



June 2022

COVID-19 Vaccines for 6-Month Through 5-Years Population

Virginia Academy of Family Physicians (VAFP)

In Partnership with the Virginia Department of Health (VDH)

Webinar Reminders

- This webinar is recorded and will be shared with VAFP members
- Attendees will be in listen-only mode to decrease background noise
- Please type questions into the Q&A box at any time
- Questions will be addressed during the Q&A session to help manage time
- This webinar is eligible for 1 CME credit for VAFP Members, and can be requested via survey using the provided QR Code



Introduction



Neeta Goel, MD

President, VAFP

Chief Medical Officer, Ambulatory Services, INOVA

*VDH & VAFP encourage that **all Virginia family physicians vaccinate this young population**, which includes providing the COVID-19 vaccine via routine patient care. Even vaccinating one child a day will make a difference.*

Speakers



Dr. Rebecca Levorson, MD
Medical Director of Infectious Disease
Pediatric Specialists of Virginia



Dr. Chelsea Sprouse, PharmD
COVID-19 Vaccine Pharmacy Coordinator
Virginia Department of Health

Impact of COVID-19 on Children

Children under 18 years currently make up 18.8% of all COVID-19 cases reported nationally. This includes a total of over 13.6 million COVID-19 child cases since the onset of the pandemic. The overall rate for child COVID-19 cases is **18,102 cases per 100,000 children.**

Child COVID-19 cases are far higher than one year ago, as **children made up 13.7% of the cases reported the week of ending 6/16/22.**

Within the last 6 months, **children ages 6 months to 4 years have experienced higher hospitalization rates** than children ages 5 to 11 years.



COVID-19 Vaccines for Children Ages 6 Months Through 5 Years

Vaccine Trial Data: Immunogenicity Results

Summary of End Points for Both Pfizer-BioNTech & Moderna Vaccines

- Both Pfizer-BioNTech & Moderna conducted immuno-bridging studies that inferred vaccine efficacy in creating an immunization response in this age group
- Immune responses in terms of GMT ratio and SRR rates were non-inferior, compared to other studies with young adults
- Vaccine efficacy consistent with that of other age groups

	Pfizer-BioNTech	Moderna
Study Group	6 months through 4 years: Participants were randomized to receive a <i>three-dose primary series</i> of 3µg of the mRNA vaccine or placebo	6 months through 5 years: Participants were randomly assigned to receive a <i>two-dose primary series</i> of 25µg of the mRNA vaccine or placebo
Measure of Efficacy	GMR/GMT: Compared pediatric age group to 16-25 age group SRR: % of participants with ≥4-fold rise in SARS-CoV-2 neutralizing antibody titer from baseline *Success criteria was not met 1 month after dose 2; was met after dose 3	GMR/GMT: Compared pediatric age group to 18-25 age group SRR: % of participants with ≥4-fold rise in SARS-CoV-2 neutralizing antibody titer from baseline *Success criteria was met one month after dose 2
Strain Activity	Post dose 3 neutralizing antibody GMTs: <ul style="list-style-type: none"> Reference strain and against Delta variant were similar Activity against Omicron variant was notably lower 	<ul style="list-style-type: none"> Efficacy observed against reference strain, Delta, Omicron Efficacy following 2-dose series is highly consistent with real-world vaccine effectiveness observed against Omicron in adults

Key:

GMR: Geometric Mean Ratio

GMT: Geometric Mean Titer

SRR: Seroresponse Rate


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Vaccine Trial Data: Safety Considerations & Side Effects

Safety Considerations for Both Vaccines:

- **Anaphylaxis:** Epinephrine 0.15 mg auto-injector has specific weight range
 - Consider having epinephrine vials to draw up the correct dose based on weight
- Vaccine generally well tolerated in trials, and the safety profile is consistent with that seen in young adults
- **No reports of myocarditis/pericarditis, no cases of anaphylaxis caused by vaccination, no deaths**

Commonly Experienced Side Effects:

The following side effects were seen for both vaccines:

- Injection Site Reactions
- Irritability
- Fatigue
- Fever (more with Moderna)
- Decreased Appetite in lower age range (more with Moderna)

Overview of Available Vaccines

- Both the Pfizer-BioNTech and Moderna vaccines are effective in preventing symptomatic COVID-19 in this population.
- These vaccines are NOT the same formulation as their adult counterparts, and the adult formulations should NOT be used in this population.

	Pfizer-BioNTech	Moderna
Eligibility	6 months through 4 years	6 months through 5 years
Series	Three doses	Two doses
Interval	Between Doses 1 and 2: 3 weeks Between Doses 2 and 3: ≥ 8 weeks	4 weeks apart
Vial Color	Maroon Cap & Maroon Border	Dark Blue Cap & Magenta Border
Dose Volume	3 mcg/ 0.2 mL (<i>diluent provided in ancillary supply kit</i>)	25 mcg/ 0.25mL (<i>no diluent required</i>)

Additional Information

	Pfizer-BioNTech	Moderna
Ancillary Kits	Same supplies as Pfizer 5-11 Vaccine (including 1” needles and diluent)	Same supplies as Moderna Adult Vaccine (including 1” needles)
Shipment	<ul style="list-style-type: none">● Ships frozen at -80°C● Arrives in a single-use thermal shipper. Do NOT use shipper for extended storage.● Once received, vaccines should be put in a ULT freezer or refrigerator. Do NOT store in regular freezer.	<ul style="list-style-type: none">● Ships frozen at -20°C● Once received, vaccines should be put in a freezer or refrigerator.
Order Quantity	The minimum order quantity is 100 doses	The minimum order quantity is 100 doses
Training	Visit Pfizer’s website for training session links and information	Visit Moderna’s website for training session links and information (<i>Pending</i>)

Pfizer-BioNTech 6 Months through 4 Years COVID-19 Vaccine

Pfizer-BioNTech: Vaccine Vial & Package Mislabeling

Initial shipments of the Pfizer-BioNTech vaccine are mislabeled because they were made prior to receiving Emergency Use Authorization (EUA). **Always refer to the [EUA Fact Sheet](#).**

Maroon Cap Ages 6 months through 4 years

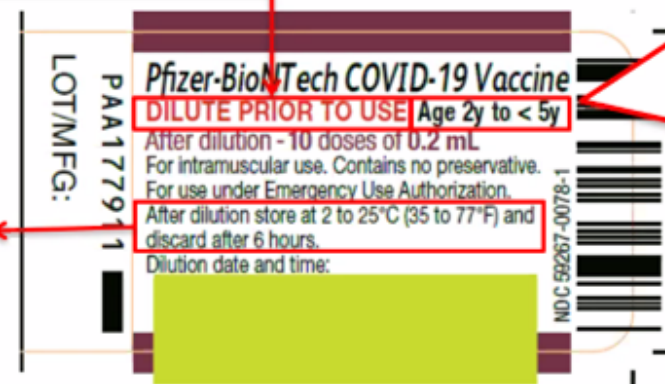


If authorized by the FDA, **Maroon Cap** vaccine vials and cartons you receive will be labeled as Pfizer-BioNTech COVID-19 Vaccine

Initial shipments of Maroon Cap vials and cartons will have the following label characteristics:

Maroon Cap vaccine requires dilution prior to use

Maroon Cap vial labels and cartons may state that a vial should be discarded **6 hours** after the first dilution. Results from recent stability studies will supersede the current vial label and support discarding the vaccine after **12 hours** from the time of dilution






IMPORTANT INFORMATION

- The vial labels may state:
Age 2y to < 5y or **Age 6m to < 5y**
- Carton labels may state:
For age 2 years to < 5 years or
For age 6 months to < 5 years.
- Vials with either printed age range
**can be used for individuals
6 months through 4 years of
age***



Pfizer-BioNTech: Storage & Handling




Age Indications ^a	12 years and older	5 through 11 years	6 mos through 4 years ^d
Vial Cap Color and Label with Color Border	GRAY 	ORANGE 	MAROON 
Storage Conditions			
ULT Freezer (-90°C to -60°C) ^c	12 months	12 months	12 months
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

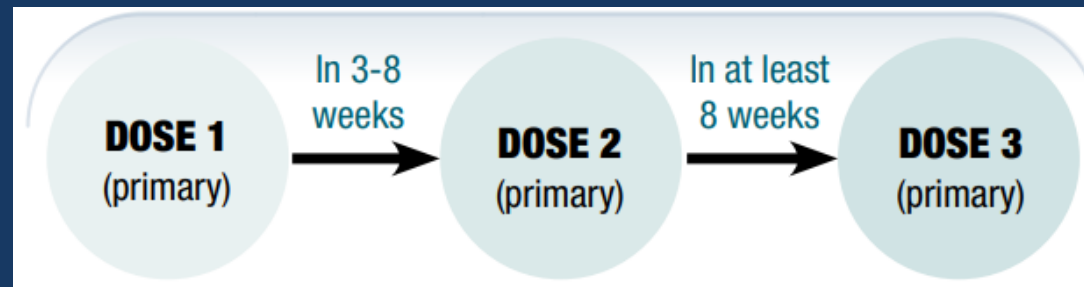
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.



www.cvdvaccine-us.com

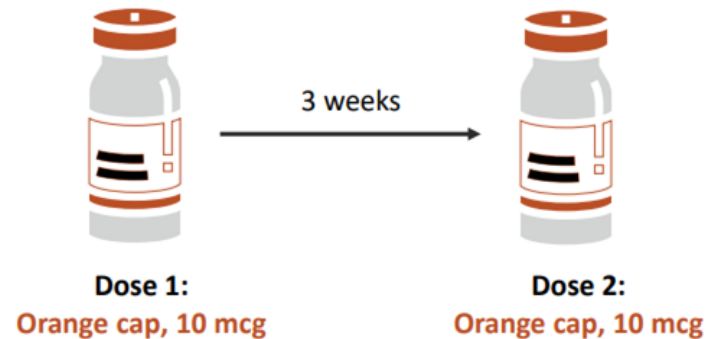
Pfizer-BioNTech: Product Characteristics

Age Indications ^a	12 years and older	5 through 11 years	6 mos through 4 years ^d
Vial Cap Color and Label with Color Border	GRAY 	ORANGE 	MAROON 
Preparation	Do Not Dilute	Dilute Before Use	Dilute Before Use
Amount of Diluent Needed per Vial ^b	Do Not Dilute	1.3 mL	2.2 mL
Dose Volume/Dose	0.3 mL/30 mcg	0.2 mL/10 mcg	0.2 mL/3 mcg
Doses per Vial	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)

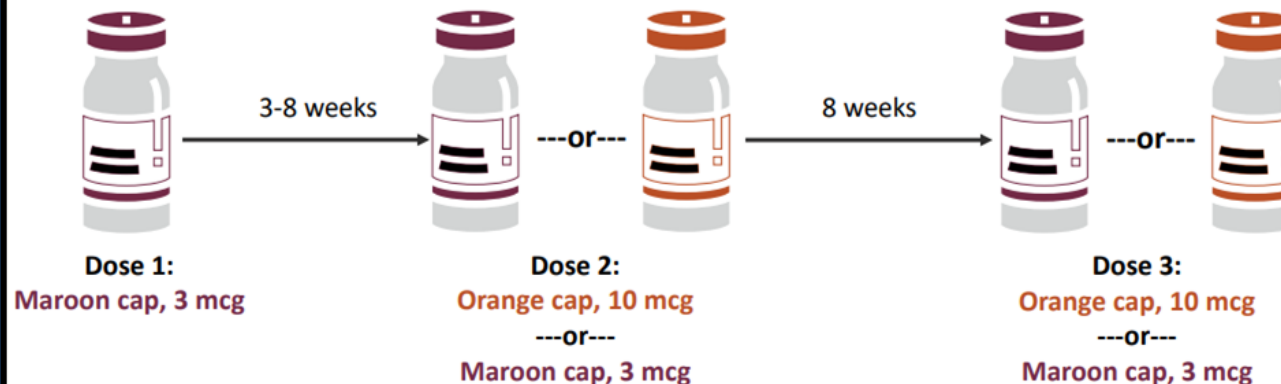


Children Who Will Turn From Age 4 to 5 years Between Any Pfizer Dose in the Primary Series May Receive...

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



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.



Source:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/04-COVID-Hall-508.pdf>



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Moderna 6 Months through 5 Years COVID-19 Vaccine

Moderna: Storage & Handling

Storage Condition	Expiration Date	Notes
Freezer -50°C to -15°C (-58°F to 5°F)	Until expiration date (Scan QR code on carton)	<ul style="list-style-type: none"> Do not store on dry ice or below -50°C If frozen, may thaw in refrigerator for
Refrigerator 2°C to 8°C (36°F to 46°F)	30 days prior to first use	<ul style="list-style-type: none"> If punctured, 12 hours Once thawed, do not refreeze If frozen, allow 3 hours for thawing in the fridge
Room Temperature 8°C to 25°C (46°F to 77°F)	24 hours	<ul style="list-style-type: none"> If punctured, 12 hours If in the fridge, let it stand at room temp for 15 mins If frozen, let it stand at room temp for 1 hour and 30 mins





- Same storage requirements as other Moderna vaccines
- [Moderna's Temperature Excursion Tool](#)

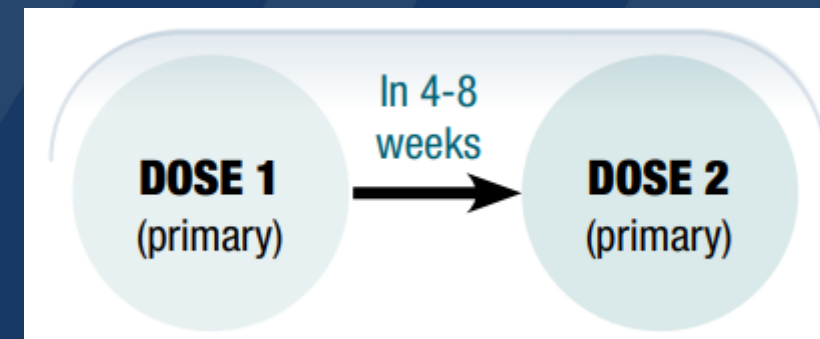
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.



www.modernatx.com/covid19vaccine-eua

Moderna: Product Characteristics

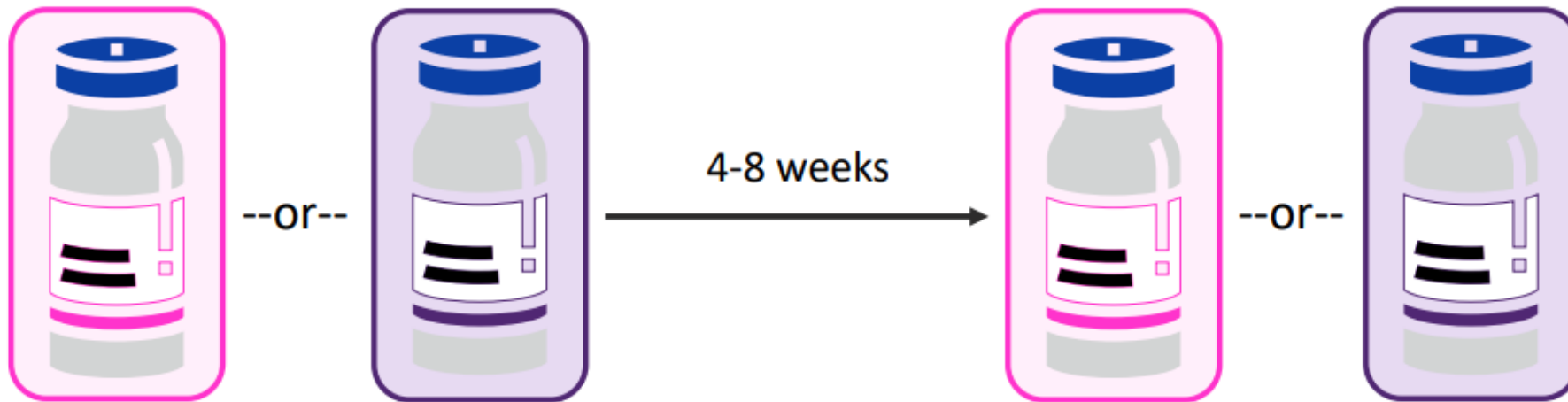
Age Group	6 months through 5 years (Primary Series)	6 years through 11 years (Primary Series) Currently unavailable (Use the vial with dark blue cap and a label with a purple border)	6 years through 11 years (Primary Series) 18 years and older (Booster Dose)	12 years and older (Primary Series) 18 years and older (Booster Dose)
Vial Cap Color	Dark Blue	Dark Blue	Dark Blue	Red
Vial Label Border Color	MAGENTA	TEAL	PURPLE	LIGHT BLUE
Vial Image				
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



- **Third primary series** dose for individuals with certain kinds of **immunocompromise**
 - Administered at least **4 weeks** after 2nd dose
- **Do not dilute**

Children Who Will Turn From Age 5 to 6 Years Between Any Moderna 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

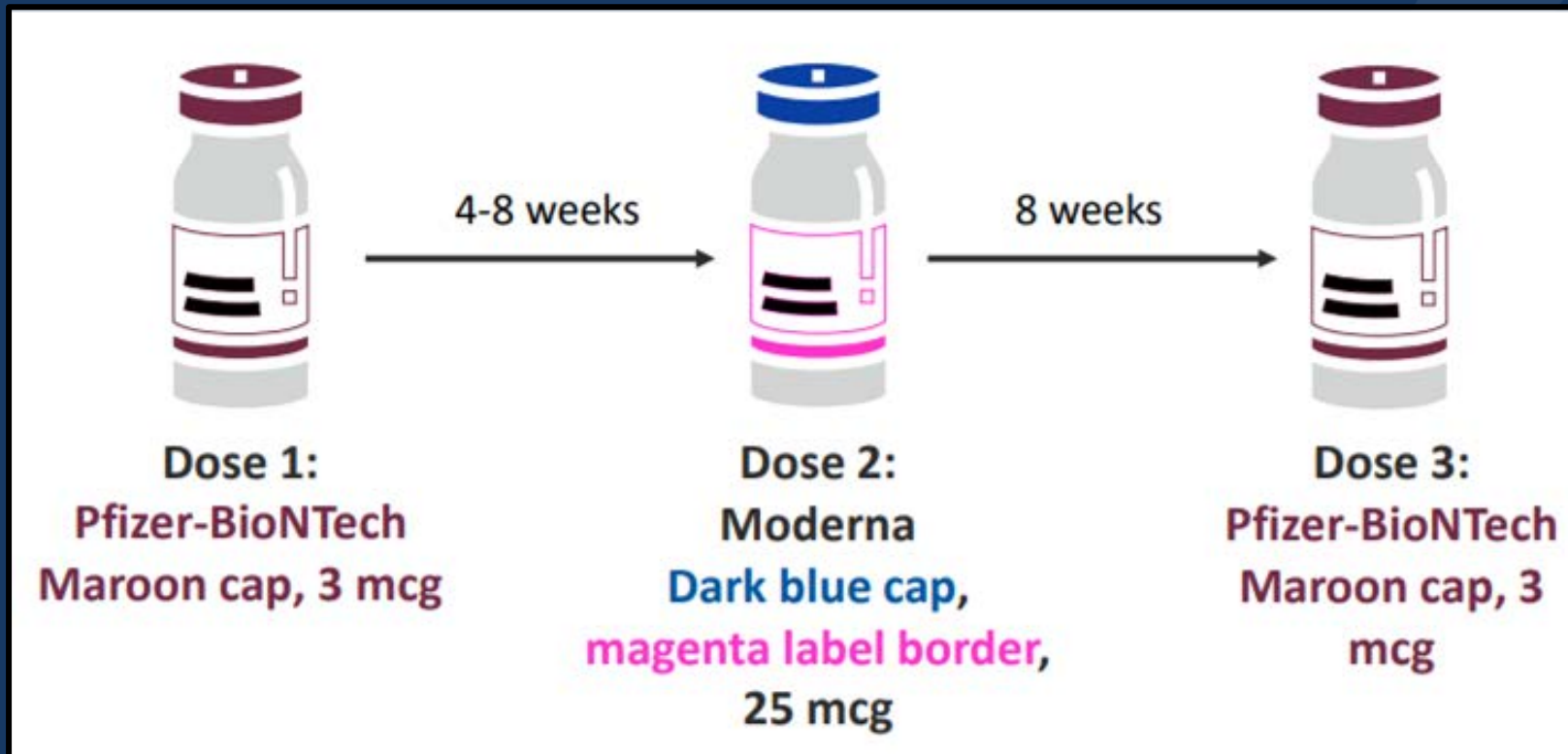
---or---

Dark blue cap, purple border



Mixed mRNA Series For Ages 6 Months through 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.



Information for Vaccinators

Refer parents/guardians
to [Vaccines.gov](https://www.vaccines.gov)

Pharmacy Eligibility

Are pharmacies eligible to vaccinate the 6 Month through 5 Year population?

- Through the PREP Act, licensed pharmacists, interns, technicians can order and administer:
 - (1) **Routine childhood ACIP recommended vaccines** to persons **ages 3 through 18** or
 - (2) **FDA authorized or FDA licensed COVID-19 vaccines** to persons **ages 3 or older**
- Even though there are COVID-19 vaccines underway that can be administered down to 6 months of age, **pharmacy personnel CANNOT vaccinate under 3 years of age** per the PREP Act and the COVID-19 Vaccine Standing Order signed by Dr. Greene

Which pharmacies will carry these vaccines?

- The following pharmacy chains plan to carry the vaccines at select locations: Walgreens, Walmart, Rite Aid, Publix, Kroger, CVS/MinuteClinic, Costco, Safeway, Giant
 - Note: Encourage parents/guardians to check with pediatrician first, then call the pharmacy to confirm vaccine availability
 - Note: Pharmacist preference/comfortability may vary across locations

Information for Parents & Guardians

How COVID-19 Affects Children's Lives

- COVID-19 infection affects children's everyday educational, social, and physical activities.
- **COVID-19 infection poses a risk of serious illness and hospitalization for children**, even though it is significantly lower than the risk to older unvaccinated age groups.
- Children may also develop long-term illness, such as multisystem inflammatory syndrome in children ([MIS-C](#)) or [long COVID](#).

Vaccination is the best way to protect your child so that they can get back to their everyday routines.



What Parents and Guardians Need to Know



1

COVID-19 vaccines
are safe and
effective.

2

Vaccination protects
your child, family and
your community.

3

COVID-19 vaccines are
free and readily
available.

4

Vaccination allows
children to attend
preschool and other
activities.

5

Children can get the
COVID-19 vaccine with
their other routine
immunizations.



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Frequently Asked Questions

Does my child need a vaccine if they aren't going to get very ill from COVID-19?

Will my child have to get a booster shot?

Will my child get sick after getting the vaccine?

What about co-administration of vaccines (i.e., flu shot)?

Should my child still get vaccinated if they've had COVID-19?

Should my child get the vaccine if they are immunocompromised or have a pre-existing condition?

How soon after COVID infection can my child get vaccinated?



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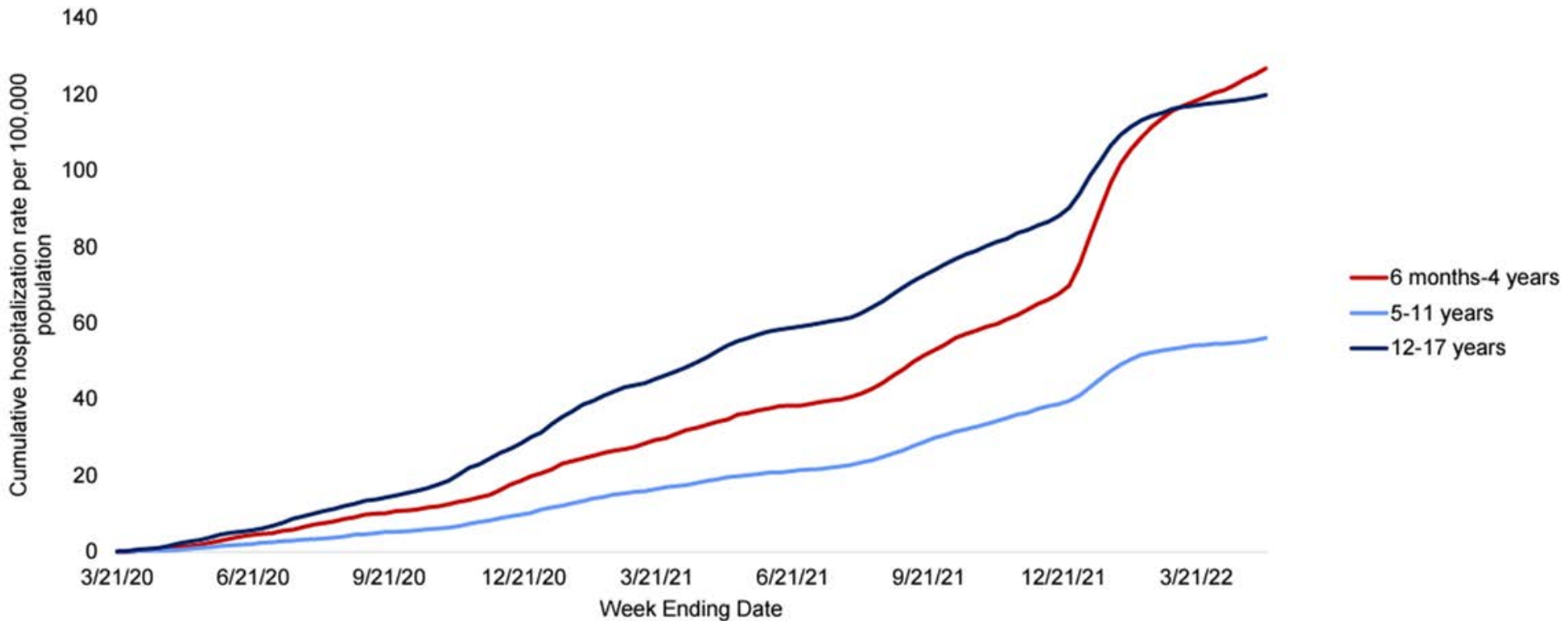
Does my child need a vaccine if my child is not going to get very ill from COVID-19 infection?

YES

- We cannot predict which children will get very sick or die from COVID-19
- Health status changes over time
- Prior infection does not provide sufficient protection against the next variants compared to vaccination

Cumulative COVID-19-associated hospitalizations among children and adolescents ages 6 months – 17 years, COVID-NET

March 21, 2020 – May 7, 2022



Source: COVID-NET, https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html. Accessed 5/21/2022

COVID-19 was a leading cause of death among children ages 0 – 4 years

March 1, 2020 – April 30, 2022

Age group	Rank of COVID-19 among causes of death
<1 year	4
1 – 4 years	5
5 – 9 years	5
10 – 14 years	4
15 – 19 years	4

Based on death certificate data from the National Center for Health Statistics. COVID-19 based on cumulative total incidence of COVID-19 deaths from March 1, 2020-April 30, 2022.

Source: Preprint: Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; doi: <https://doi.org/10.1101/2022.05.23.22275458>

Will my child get sick after getting the vaccine?

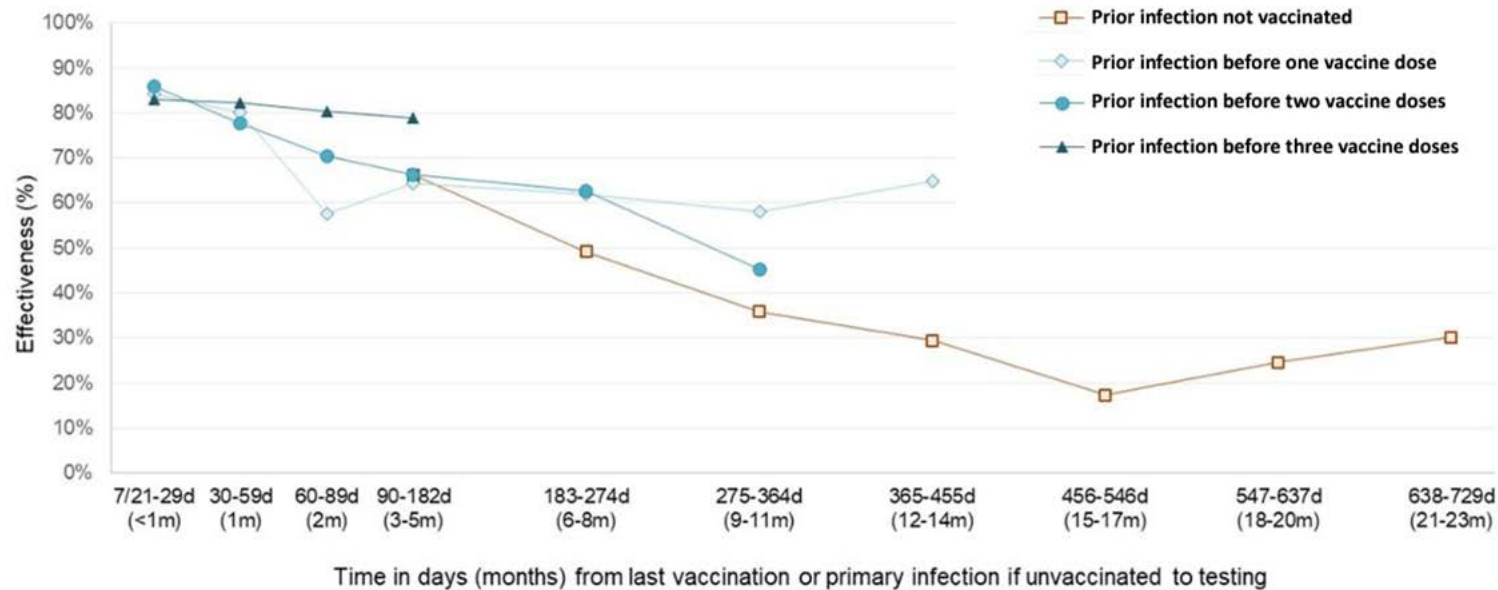
Local Reactions	Moderna Dose 1	Moderna Dose 2	Pfizer Dose 1	Pfizer Dose 2	Pfizer Dose 3
Pain at Injection Site	37-61% vs 30-39%	46-71% vs 26-41%	17-31% vs 11-21%	15-31% vs 9-20%	16-27% vs 12-13%
Erythema	6-9% vs 1-4%	9-14% vs 2-4%	9-11% vs 7-9%	9-11% vs 6-7%	7-11% vs 5-6%
Swelling	5-8% vs 2-3%	8-15% vs 1-2%	4% vs 3%	4-6% vs 2%	3% vs 1-2%
Axillary Swelling/Tenderness	6-7% vs 5-6%	9% vs 3-5%	N/A	N/A	N/A



Systemic Reactions	Moderna Dose 1 vs. Placebo	Moderna Dose 2	Pfizer Dose 1	Pfizer Dose 2	Pfizer Dose 3
Fever	8-11% vs 5-8%	15-16% vs 5-8%	5-7% vs 5-7%	5-7% vs 5-6%	5-7% vs 4-6%
Irritability	67% vs 62%	64% vs 59%	51% vs 47%	47% vs 41%	44% vs 38%
Sleepiness/ Fatigue	37-40% vs 36-37%	35-48% vs 29-33%	27-30% vs 29-30%	24-26% vs 21-23%	20-25% vs 13-22%
Myalgias	10% vs 9%	16% vs 8%	2% vs 2%	3% vs 2%	2% vs 2%
Loss of appetite	30% vs 26%	32% vs 25%	22% vs 21%	22% vs 18%	20% vs 14%
Headache	12% vs 12%	16% vs 8%	5% vs 5%	5% vs 4%	5% vs 4%
Arthralgia	6% vs 5%	9% vs 5%	1% vs 2%	1% vs 1%	1% vs 1%
Nausea/Vomit	7% vs 8%	10% vs 5%	3% vs 3%	3% vs 3%	2% vs 4%
Chills	6% vs 6%	12% vs 5%	2% vs 2%	3% vs 3%	3% vs 3%
Use of Antipyretics with reactogenicity	15-28% vs 10-24%	26-34% vs 7-21%	11-24% vs 9-20%	10-21% vs 8-19%	9-19% vs 7-17%

Should my child still get vaccinated if they've had COVID-19?

Reinfection occurs more frequently in those previously infected and not vaccinated compared to infected and vaccinated



Carazo S, Skowronski DM, Brisson M, et al. "Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination" *medRxiv*, May 2022. [Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination | medRxiv](https://doi.org/10.1101/2022.05.11.22271152)

Data on hospitalizations: Plumb ID, Feldstein LR, Barkley E, et al. Effectiveness of COVID-19 mRNA Vaccination in Preventing COVID-19–Associated Hospitalization Among Adults with Previous SARS-CoV-2 Infection — United States, June 2021–February 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:549-555. DOI: <http://dx.doi.org/10.15585/mmwr.mm7115e2>

Children and adults with prior COVID infection had a much more robust antibody response after disease and vaccine.

How soon after COVID infection can my child get vaccinated?

- You do not have to wait 90 days from illness to get vaccinated.
- As soon as your child is out of isolation from disease, they can get vaccinated.
- BA.1 (Omicron) does not provide adequate protection against BA.4 and BA.5, which are now circulating in US at about 21%.

What is the risk for vaccine related myopericarditis?

VAERS reporting rates of myocarditis (per 1 million doses administered) after mRNA COVID-19 vaccination, days 0–7 and 8–21 post-vaccination^{*,†}

	Age (yrs)	0–7 days			8–21 days			0–7 days			8–21 days		
		Males			Males			Females			Females		
		Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster
Pfizer-BioNTech	5–11	0.2	2.6	0.0	0.6	0.0	0.0	0.2	0.7	0.0	0.2	0.0	0.0
	12–15	5.3	46.4	15.3	1.2	1.2	0.9	0.7	4.1	0.0	0.4	0.2	0.9
	16–17	7.2	75.9	24.1	1.7	3.2	1.3	0.0	7.5	0.0	0.7	0.4	0.0
Pfizer-BioNTech and Moderna	18–24	4.2	38.9	9.9	1.1	2.2	0.4	0.6	4.0	0.6	0.2	0.7	0.0
	25–29	1.8	15.2	4.8	0.4	1.1	0.5	0.4	3.5	2.0	0.2	0.0	0.8
	30–39	1.9	7.5	1.8	0.4	0.8	0.2	0.6	0.9	0.6	0.3	0.2	0.0
	40–49	0.5	3.3	0.4	0.2	0.5	0.0	0.4	1.6	0.6	0.2	0.2	0.0
	50–64	0.5	0.7	0.4	0.2	0.3	0.1	0.6	0.5	0.1	0.2	0.5	0.1
	65+	0.2	0.3	0.6	0.3	0.2	0.1	0.1	0.5	0.1	0.1	0.2	0.1

* As of May 26, 2022; reports verified to meet case definition by provider interview or medical record review; primary series and 1st booster doses only

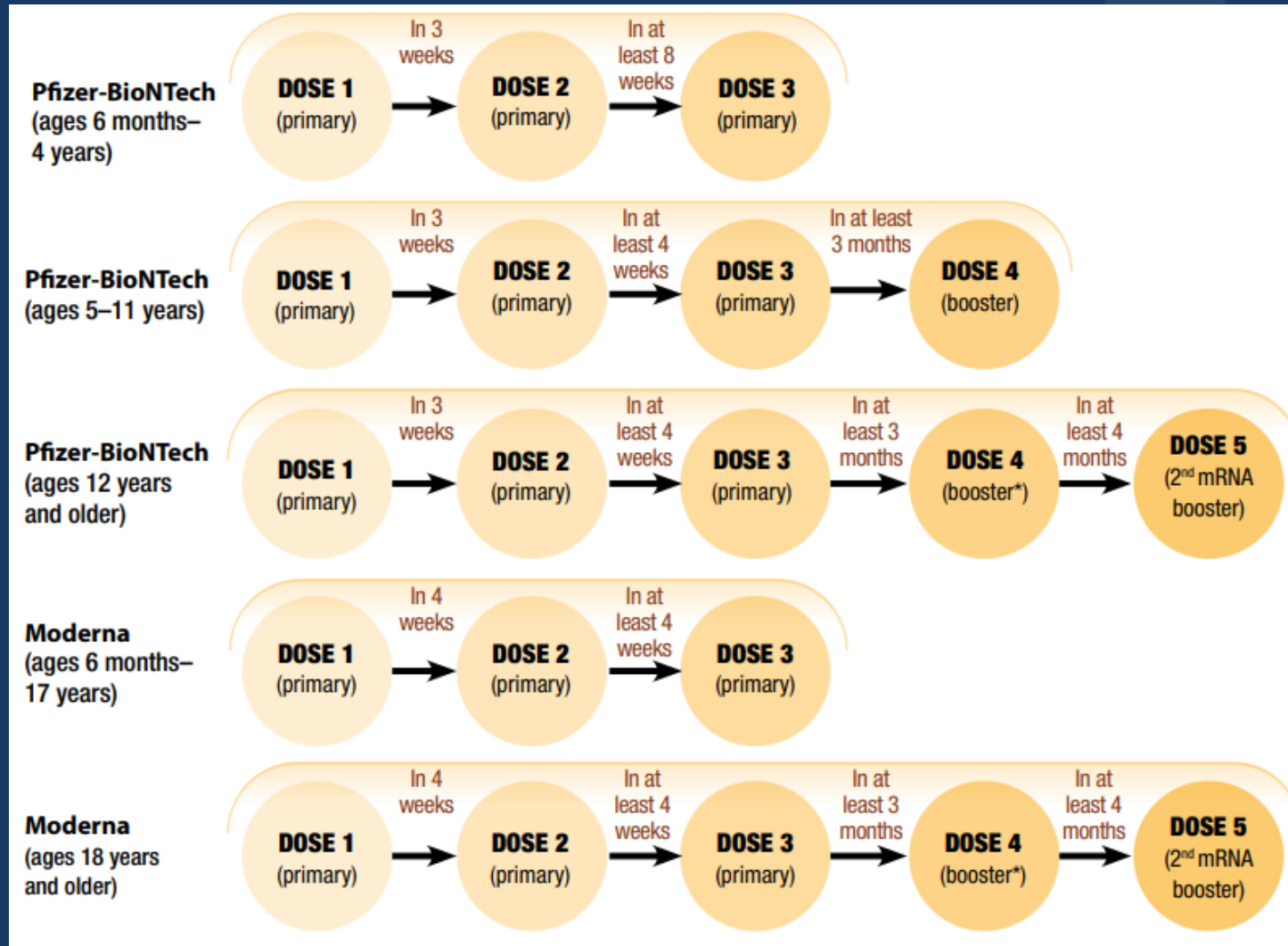
† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 and 8–21 risk intervals, this estimated background is 0.2 to 2.2 per 1 million person-day 0–7 risk interval and 0.4 to 3.8 per 1 million person-day 8–21 risk interval (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

- No cases seen in 8000 children in clinical trial (6mo-5yr)
- Baseline very low rate of myopericarditis
- Expected very low rate of vaccine related myopericarditis in this age group due to epidemiology & lower dose
- Consideration for 8-week interval between doses
- Long-term follow up on vaccine related myocarditis showed 80+% fully recovered/probably fully recovered at 90-days

What about co-administration of vaccines (i.e., flu shot)?

- AAP supports co-administration of COVID-19 vaccines with other vaccines on the immunization schedule.
- No dedicated studies on immune responses with co-administration yet.
- We know with other vaccines, that co-administration does **not** decrease immune response to individual vaccine components.

Should my child get the vaccine if they are immunocompromised or have a pre-existing condition?



Will my child have to get a booster shot?

- Possibly, but this is not certain at this time.
- Both companies are studying different formulations of vaccine (ancestral & Omicron variant) and the next FDA meeting on 6/28/22 will discuss this

Which of the 2 available vaccines should my child get?

- Both EUA'd and met immunobridging endpoint
- Uncertainty regarding data with unblinding in Pfizer between Dose 2 and Dose 3
 - Very wide confidence intervals in EFFICACY of ~80%
- Possible signal of Moderna increased risk of fever
 - One trial participant had febrile seizure with vaccine. Went on to get 2nd dose without fever or febrile seizure.
- Must complete the primary series for protection (Moderna x2 OR Pfizer x3)

COVID-19 Vaccines for 6 Months Through 5 Years Old

- You are a trusted source for COVID-19 infection and COVID-19 vaccination information.
- Parents want to discuss the **PROS** and **CONS** of vaccination for their children
 - Reactogenicity profile
 - History of disease + Vaccination >> History of disease
 - Vaccine goal: Prevent severe disease, hospitalization, and death
 - 50% of young children hospitalized due to COVID: no risk factors
 - Must complete vax series → Protection (Moderna x2, Pfizer x3)

Q&A

Additional Resources

Please note that some of the resources listed below may be pending updates to reflect these new vaccines.

CDC Resources:

- [COVID-19 Clinical Considerations:](#)
- [COVID-19 Vaccines for Children and Teens](#)
- [Resources to Promote the COVID-19 Vaccine for Children & Teens](#)
- [ACIP June 18th Meeting Deck](#) (Details on the trials & effectiveness of the Pfizer and Moderna vaccines)

VDH Resources:

- [COVID-19 Vaccination FAQs](#)
- [COVID-19 Resources for Healthcare Professionals](#)
- [Vaccinate.Virginia.Gov](#)
- [Communications Hub](#)

VAFP Resources:

- [AAFP COVID-19 Resources](#)

CME Information

This activity, COVID-19 Vaccines for 6-Month Through 5-Years Population, has been reviewed and is acceptable for up to 1 live Prescribed credit by the American Academy of Family Physicians. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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The VAFP will report CME credits to the AAFP for all Active and Life Members. Other attendees will be responsible for reporting their own CME.

To submit your request for CME credits to VAFP, complete the survey by accessing the provided QR Code.

If you have questions, please do not hesitate to contact Cheryl Modesto at cmodesto@vafp.org or call 804-968-5200.

