a child moves from a younger age group to an older age group (e.g., moves from age 11 years to age 12 years) 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.

Children who Turn from Age 5 to 6 Years Between Any Dose in the Primary Series May Receive...

...for either dose: 1) The Moderna product authorized for children ages 6 months—5 years or 2) the Moderna product authorized for children ages 6—11 years.



Dose 1:

Dark blue cap, magenta label border

---or---

Dark blue cap, purple border

Dose 2:

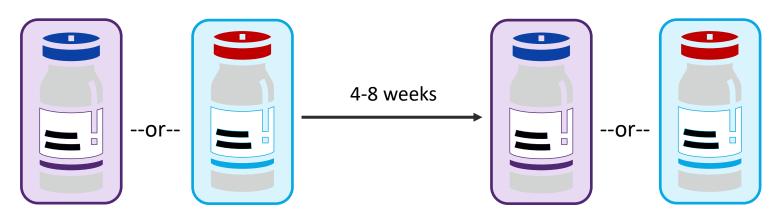
Dark blue cap, magenta label border

---or---

Dark blue cap, purple border

Children who Turn from Age 11 to 12 Years Between Any Dose in the Primary Series May Receive...

...for either dose: 1) the Moderna product authorized for children ages 6–11 years, 2) The Moderna product authorized for children ages 12–17 years.



Dose 1:

Dark blue cap, purple border
---or---

Red cap, light blue border

Dose 2:

Dark blue cap, purple border

---or---

Red cap, light blue border

Vaccine Administration



Administration

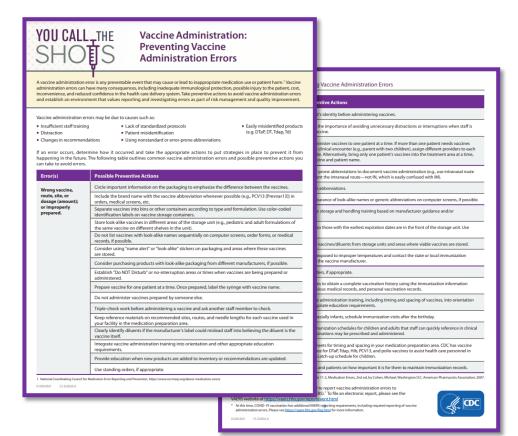
- Existing guidance applies to children and adolescents ages 6–17 years.
- Coadministration: COVID-19 vaccines may be administered without regard to timing of other vaccines.
 - Considerations included in the interim clinical considerations
- Interchangeability: COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series.

Potential Vaccine Administration Errors

- More opportunities for errors with:
 - More products
 - Products not labeled for the indicated age group
 - New pediatric providers that may be unfamiliar with COVID-19 vaccines
- Most likely errors with this context:
 - Incorrect product and/or dose volume, resulting in a higher-thanauthorized dose
 - Incorrect product and/or dose volume, resulting in a lower-thanauthorized dose
 - Correct dose from an incorrect product
 - Vaccine administered past beyond-use date

Resources for Preventing Vaccine Administration Errors

- Web-on-demand "mini" webinar: https://www2.cdc.gov/vaccines/ed/covid19/videos/va/va.asp
- Vaccine Administration: Preventing
 Vaccine Administration Errors
 https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf
- Vaccine storage, handling, preparation, and administration materials: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html



Resources

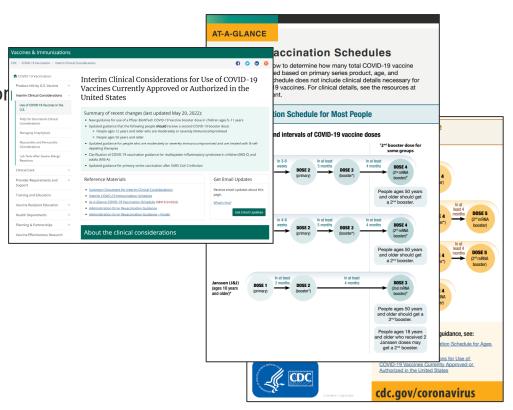


Interim Clinical Considerations

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

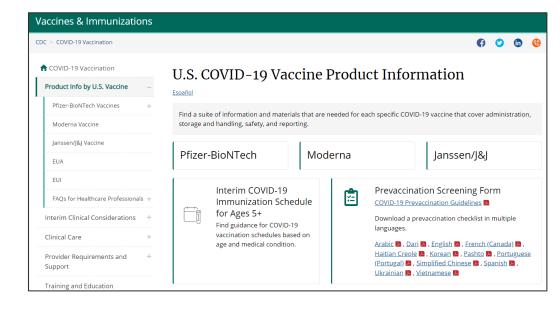
At-A-Glance COVIDI9 Vaccination

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



Clinical Resources

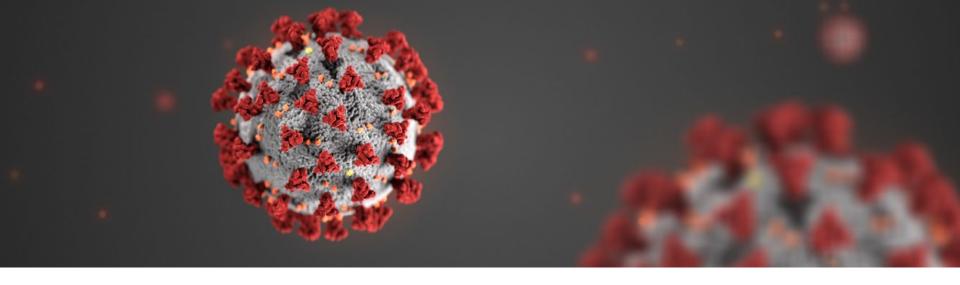
US COVID-19 Vaccine
 Product Information:
 https://www.cdc.gov/vaccin
 es/covid-19/info-by-product/index.html



Resources for Vaccine Recipient Education

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





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.

