Pediatric COVID-19 Vaccine Updates

Maine Immunization Program June 30, 2022



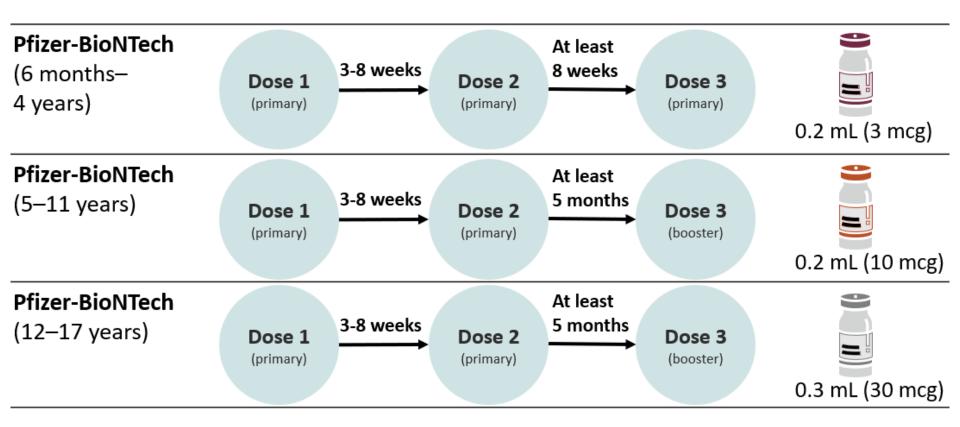
Agenda

- Vaccine Schedule
- Product Labeling
- Age Allowances
- Interchangeability
- Miscellaneous Updates
- Questions

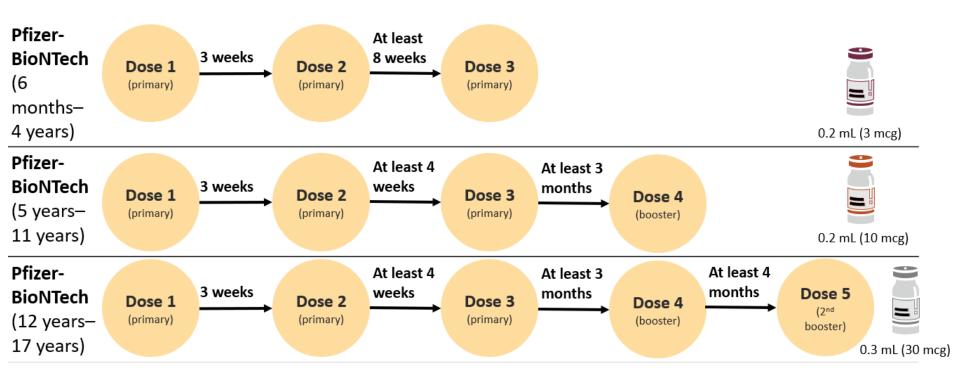
Disclaimer

All information in this presentation is subject to change. Information shared in these slides are assumptions as of 6/30/2022.

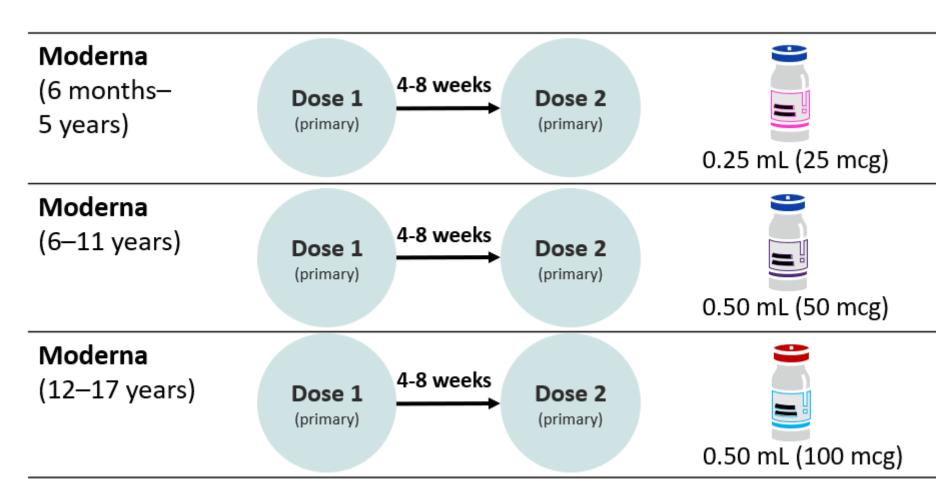
Pfizer-BioNTech Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised



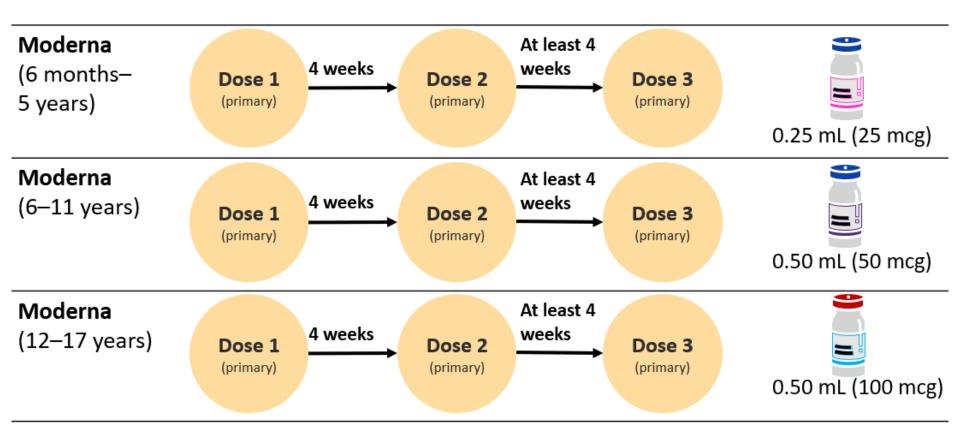
Pfizer-BioNTech Pediatric Schedule: People Who <u>ARE</u> Moderately or Severely Immunocompromised



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



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



Moderna Boosters

Moderna is **NOT** currently approved for booster doses for individuals under 18 years of age.

- Individuals that receive a primary series of Moderna vaccine should
 NOT get a booster dose of Pfizer-BioNTech vaccine
- Individuals that receive a primary series of Pfizer-BioNTech vaccine should <u>NOT</u> get a booster dose of Moderna vaccine
- FDA anticipates Moderna booster doses will be approved within the next five months

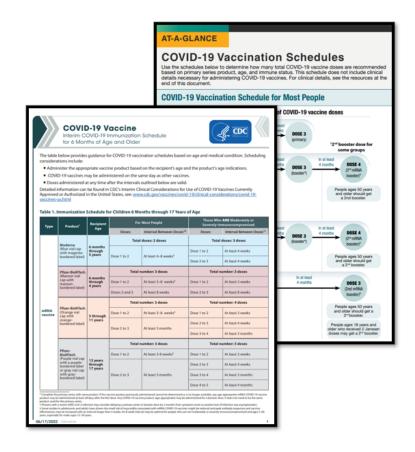
Schedule Resources

• At-a-glance schedule:

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

 Interim COVID-19 immunization schedule:

https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19immunization-schedule-ages-6months-older.pdf

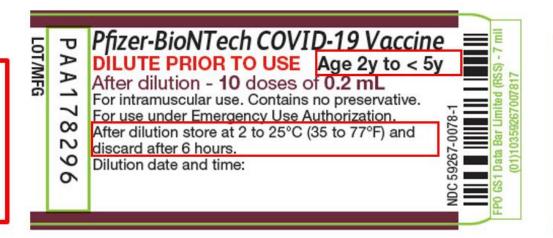


Pfizer-BioNTech COVID-19 Vaccine Products

	Product for ages 6 mons – 4 years	Product for ages 5–11 years	Product 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	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 Product for Ages 6 Months – 4 Years Label

Vaccine may be discarded 12 hours after dilution rather than 6 hours.

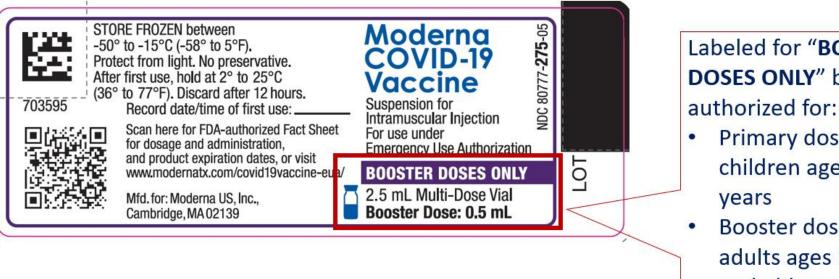


Vial label states
Age 2y to <5y
but can be used
in children ages
6 months-4
years.

Moderna COVID-19 Vaccine 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 (primary, age 12+); 50mcg (booster, age 18+)
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

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



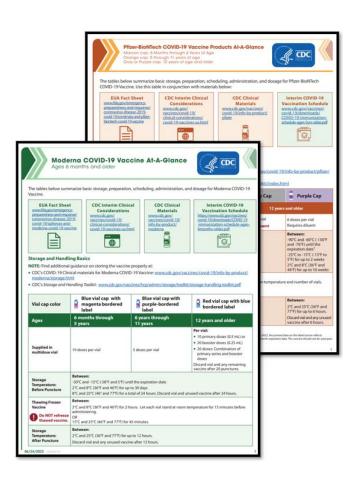
Labeled for "BOOSTER **DOSES ONLY"** but is

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

Product Resources

- Storage, handling, preparation, and administration job aids by product: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
- Pfizer-BioNTech label infographic: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/infant-label-info.pdf</u>
- Moderna label infographic: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-children-updated-label-iinfo-508.pdf</u>
- At-a-glance job aids
 - Pfizer-BioNTech:

 https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/vaccine-at-a-glance.pdf
 - Moderna: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/vaccine-at-a-glance.pdf</u>

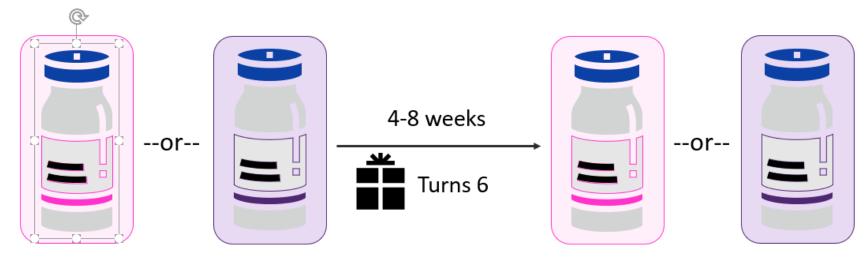


Vaccine Dosage: CDC's Recommendation

- CDC'S recommendation: 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 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.
- FDA authorization allows for dosing options for certain age transitions. If these options occur, they are not considered errors and the doses "count".

FDA Allowance for Moderna Age 5 to 6 Years

Children who will turn from age 5 years to 6 years between doses in the primary series to receive, for any primary dose: (1) the Moderna COVID-19 Vaccine product authorized for children ages 6 months—5 years or (2) the Moderna COVID-19 Vaccine product authorized for children ages 6—11 years.



Dose 1 (Age 5):

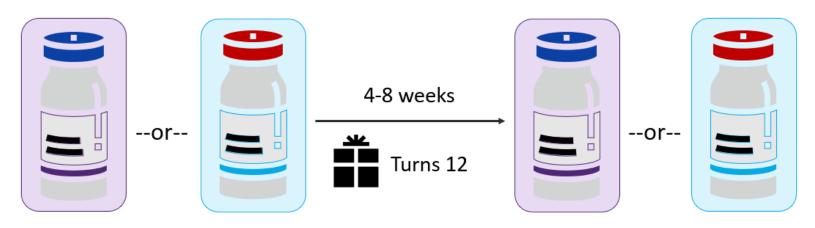
0.25 mL (25 mcg) of the product for ages 6 months–5 years <u>or</u> 0.50 mL (50 mcg) of the product for ages 6–11 years

Dose 2 (Age 6):

0.25 mL (25 mcg) of the product for ages 6 months–5 years <u>or</u> 0.50 mL (50 mcg) of the product for ages 6–11 years

FDA Allowance for Moderna Age 11 to 12 Years

Children who will turn from age 11 years to 12 years between doses in the primary series to receive, for any primary dose: (1) the Moderna COVID-19 Vaccine product authorized for children ages 6–11 years or (2) the Moderna COVID-19 Vaccine product authorized for people ages 12 years and older.



Dose 1 (Age 11):

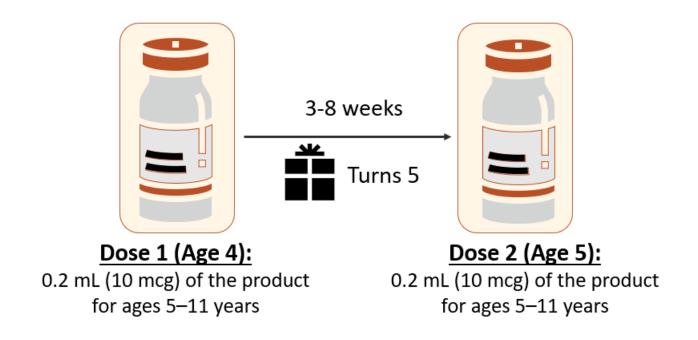
0.50 mL (50 mcg) of the product for ages 6–11 years 0.50 mL (100mcg) of the product for ages 12 years and older

Dose 2 (Age 12):

0.50 mL (50 mcg) of the product for ages 6–11 years 0.50 mL (100mcg) of the product for ages 12 years and older

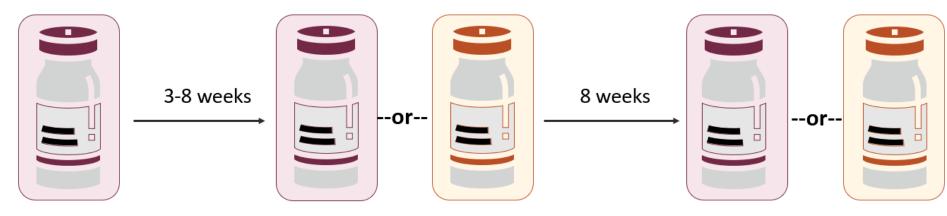
FDA Allowance for Pfizer-BioNTech Age 4 to 5 Years

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



FDA Allowance for Pfizer-BioNTech Age 4 to 5 Years

Scenario 2: A 3-dose primary series initiated with the product for ages 6 months—4 years. Dose 2 and 3 may be with: the product for ages 6 months—4 years or the product for ages 5—11 years.



Dose 1 (Age 4):

0.2 mL (3 mcg) of the product for ages 6 months-4 years

Dose 2 (Age 4 or 5):

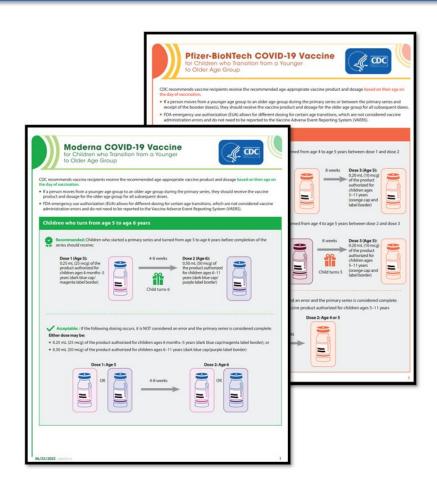
0.2 mL (3 mcg) of the product for ages 6 months-4 years, or0.2 mL (10 mcg) of the product for ages 5-11 years

Dose 3 (Age 5):

0.2 mL (3 mcg) of the product for ages 6 months-4 years, or 0.2 mL (10 mcg) of the product for ages 5-11 years

Aging up Resources

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



Interchangeability

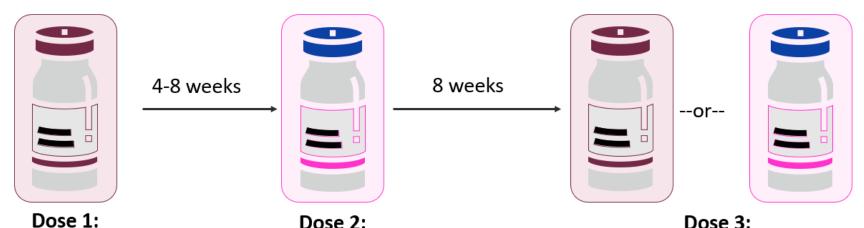
- COVID-19 vaccines are not interchangeable.
- The same mRNA vaccine product should be used for all doses of the primary series.
- In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, either age-appropriate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

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:



0.20 mL (3mcg) of the
Pfizer-BioNTech product
for ages 6 months
through 4 years

0.25 mL (25mcg) of the Moderna product for ages 6 months through 5 years

0.20 mL (3mcg) of the Pfizer-BioNTech product for ages 6 months through 4 years

0.25 mL (25mcg) of the Moderna product for ages 6 months through 5 years

--or--

Mixed Series for Children Ages 6 Months – 4 Years



Dose 1: 0.25 mL (25mcg) of the Moderna product for ages 6 months through 5 years

0.20 mL (3mcg) of the
Pfizer-BioNTech product for ages 6 months through 4
years

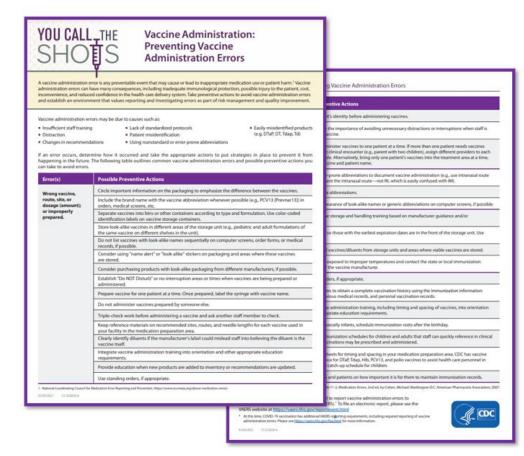
0.20 mL (3mcg) of the Pfizer-BioNTech

product for ages 6 months through 4 years
--or--

0.25 mL (25mcg) of the Moderna product for ages 6 months through 5 years

Preventing Vaccine Administration Errors

- Clinical guidance for errors:
 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c
- Handout: https://www.cdc.gov/vaccines/ hcp/admin/downloads/vaccine- administration-preventing-gerrors.pdf



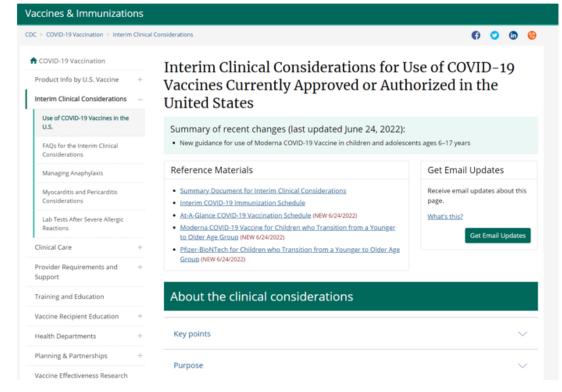
Interim Clinical Considerations

 Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

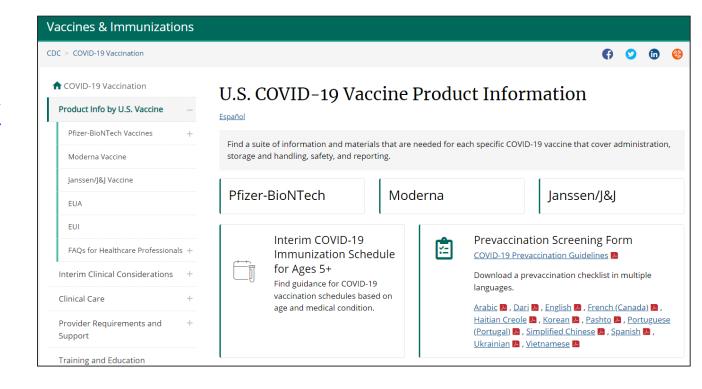
 FAQs for the Interim Clinical Considerations:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html



Clinical Resources

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



Miscellaneous

- No shipments on 4th of July
- Pfizer-BioNTech expiration look up tool available in July
- Moderna 6-11 ancillary kits packaged at 140 quantity with 1" needles
- Alternative languages not yet available for EUA Fact Sheets
- Novavax
 - Only 3 million purchased under contract
 - 100 minimum dose quantity 10 dose vials/10 vials in box
 - 2 dose series
 - Anticipated to be available in August

Questions?

Maine Immunization Program

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MIP Website: www.lmmunizeME.org
www.bravelikeme.com

