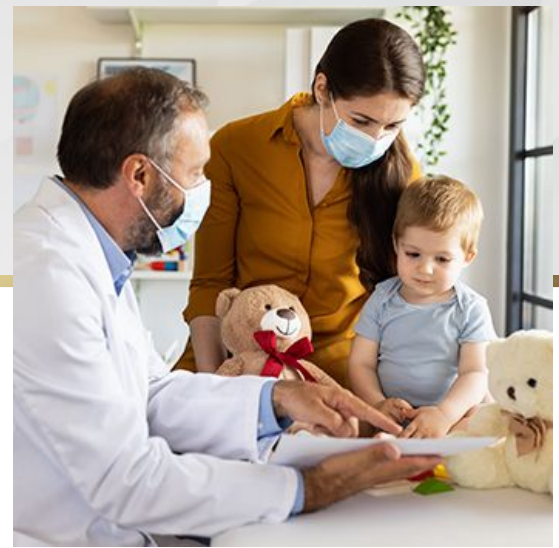


**ALL MARYLANDERS
6 MONTHS AND OLDER
COVID-19 VACCINE
ELIGIBLE**



Pediatric COVID-19 Vaccination Updates

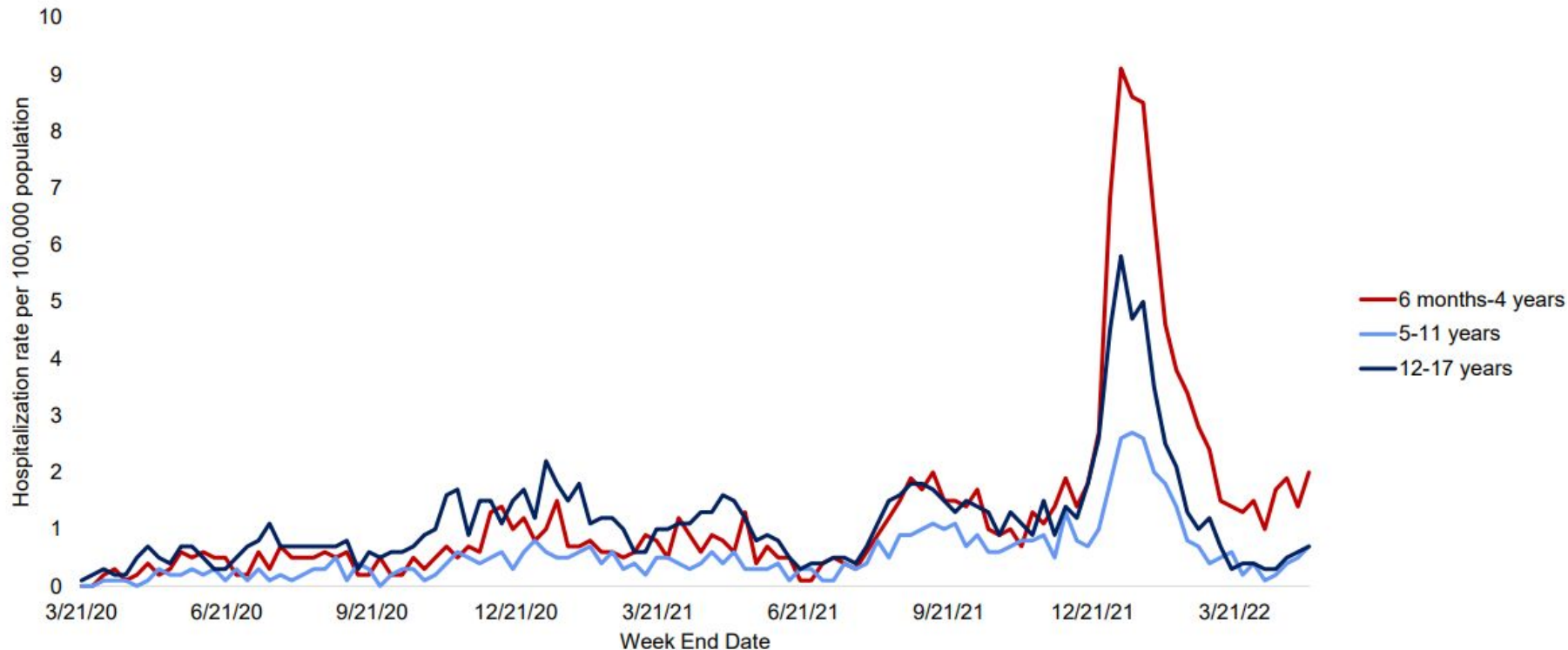
MDAAP Town Hall
June 22, 2022

Epidemiology of COVID-19 Among Children Under 5

- COVID-19 has caused **>2 million cases** among children ages 6 months to 4 years old.
- Children 6 months to 4 years of age are **at risk of severe illness** from COVID-19
 - More than half of hospitalized children ages six months to four years had **no underlying conditions.**
 - COVID-19 associated hospitalizations among children ages six months to four years have similar or increased severity compared to older children and adolescents
 - **Burden of COVID-19 associated death is similar to or exceeds that of other pediatric vaccine preventable diseases**
- Prior infection may not provide broad protection against newer COVID-19 variants
- COVID-19 pandemic continues to have significant impact on families

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

March 2020 – March 2022



Percent of children ages 6 months–4 years with COVID-19 associated hospitalization with underlying health conditions

■ At least 1 underlying medical conditions ■ No underlying medical conditions

New Vaccine Surveillance Network, March 2020
– April 2022

46%

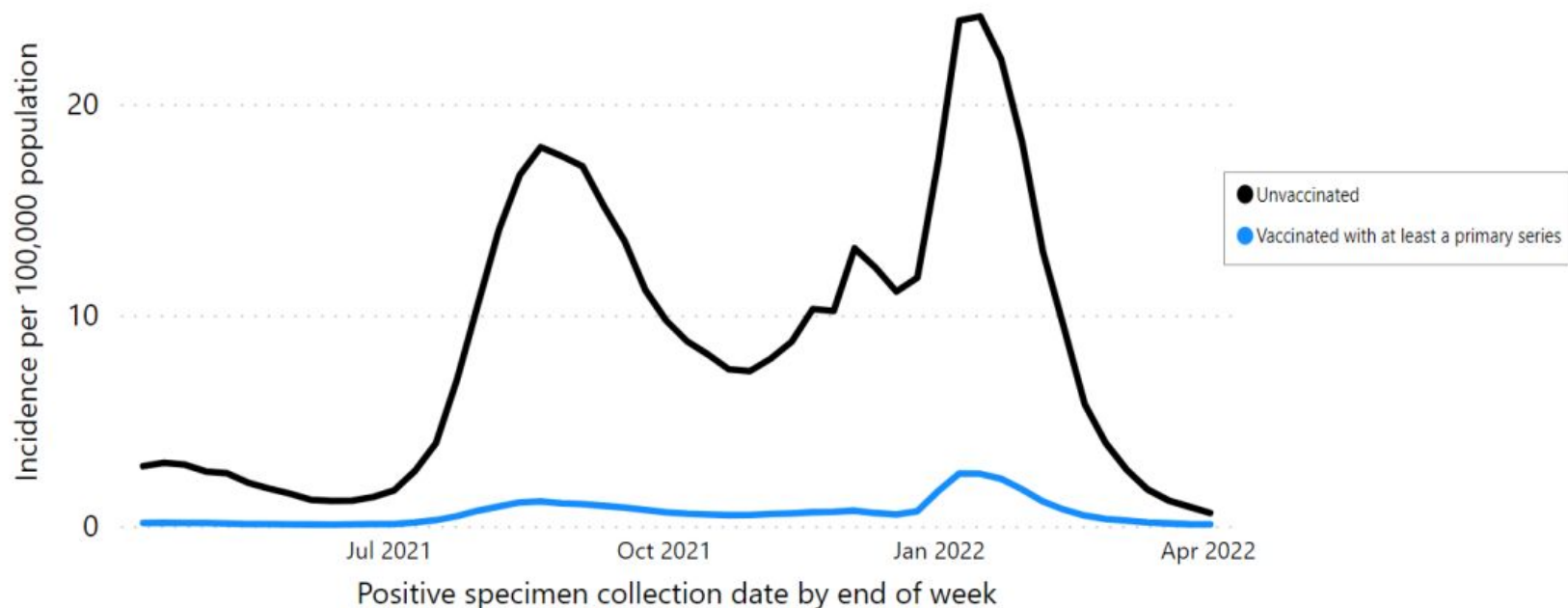
54%

COVID-NET, March 2020 – March 2022

49%

51%

Rates of COVID-19 deaths by vaccination status in people ages ≥ 5 years, United States, April 4, 2021—April 2, 2022



Unvaccinated people ages ≥ 5 years had **10X** the risk of dying from COVID-19 through March compared to people vaccinated with at least the primary series.

Pediatric vaccine preventable diseases:

Deaths per year in the United States prior to recommended vaccines

	Hepatitis A ¹	Meningococcal (ACWY) ²	Varicella ³	Rubella ⁴	Rotavirus ⁵	COVID-19 ⁶
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months – 4 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Jan 2020–May 2022
Average deaths per year	3	8	16	17	20	86

¹Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis 2008; 197:1282–8.

²National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015–2019.

³Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970–1994. J Infect Dis. 2000;182(2):383–390. doi:10.1086/315714

⁴Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63.

⁵Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5–11.

⁶<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data>.

ACIP Interpretations for 6 months to 4 / 5 Vaccines

- The mRNA COVID-19 vaccine clinical trials in young children were both conducted during Omicron predominance, but different months and incidence levels.
 - In addition to differences in number of participants in the efficacy analyses and differences in follow-up time, the incidence levels impacted COVID-19 case accrual and certainty in efficacy estimates.
- **Efficacy estimates for these two mRNA vaccines cannot be directly compared.**
- Both vaccines met non-inferiority criteria for neutralizing antibodies.
- In other age groups during Omicron, mRNA COVID-19 vaccine post authorization effectiveness was lower against infection, but higher protection against severe disease.
- Clinical trials were not powered to detect efficacy against severe disease in young children, but similar patterns in this age group are expected to what is seen in everybody ages 5 years and older.

Planning Considerations for COVID Vaccines for Children < 6 - Overview

- Packaging configuration for both vaccine products: 10-dose vials in cartons of 10 vials each (100 doses total).
- Minimum order quantity of 100 doses per product.
- Ancillary supplies will be provided for both vaccine products, including 1-inch needles and syringes to support 100 doses of vaccine.
- COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- [PREP Act](#) permits certain providers to order and administer doses only to children ages 3 and older. While many pharmacies are planning for a COVID-19 vaccination program for children under 5 years, their ability to vaccinate these children may be limited.
- Pharmacies and FQHCs will receive doses directly from federal programs.



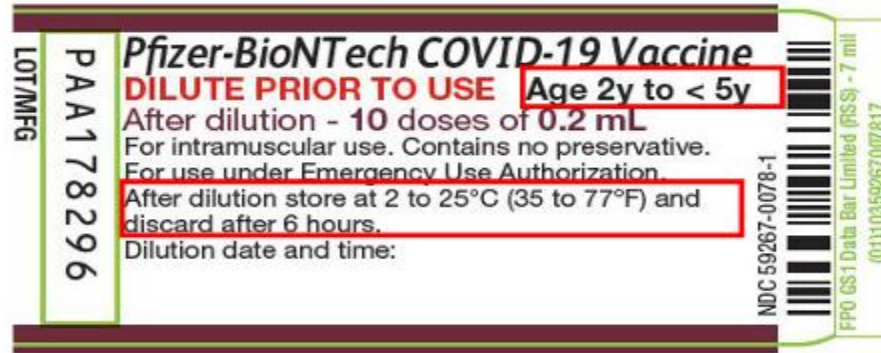
Planning Considerations: Pfizer COVID-19 Vaccines - 6 months through 4 years old

- **The Pfizer vaccine** for children ages six months through four years will be a different product; the current products approved for adolescents 12-17 and children ages 5–11 years old should NOT be used in children under 5.
- The Pfizer vaccine will be a **three-dose series** with a **maroon color cap**, **different dose** (3 micrograms/0.2mL), **different amount of diluent added (2.2mL)**, and a **new NDC**.
- In general, 21 days between doses 1 and 2; 8 weeks between doses 2 and 3
- Diluent will be provided with ancillary supplies to support 100 doses per kit.
- The Pfizer vaccine ships at -80°C and can be stored in an ultracold freezer (between -90°C to -60°C) for up to 12 months and/or in a refrigerator for up to 10 weeks.



Pfizer Labels

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.

NOTE: Initial shipments of the Pfizer vaccine for children ages 6 months to 4 years may state “2y to <5y” or “6m to <5y.” Vials with labels that state “2y to <5y” can be used for children aged 6 months to 4 years.

Checking Expiration Labels

- Expiration dates for the **Pfizer** vaccine based on 12 months from the date of the manufacture (found on the bottle) are shown below:

Printed Manufacturing Date

01/2022
02/2022
03/2022
04/2022
05/2022
06/2022

12-Month Expiry Date

31-Dec-2022
31-Jan-2023
28-Feb-2023
31-Mar-2023
30-Apr-2023
31-May-2023

Note: Date listed is the manufacturing date, NOT the expiration date.

- To find the expiration date for **Moderna** COVID-19 vaccines, locate the lot number printed on the carton and vial. Enter the lot number in the field below and press "Submit."
- Please note, this tool is not validated to authenticate or confirm legitimacy of vaccine.









<https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup>



Enter Lot #

Enter lot number exactly as shown indicating all characters.

Pfizer-BioNTech COVID-19 Vaccine Presentations

Age Group	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Vial Cap Color and Label Border Color	MAROON 	ORANGE 	PURPLE** 	GRAY** 
Is Dilution Needed?	Dilute Before Use	Dilute Before Use	Dilute Before Use	Do Not Dilute
Amount of Diluent* Needed per Vial	2.2 mL	1.3 mL	1.8 mL	NO DILUTION
Dose Volume	0.2 mL	0.2 mL	0.3 mL	0.3 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

** The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.









Planning Considerations: Moderna COVID-19 Vaccines - 6 months through 5 years old

- The **Moderna vaccine** for children ages six months through five years will be a different product; the current vaccine approved for 18+ should NOT be used in children under 6.
- Compared to Moderna 18+, the under 5 vaccine has a **different concentration** (25 micrograms/0.25mL) and a **new NDC**. It **does not require diluent**. It will have a **blue cap** and the vial label will have a **magenta border**. It will be a **two-dose series**.
- The Moderna vaccine **ships at -20°C**. It can be stored in a freezer between -50°C and -15°C (-58°F and 5°F) until expiration and store in a refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days. The time spent in the refrigerator cannot exceed 30 days and cannot exceed the expiration date.
- In general, 28 days between doses 1 and 2

NOTE: ACIP meeting 6/23 for Moderna 6 yrs to 17 yrs

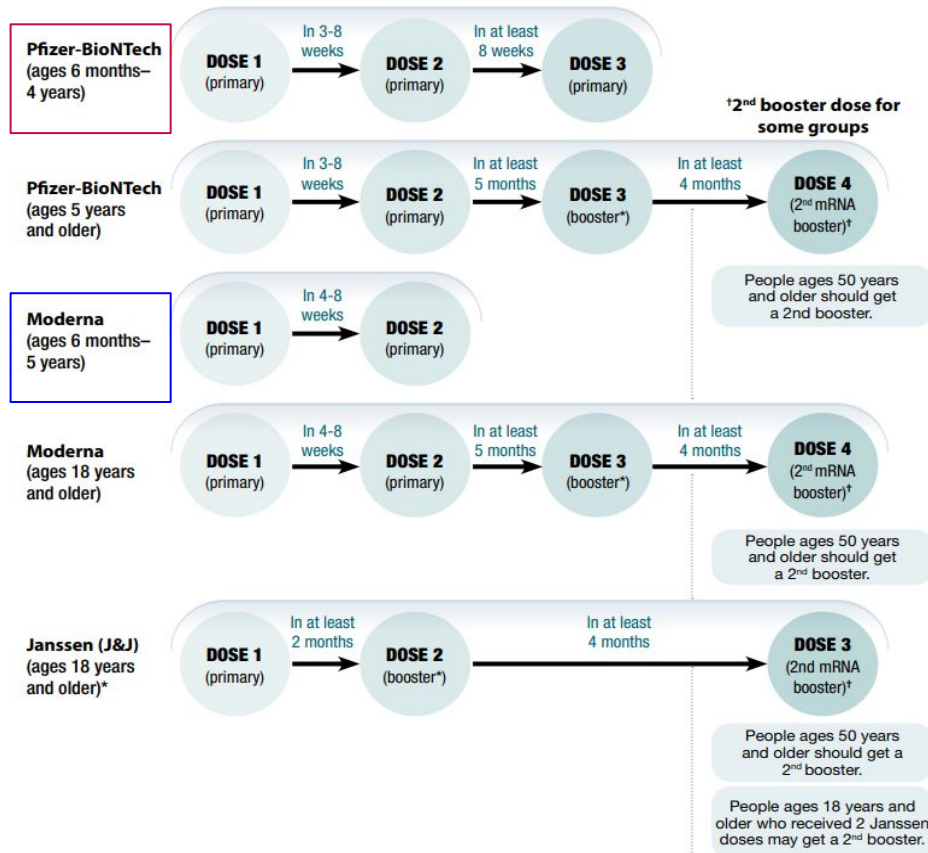


MODERNA COVID-19 VACCINE PRESENTATIONS

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
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/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua

COVID-19 Vaccination Schedule for Most People

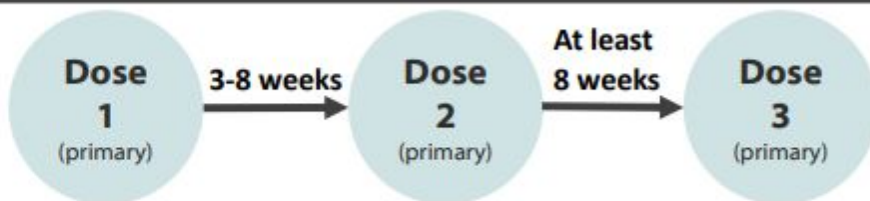
Number and intervals of COVID-19 vaccine doses



Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised

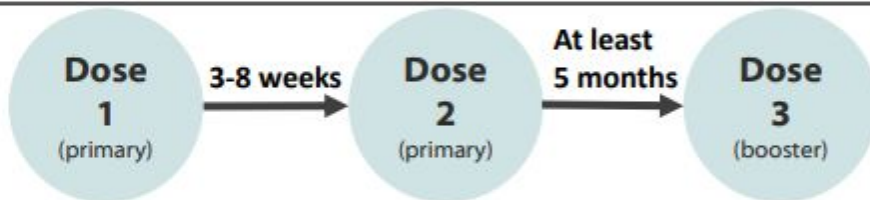
Pfizer-BioNTech

(6 months–
4 years)



Pfizer-BioNTech

(5–17 years)



Moderna

(6 months–
5 years)



Pediatric Schedule: People Who ARE Moderately or Severely Immunocompromised

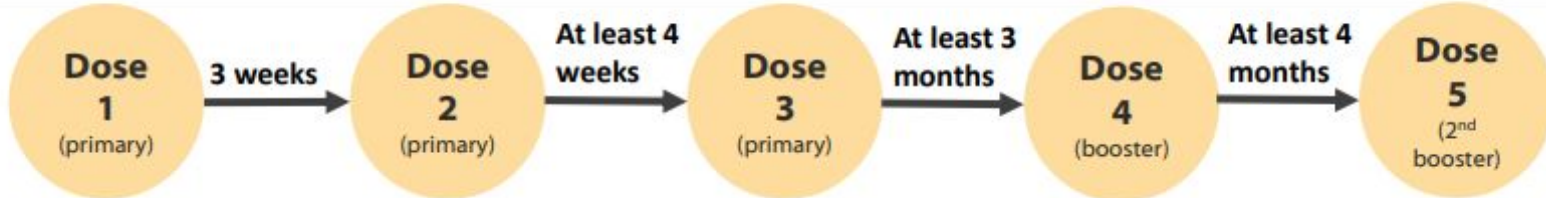
Pfizer-BioNTech
(6 months–
4 years)



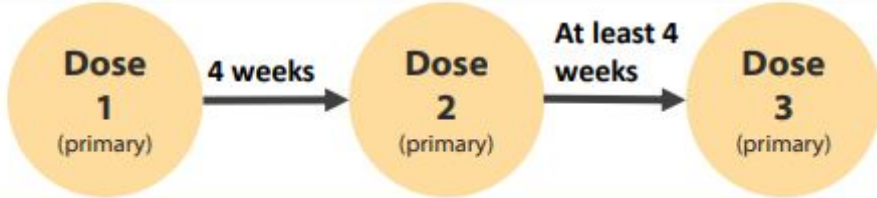
Pfizer-BioNTech
(5–11 years)



Pfizer-BioNTech
(12–17 years)



Moderna
(6 months–
5 years)



Planning Considerations for COVID Vaccines for Children < 6 - Dosing

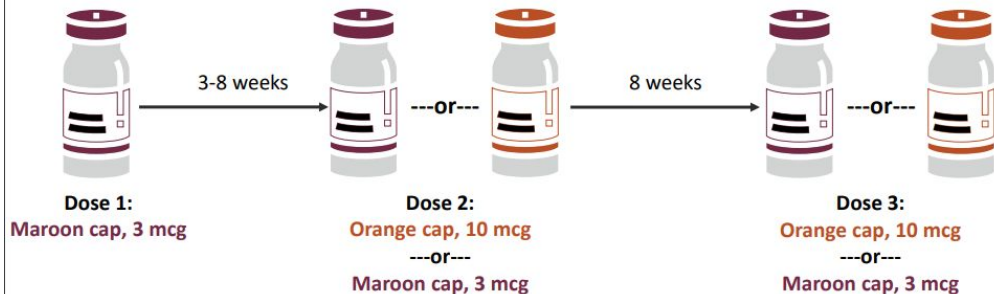
- Children should receive the age-appropriate vaccine product and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.
- If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt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

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 product for people ages 5–11 years (orange cap)



- **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 6–11 years.



Planning Considerations for COVID Vaccines for Children < 6 - Interchangeability/Mixed Dosing

- **COVID-19 vaccines are not interchangeable and 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.
- 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.

Planning Considerations for COVID Vaccines for Children < 6 - Pre-Ordering and Allocations

- There will be an initial pre-EUA threshold for each vaccine followed by a threshold increase; a post-EUA threshold for each vaccine will be refreshed following EUA(s) and CDC recommendations to ensure that each authorized product is able to continuously flow to sites and ensure no interruption in product availability.
- **Wave 1** Pre-Ordering was scheduled for **June 3-8**, with expected deliveries **June 20th**.
- **Wave 2** was scheduled for **June 9 – 14** with that **delivery schedule between June 23 – June 29 (estimated)**.
- The state will keep providers and jurisdictions updated on when the next round of ordering will take place and/or when direct ordering will be made available - come from mdh.covidvax@maryland.gov.

Resources for Providers

Maryland COVID-19 Vaccine Search Tool

- Maryland has expanded the [COVID-19 Vaccine Site Search Tool](#) to include vaccines for children in this age group, allowing patients to find vaccine of their choice.
- Locations are still being added; providers can reach out to traci.ayub@maryland.gov to request their location be added.

All Marylanders 6 months and older are eligible for vaccination. Schedule an appointment today with a health care professional near you.

- Search All Sites
- Search Vaccination Sites for Pfizer-BioNTech or Moderna for ages 6 months - 5 years
- Search Vaccination Sites for Pfizer-BioNTech for ages 6 months - 4 years
- Search Vaccination Sites for Moderna for ages 6 months - 5 years

V-safe After Vaccination Health Checker

- Website: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>
- V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you, or your dependent, feel after getting a COVID-19 vaccine. This information helps CDC monitor the safety of COVID-19 vaccines in near real time.
- V-safe features:
 - Enrolling is fast and easy! Sign up during the waiting period after you get any dose of COVID-19 vaccine or at any time after vaccination
 - Add a dependent and complete health check-ins on their behalf
 - Enter and report how you, or your dependent, feel after first, second, additional, and booster doses
 - Available in multiple languages including English, Spanish, Chinese, Korean, and Vietnamese



NEW!

People who have already been vaccinated can enter an additional dose.
Parents or guardians can enroll their vaccinated children.

New EUA Information

- **Pfizer 6mos-4 Fact Sheet for Healthcare Providers**
<https://www.fda.gov/media/159312/download>
- **Pfizer 6 mos-4 Fact Sheet for Recipients and Caregivers**
<https://www.fda.gov/media/159313/download>
- **Pfizer All Products Wall Chart**
<https://www.fda.gov/media/159304/download>
- **Moderna 6mos-5 Fact Sheet for Healthcare Providers**
<https://www.fda.gov/media/159307/download>
- **Moderna 6mos-5 Fact Sheet Recipients and Caregivers**
<https://www.fda.gov/media/159309/download>
- **Moderna All Products Wall Chart**
<https://www.fda.gov/media/159306/download>

QR Codes to document recipient are found on the last page of the Fact Sheet for Recipients/Caregivers



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000486



Resources for Communication/Social Media

- **MDH Pediatric Communications Toolkit**
 - Video, social media, and print resources for pediatric vaccines
https://gkvclients.com/public/folder/TOPr01VJd0ujflee_rBC1w/5-11%20Assets
 - Password: pediatrics
- **Greater than COVID: The Conversation About the COVID Vaccines and Kids**
 - Video and social media resources about pediatric vaccines
<https://www.greaterthancovid.org/theconversation-children-and-vaccines/>
- **National Resource Center for Refugees, Immigrants, and Migrants (NRC-RIM)**
 - Print Resources in 40+ languages (this age is coming soon)
<https://nrcrim.org/vaccines/special-topics/vaccines-children>

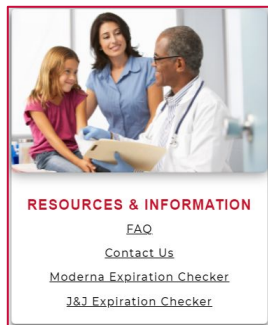
Resources for Communication/Social Media

- MDH has launched a new GoVAX campaign featuring Maryland families stressing the importance of vaccinating against COVID.
- These videos feature families with young children and the full campaign will include messaging for vaccinating this age group.
- Video in press release:



Maryland PROPS Portal

- Maryland providers can now submit COVID-19 wastage and temperature excursion reports, vaccine transfer forms, and the optional weekly inventory survey within the Provider Portal.
- VFC Wastage (not COVID-19) can continue being reported through the VFC Wastage form.
- Website: <https://props.health.maryland.gov/>
- Features: Transfer marketplace, FAQ Page, help ticket requests, inventory survey



Maryland PROPS Portal

- To access PROPS Provider Portal:
 - Once you have read these instructions, select 'Continue'
 - Select 'Create account here' on the next page and fill out the required fields
 - You will need your Organization Name and corresponding COVID PIN (as listed/registered in ImmuNet)
 - If you are completing reporting activities and/or interacting on behalf of more than one organization, select Add Providers and add the organization name(s) and PIN(s)
 - After you complete the required fields and click Register, feel free to email the Provider Portal team to expedite your approval request
 - Full Guide [here](#).

Contact Information

Providers can communicate questions using the “Help Ticket” feature on PROPS Portal or by reaching out to the PROPS Support Team at Sam.Bagley@maryland.gov.

Be sure to check out the FAQ page as your question may have already been addressed.

For general information

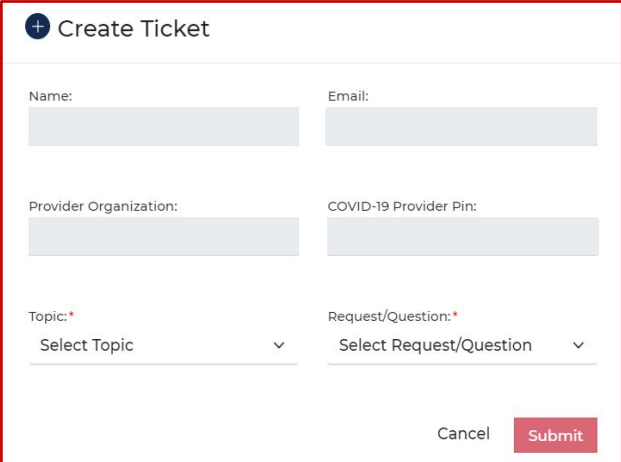
Sam.Bagley@maryland.gov

For system/access-related issues

Sam.Bagley@maryland.gov

For hub-related inquiries

courtney.cole@maryland.gov, jill.torla@maryland.gov



The screenshot shows a "Create Ticket" form with the following fields:

- Name: [Text input field]
- Email: [Text input field]
- Provider Organization: [Text input field]
- COVID-19 Provider Pin: [Text input field]
- Topic: * [Dropdown menu with "Select Topic" option]
- Request/Question: * [Dropdown menu with "Select Request/Question" option]

At the bottom right, there are "Cancel" and "Submit" buttons.

Resources for Managing Multiple Vaccines and Preventing Administration Errors

- Triple Checking COVID-19 Vaccine Administration

<https://health.maryland.gov/phpa/Documents/Triple%20Checking%20COVID.pdf>

- Pre-Vaccination Checklist for COVID-19 Vaccines Information for Healthcare Professionals

<https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>

- Preventing Vaccine Administration Errors: A Primer for Healthcare Workers (CEUs available)

<https://www2.cdc.gov/vaccines/ed/covid19/videos/va/va.asp>

Resources For Vaccine Hesitancy & Talking to Families about Vaccines

- MDH - Information for Parents Page
<https://covidlink.maryland.gov/content/vaccine/information-for-parents/>
- CDC - How to Talk with Parents about COVID-19 Vaccination
<https://www.cdc.gov/vaccines/covid-19/hcp/pediatrician.html>
- Ask the Pediatrician: COVID-19 Roundup - HealthyChildren.org
<https://healthychildren.org/English/health-issues/conditions/COVID-19/Pages/Ask-the-Pediatrician-COVID-19-Round-Up.aspx>
- Johns Hopkins University COVID Vaccine Ambassador Training: How to Talk to Parents
https://www.coursera.org/learn/covid-vaccine-ambassador?fbclid=IwAR3G0Bv1fPjGtNa5FD8gASaGRUIUn4sb3UIjvGleiTAe5DaPTIBQL0Td_Kc

THANK YOU!

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Permanent: Director, Center for Tobacco Prevention and Control

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