EPIC Immunization 2023 Update

SARS-CoV-2 (COVID-19) – Brief Version

Updated May 4, 2023

Reviewed May 4, 2023

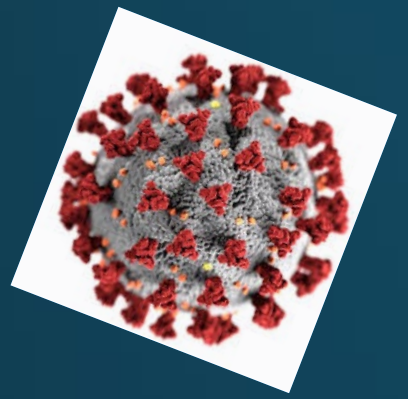
Disclaimer

A compendium of slides related to COVID-19 disease manifestations, current epidemiology, COVID-19 vaccines and recommendations for their use, and practical considerations for use of the vaccines in clinical practice.

EPIC trainers should feel free to use any or all of the slides as needed based on their audience and time allotment.

For the most up to date clinical guidance, please refer to CDC's Interim Clinical Considerations at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Overview COVID-19 disease



SARS-CoV-2 virus (COVID-19 disease)*

SARS-CoV-2, the virus that causes COVID-19 disease affects the respiratory system primarily, but other organ systems may also be impacted

Transmission is through droplet and respiratory spread but may also include indirect contact with contaminated objects

Access current data on COVID-19 cases and deaths in Georgia** and nationally***

*Georgia data**Georgia data (2)

***National data

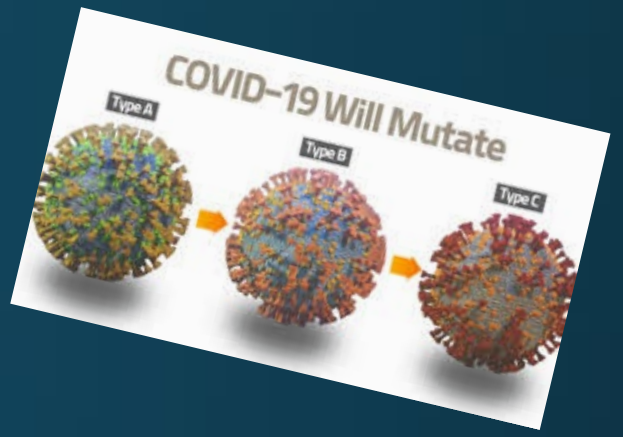
COVID-19 disease

Symptoms can be mild to severe and can develop 2-14 days after exposure

Fever or chills	Cough	Shortness of breath
Fatigue	Myalgia	Headache
Loss of taste or smell	Sore throat	GI symptoms (nausea, vomiting, diarrhea)

Source: CDC

COVID-19 VARIANTS



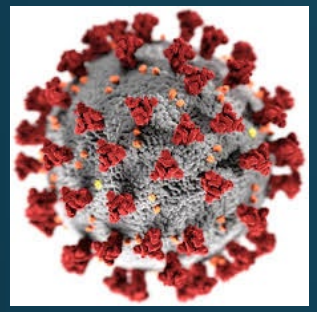
Viruses constantly change through mutation, and new variants are expected to occur over time.

Multiple COVID-19 variants are circulating globally. The Omicron variant is the most prevalent variant currently circulating in the U.S. (6/22)

CDC is studying these variants quickly to understand whether the variants

- Spread more easily from person to person
- Cause milder or more severe disease in people
- Are detected by currently available viral tests
- Respond to medicines currently being used to treat people for COVID-19
- Change the effectiveness of COVID-19 vaccines.

SOURCE: CDC



SARS-CoV-2 virus (COVID-19 disease) in children and adolescents

Children can be infected with the virus that causes COVID-19, can get sick from COVID-19, and can spread the virus that causes COVID-19 to others. Children, like adults, who have COVID-19 but have no symptoms (“asymptomatic”) can still spread the virus to others.

(3/2023) Over 15 million children have tested positive for COVID-19 since the onset of the pandemic.

A significant increase seen during the most recent Omicron wave.

Children represented nearly 18% of total cumulated cases since the pandemic began.

Data may vary. Access current pediatric data on COVID-19 cases, hospitalizations and deaths at AAP’s site.

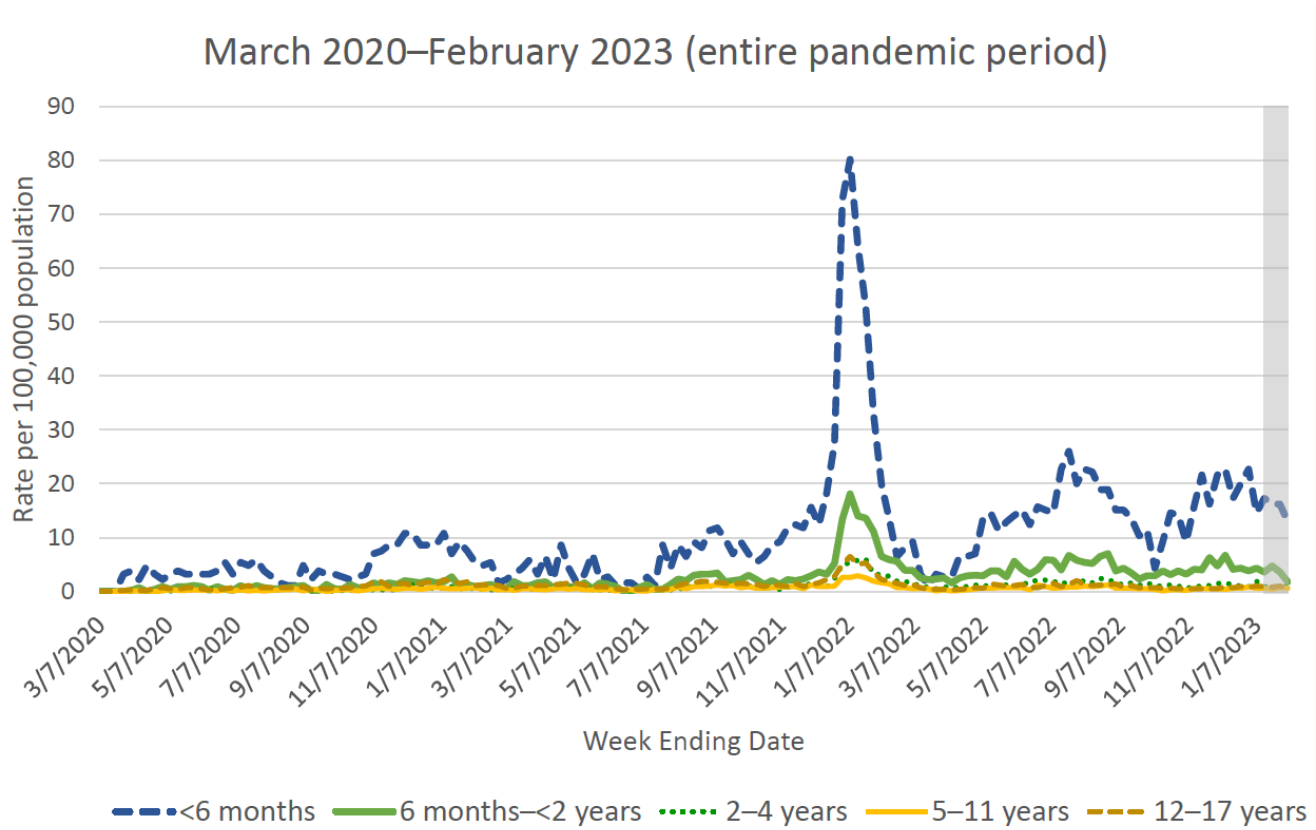
For data on cases in Georgia, visit Georgia data and Georgia data (2)

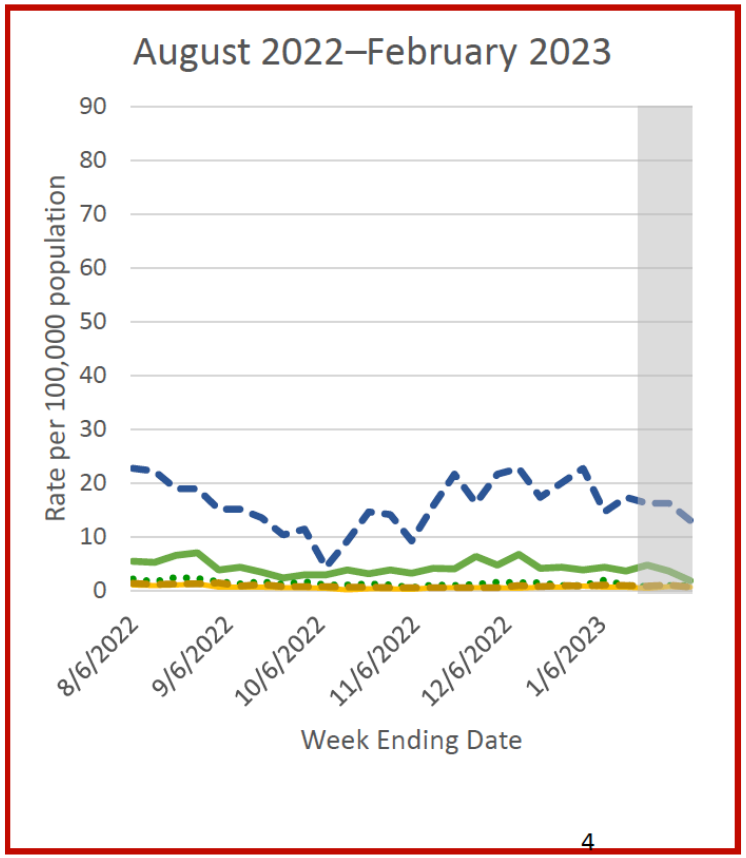
National data

05/4/2023

Cases/Hospitalizations among Children

Weekly Population-Based Rates of COVID-19-Associated Hospitalizations among Children and Adolescents Ages ≤17 Years — COVID-NET, March 2020–February 2023





Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

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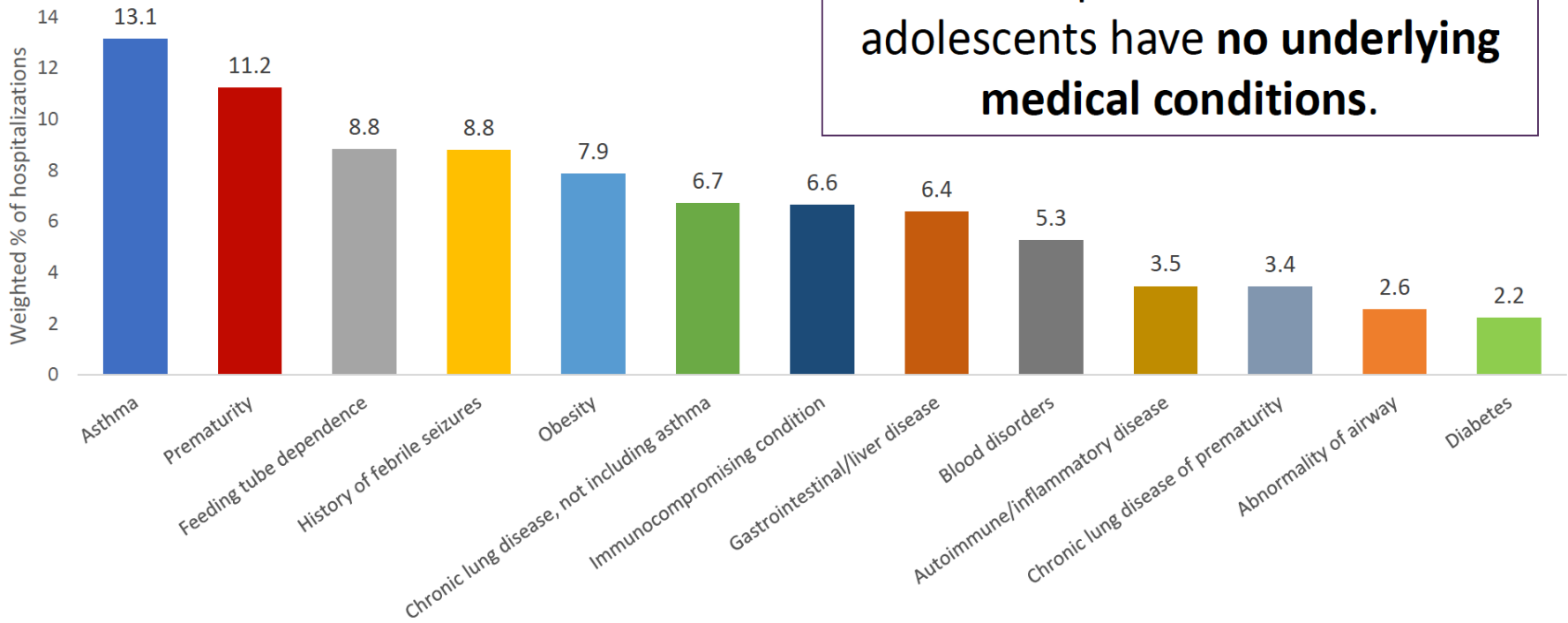
Hospitalizations among Children (2)

Underlying Medical Conditions among Children and Adolescents Ages ≤17 Years — COVID-NET, June–November 2022

49% of hospitalized children and adolescents have **no underlying medical conditions.**



Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission.

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JAMA Network™

From: **Assessment of COVID-19 as the Underlying Cause of Death Among Children and Young People Aged 0 to 19 Years in the US**

JAMA Netw Open. 2023;6(1):e2253590. doi:10.1001/jamanetworkopen.2022.53590

Table 1. Deaths Among Individuals Aged 0 to 19 Years

Leading causes of death (*ICD-10* codes)[a]	Crude rate per 100 000	Deaths, No.	Rank	% Of all causes
#Certain conditions originating in the perinatal period (P00-P96)	12.7	10 387	1	25.7
#Accidents (unintentional injuries) (V01-X59, Y85-Y86)	9.1	7444	2	18.4
#Congenital malformations, deformations, and chromosomal abnormalities (Q00-Q99)	6.5	5286	3	13.1
#Assault (homicide) (*U01-*U02, X85-Y09, Y87.1)	3.4	2770	4	6.9
#Intentional self-harm (suicide) (*U03, X60-X84, Y87.0)	3.4	2756	5	6.8
#Malignant neoplasms (C00-C97)	2.1	1704	6	4.2
#Diseases of heart (I00-I09, I11, I13, I20-I51)	1.1	867	7	2.1
#COVID-19 (U07.1)	1.0	821	8	2.0
#Influenza and pneumonia (J09-J18)	0.6	472	9	1.2
#Cerebrovascular diseases (I60-I69)	0.4	297	10	0.7

[a] Leading causes of death from the rankable causes on the National Center for Health Statistics 113 Selected Causes of Death List, for children and young people aged 0 to 19 years in 2019 in the US ranked, compared with COVID-19 deaths (August 1, 2021-July 31, 2022). COVID-19 was the eighth leading cause of death, and the fifth leading cause of death in disease-related causes of deaths (excluding unintentional injuries, assault, and suicide). The National Center for Health Statistics 113 Selected Causes of Death can be grouped into rankable causes of death, indicated by the # symbol. The * symbol indicates that U01-U03 are not *ICD-10* codes but were introduced by NCHS in 2001 to classify deaths due to acts of terrorism.

Table Title: Deaths Among Individuals Aged 0 to 19 Years[a] Leading causes of death from the rankable causes on the National Center for Health Statistics 113 Selected Causes of Death List, for children and young people aged 0 to 19 years in 2019 in the US ranked, compared with COVID-19 deaths (August 1, 2021-July 31, 2022). COVID-19 was the eighth leading cause of death, and the fifth leading cause of death in disease-related causes of deaths (excluding unintentional injuries, assault, and suicide). The National Center for Health Statistics 113 Selected Causes of Death can be grouped into rankable causes of death, indicated by the # symbol. The * symbol indicates that U01-U03 are not ICD-10 codes but were introduced by NCHS in 2001 to classify deaths due to acts of terrorism.

Similar to adults there is a wide range in prevalence of post-COVID conditions among children

- Symptoms lasting 4 weeks or longer following SARS-CoV-2 infection are common among children and adolescents.
- The most common symptoms include:
  - Headache or respiratory symptoms (~7%)
  - Sleep disorders (~8%)
  - Fatigue (9%)
  - Mood disorders (~16%)

Zimmermann et al. The Challenge of Studying Long COVID: An Updated Review : The Pediatric Infectious Disease Journal (lww.com)
Lopez-Leon et al. Long-COVID in Children and Adolescents: A Systematic Review and Meta-analyses | medRxiv

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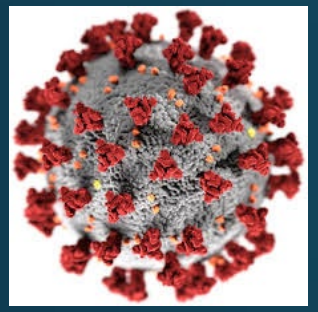


MIS-C in children and adolescents

Multisystem inflammatory syndrome in children (MIS-C) is a rare condition that can occur in children and adolescents who develop COVID-19 disease. However, though rare, when it occurs, it can be serious.

In MIS-C, different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. We do not yet know what causes MIS-C. MIS-C can be serious, even deadly, but most children diagnosed with this condition have gotten better with medical care.

Over 9300 MIS-C cases and over 76 deaths due to MIS-C have been reported in the U.S. as of February 2023. Half of children with MIS-C were between the ages of 5 and 13 years, with a median age of 9 years. MIS-C cases have occurred in children and adolescents from <1 year old to 20 years old.

CDC: MIS-C

COVID-19 vaccines

mRNA vaccines

Pfizer-BioNTech and Moderna are the two mRNA COVID-19 vaccines authorized for use in the U.S. under an EUA. Pfizer-BioNTech is approved for persons 12 years and older

The vaccines work by:

- Teaching our cells how to make the spike protein of the SARS- CoV2 virus. This triggers an immune response inside our bodies through the formation of antibodies to prevent infection and to develop ‘memory cells’ to help protect us against infection with the actual SARS-CoV2 virus in the future.

Myths and facts about mRNA vaccines:

- mRNA vaccines cannot give someone COVID-19.
- mRNA vaccines do not use the live virus that causes COVID-19.
- They do not affect or interact with our DNA in any way.
- mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept.
- The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

SOURCE: CDC

COVID-19 vaccination schedule for most people

Ages 6 months–4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna *—or—* Pfizer BioNTech†				
1 dose monovalent Moderna	Moderna				
2 doses monovalent Moderna	Moderna				
2 doses monovalent Moderna and 1	NA; previously received 1				

Age 5 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna *—or—* Pfizer BioNTech	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
		1	0.2 mL/10 ug	Orange	
1 dose monovalent Moderna	Moderna *—or—* Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	4–8 weeks after monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after monovalent dose
	Moderna *—or—*	1	0.2 mL/10 ug	Dark pink cap; yellow label	At least 8 weeks after last monovalent dose

Ages 6–11 years

COVID-19 vaccination history	Bivalent vaccine	Number of bi doses indic
Unvaccinated	Moderna *—or—* Pfizer BioNTech	1
		1
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna *—or—* Pfizer BioNTech	1
		1
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA

Ages 12 years and older

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna *—or—* Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	—
		1	0.3 mL/30 ug	Gray	—
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna *—or—* Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).					

Table 2. Recommended COVID-19 vaccination schedule for people who are moderately or severely immunocompromised COVID-19 vaccination history, May 2023

mRNA COVID-19 vaccines

Ages 6 months–4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses

Ages 5 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between
Unvaccinated	Moderna† *or* Pfizer BioNTech	3	0.25 mL/25 ug	Blue cap; gray label border	Dose 1 and Dc 4 weeks Dose 2 and Dose 3 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dc 3 weeks Dose 2 and dose 3 4 weeks
1 dose monovalent Moderna	Moderna†	2	0.25 mL/25 ug	Blue cap; gray label border	Dose 1: 4 weeks monovalent c Dose 1 and Dc At least 4 we
2 doses monovalent Moderna	Moderna†	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks a monovalent c
3 doses monovalent Moderna	Moderna *or* Pfizer BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks a monovalent c
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent mRNA	—	See footnote	—	—	—
1 dose monovalent Pfizer-BioNTech	Pfizer-BioNTech	2	0.2 mL/10 ug	Orange	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks

Ages 6-11 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna† *or* Pfizer-BioNTech‡	3	0.25 mL/25 ug	Blue cap; gray label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dose 2: 3 weeks Dose 2 and dose 3: At least 4 weeks
1 dose monovalent Moderna	Moderna†	2	0.25 mL/25 ug	Blue cap; gray label border	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses n					
3 doses n					
3 doses n dose biva					
1 dose m					

Ages 12 years and older

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna† *or* Pfizer BioNTech‡	3	0.5 mL/50 ug	Blue cap; gray label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
		3	0.3 mL/30 ug	Gray	Dose 1 and Dose 2: 3 weeks Dose 2 and dose 3: At least 4 weeks
1 dose monovalent Moderna	Moderna†	2	0.5 mL/50 ug	Blue cap; gray label border	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna†	1	0.5 mL/50 ug	Blue cap; gray label border	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna *or* Pfizer-BioNTech	1	0.5 mL/50 ug	Blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent mRNA	—	See footnote	—	—	—

COVID-19 Vaccine schedule for people moderately or severely immunocompromised

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

Additional vaccine dose versus a booster dose

Additional dose: A dose of vaccine administered after the primary series to people who may be less likely to mount a protective immune response after initial vaccination. People who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for their primary series are recommended to receive an additional dose using an mRNA vaccine.

Booster dose: A subsequent dose of vaccine administered to enhance or restore protection which might have waned over time after primary series vaccination.

SOURCE: CDC

Monovalent vaccine and Bivalent vaccine

Monovalent vaccine: The vaccine product is based on the original (ancestral) strain of SARS-CoV-2.

Bivalent booster vaccine ("updated vaccine"): The vaccine product is based on the original (ancestral) strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 (BA.4/BA.5) variants of SARS-CoV-2.

SOURCE: CDC

Updated Guidance on use of the COVID-19 Bivalent Vaccine

FDA and CDC April 2023 Simplifying the COVID-19 Vaccine Schedule

What are the main updates?

- The new guidance will allow:
  - older adults and
  - immunocompromised adults (adults with a weakened immune system)
  - to get a second dose of the updated bivalent vaccine.

- The FDA and CDC made this recommendation because older adults and people with weakened immune systems are at higher risk for severe COVID-19, and data show that the effectiveness of COVID-19 vaccines wanes over time. An additional dose of the updated vaccine offers these two groups of individuals extra protection from getting seriously ill with COVID-19

SOURCE: CDC

05/4/2023

What are the main updates (2)?

- Also moving forward, the monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines (the first COVID-19 vaccines that protect against the original COVID-19 virus strain only) are no longer authorized for use in the United States.

SOURCE: CDC

05/4/2023

Vaccination of Children and Adolescents

- CDC recommends that people ages 6 months and older receive at least 1 bivalent mRNA COVID-19 vaccine.
- At the time of initial vaccination, depending on vaccine product, children ages 6 months–4 years are recommended to receive 2 or 3 bivalent mRNA vaccine doses; children age 5 years are recommended to receive 1 or 2 bivalent mRNA vaccine doses
- Please utilize the schedule based on age and receipt of prior doses.

COVID-19 vaccination schedule changes for people moderately or severely immunocompromised

- At the time of initial vaccination, people ages 6 months and older are recommended to receive 3 bivalent mRNA doses

- People ages 6 months and older who previously received only monovalent doses are recommended to receive 1 or 2 bivalent mRNA vaccine doses, depending on age and vaccine product

- People who previously received a bivalent mRNA vaccine dose(s) have the option to receive 1 or more additional bivalent mRNA doses

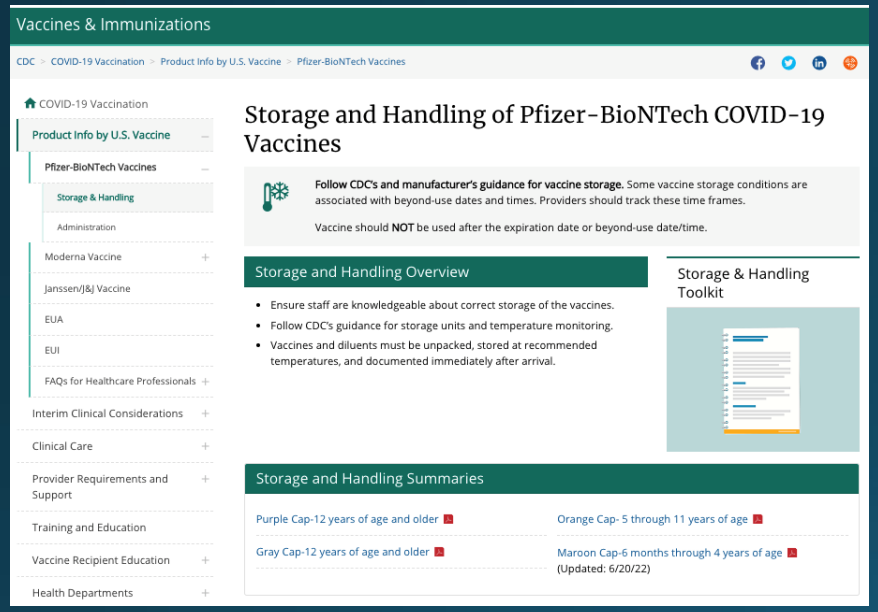
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01

Use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people (2)

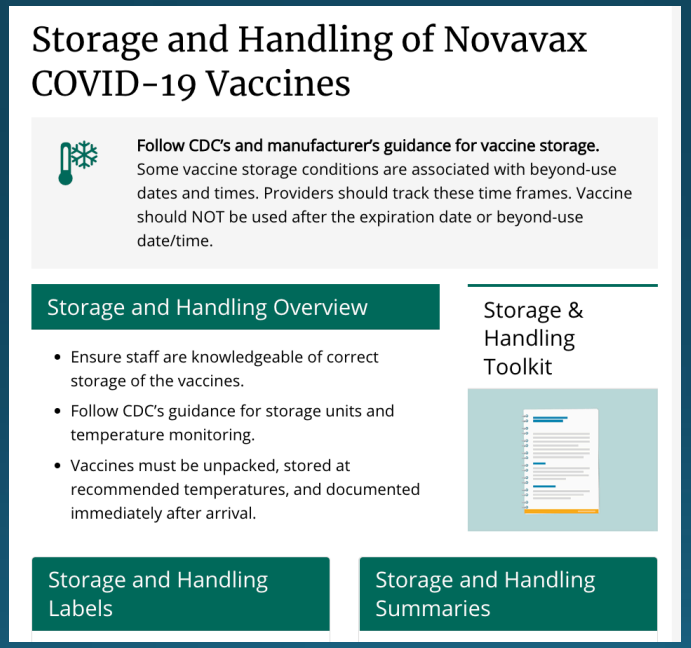
Description of moderate and severe immunocompromising conditions and treatment

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

STORAGE AND HANDLING GUIDELINES
(See detailed guidelines for each vaccine)
Follow Georgia Department of Health guidelines

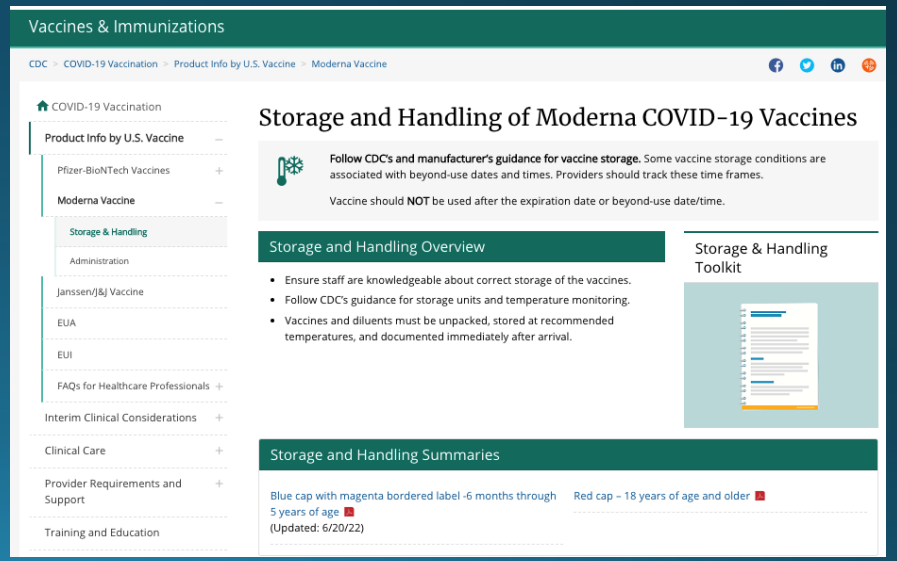


CDC: Pfizer



CDC: Novavax

CDC:Moderna



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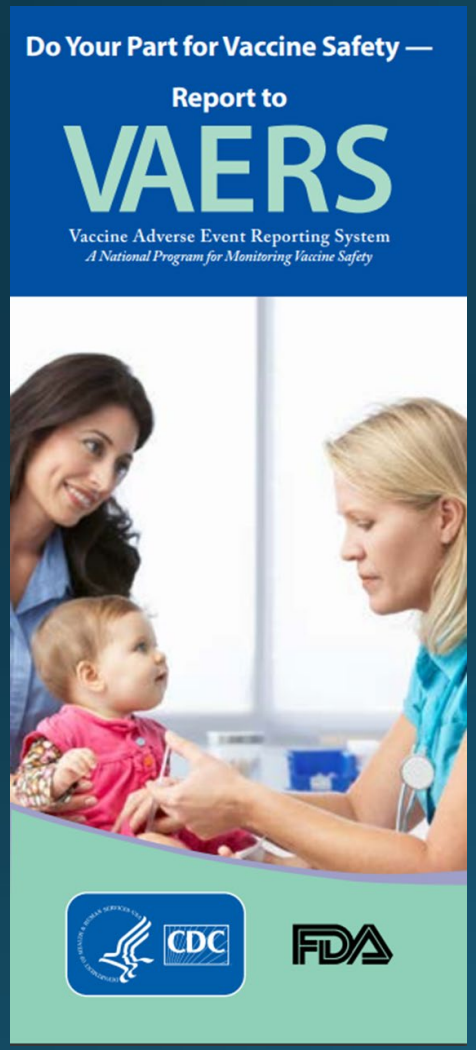
COVID-19 Vaccine Administration errors

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group (recipients younger than 6 months)	• Do not give another dose at this time.*

	• Unauthorized age group (recipients ages 6 months–17 years)	• If Moderna vaccine administered:
		  ◦ As a booster dose, do not repeat the dose with Pfizer-BioNTech vaccine
		• If Janssen vaccine administered
		  ◦ As a primary dose, do not count the dose and begin or continue the age-appropriate mRNA COVID-19 vaccine primary series (Table 1) at least 28 days after the Janssen vaccine
		  ◦ As a booster dose, do not count the dose and repeat the dose with Pfizer-BioNTech vaccine at least 28 days after the Janssen vaccine

Product and dosage	• If the incorrect product/dosage is administered, resulting in a higher-than-authorized dose	• Do not repeat dose.†‡
	• If the incorrect product/dosage is administered, resulting in a lower-than-authorized dose	• Repeat dose immediately (no minimum interval) with the age-appropriate product/dosage. • 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 years.‡‡
	• Higher-than-authorized dose volume administered of the correct product	• Do not repeat dose.†
	• Lower-than-authorized dose volume administered of the correct product (e.g., leaked out, equipment failure, recipient pulled away)	• Repeat dose immediately (no minimum interval).§ • However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose. • See Appendix D for guidance on addressing situations in which a booster dose is administered prior to completing the primary series.

Monitoring Vaccine Safety



- **VAERS—Vaccine Adverse Event Reporting System**

Option 1 - Report Online to VAERS (Preferred)
Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.

Option 2 - Report using a Writable PDF Form
Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.
If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

- **FDA and Vaccine Data Link Safety Project**

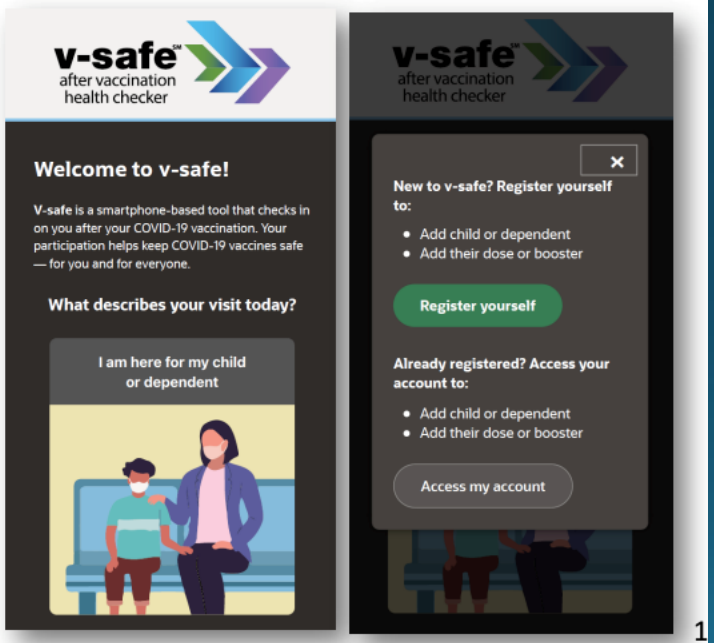
- **VERP: Vaccine Error Reporting System**
  - ✓ On-line reporting at http://verp.ismp.org/
  - ✓ Report even if no adverse events associated with incident
  - ✓ Will help identify sources of errors to help develop prevention strategies

Post vaccination: Vaccine safety monitoring

Smartphone-based safety monitoring for COVID-19 vaccines

v-safe is a CDC smartphone-based monitoring program for COVID-19 vaccine safety in the U.S.

- A parent must be registered with v-safe in order to add a child to their account
- If a parent is already registered, they can access their account to add a child
- To register or access your account go to https://vsafe.cdc.gov/en/



There may be changes after June 30, 2023

Safety considerations in Children and adolescents

VACCINE ADVERSE EVENTS (1)

- Usually appear in the first two days and then resolve within a week after vaccination
- Side effects may be more pronounced after the 2nd dose of vaccine and after prior COVID19 infection

LOCAL REACTIONS

- Pain
- Redness
- Swelling

SOURCE: CDC

SYSTEMIC REACTIONS

- Fatigue
- Headache
- Chills
- Fever
- Muscle pain
- Nausea

Vaccine Adverse Events (2)

- Syncope risk after vaccination
  - Before vaccination, counsel patients about expected local and systemic reactions, especially syncope
  - Have patient sit or lie down to receive vaccine
  - Observe for 15 minutes under medical supervision
  - Wait 30 minutes if history of allergic reaction

Preparing for the potential management of anaphylaxis at COVID-19 vaccine sites

Should be available at all locations	If feasible, include at locations (not required)
Epinephrine (e.g., prefilled syringe, autoinjector)*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine, cetirizine)†	Oxygen
Blood pressure monitor‡	Bronchodilator (e.g., albuterol)
Timing device to assess pulse	H2 antihistamine (e.g., famotidine, cimetidine)
	Intravenous fluids
	Intubation kit
	Pocket mask with one-way valve (also known as cardiopulmonary resuscitation [CPR] mask) sized for adults and children

SOURCE: CDC

- **Observation after COVID-19 vaccination**

30 minutes:

-People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen vaccine).

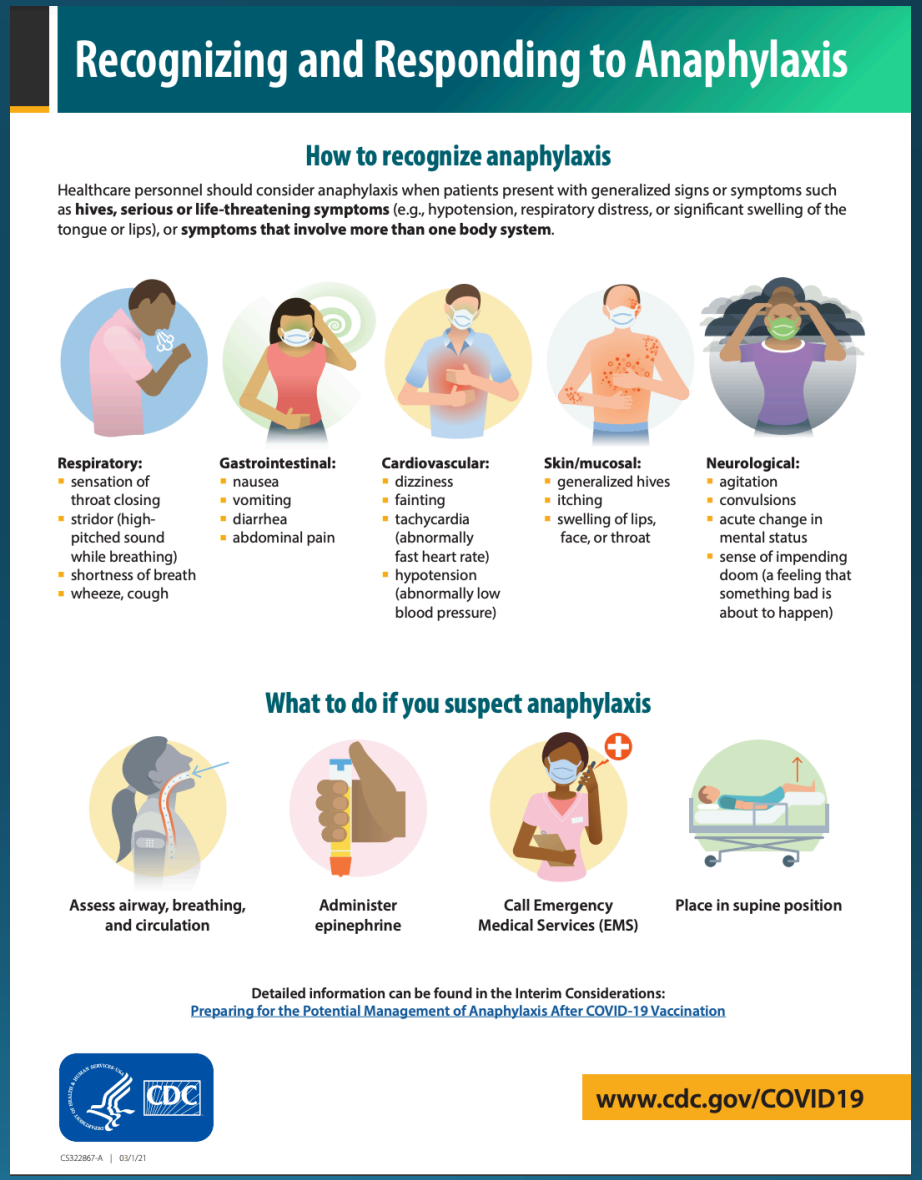
-History of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.

-History of an immediate allergic reaction of any severity to non-COVID-19 vaccines or injectable therapies.

-History of anaphylaxis due to any cause.

15 minutes:

All other people



Safety considerations for mRNA COVID-19 vaccines

- Among children, adolescents and adults, pain/tenderness at the injection site was the most frequent local reaction.
- The most common systemic symptom in older children and adults was fatigue, headache and myalgia; in younger children (ages 6–23 months), irritability/crying and drowsiness/sleepiness were most common.
- Most systemic symptoms were mild to moderate in severity, typically began 1–2 days after vaccination, and resolved after 1–2 days.

Safety considerations for mRNA COVID-19 vaccines in children

- Febrile seizures can occur in infants and young children ages 6 months–5 years with any condition that causes a fever (most common with high fevers), including COVID-19.
- Febrile seizures are not common after vaccination. Febrile seizures were rare in COVID-19 vaccine clinical trials for young children.
- In most cases, simultaneous vaccination (different vaccines on the same day) does not lead to higher rates of febrile seizures, although administering more than one vaccine at the same clinic visit has been associated with increased risk for febrile seizures in some studies of young children. The impact of coadministration of COVID-19 and routine vaccines on the risk of febrile seizures has not been specifically studied. CDC will monitor for febrile seizures following COVID-19 vaccination in young children.
- Unless people have a contraindication to vaccination, they should be encouraged to complete the series to optimize protection against COVID-19 even if they experience local or systemic symptoms following the first dose.

Myocarditis and pericarditis

- A rare risk for myocarditis and pericarditis has been observed following receipt of mRNA COVID-19 vaccines (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 Vaccine.
- Rare cases of myocarditis and pericarditis have occurred most frequently, in adolescent and young adult males within the first week after receiving the second dose.
- People who have experienced myocarditis/pericarditis after a dose of COVID-19 vaccine, generally should not receive a subsequent dose of any COVID-19 vaccine.

Myocarditis and pericarditis after vaccination in younger children

- In post-authorization surveillance, cases of myocarditis and pericarditis among children ages 5–11 years after Pfizer-BioNTech COVID-19 vaccination have been rarely reported, primarily in males and after dose 2.
- No cases of myocarditis or pericarditis were reported in children in the pre-authorization clinical trials of Pfizer-BioNTech (ages 6 months–4 years) or Moderna (ages 6 months–5 years) vaccines.
- To date, post-authorization surveillance has not detected an increased risk for myocarditis and pericarditis following mRNA COVID-19 vaccination in children ages 6 months–4 years (i.e., Pfizer-BioNTech) and ages 6 months–5 years (i.e., Moderna).

Myocarditis and pericarditis (2)

- People receiving Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and pericarditis following receipt of these vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae.
- Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, *such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination.* In younger children, symptoms of myocarditis may also include non-specific symptoms such as irritability, vomiting, poor feeding, tachypnea, or lethargy.

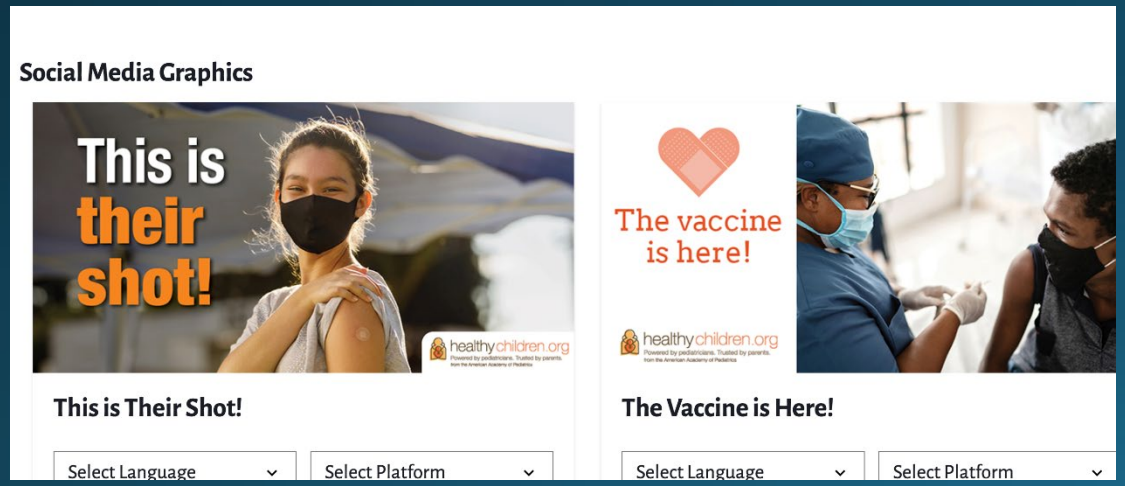
Considerations for extending intervals for mRNA COVID-19 vaccine primary series (Pfizer and Moderna)

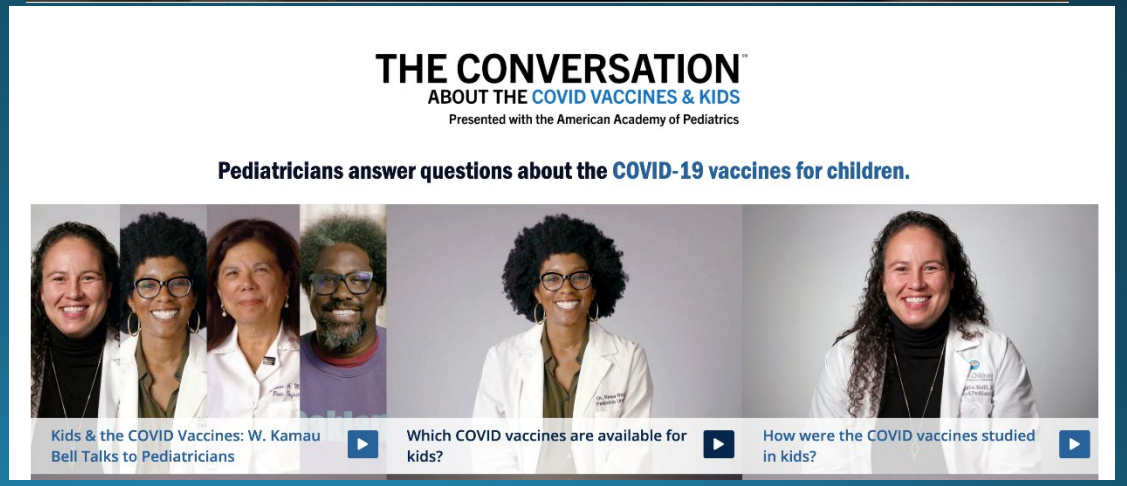
- An 8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people as it may reduce the small risk of myocarditis and pericarditis associated with these COVID-19 vaccines.
- People who have a history of myocarditis or pericarditis unrelated to COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team).
- People who have a history of other heart disease, including congenital heart disease and Kawasaki disease, may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine.

Health Care Provider Training

- Training opportunities for HCPs (COVID-19 vaccines, talking to patients, FAQs)
  - https://www.cdc.gov/vaccines/covid-19/training.html
  - https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp
  - https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp
  - https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/
  - https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-frequently-asked-questions/
  - https://www.gritstest.state.ga.us/docs/COVID-19_Clinical_Training_and_Resources_for_HCPs.pdf

AAP Resources for Providers and Parents (Vaccine Campaign Toolkit)





SOURCE:AAP

05/4/2023

How to Talk with Parents about COVID-19 Vaccination

Tips for Pediatricians, Family Medicine Practitioners, Pharmacists & Other Pediatric Providers

Parents consider their child's healthcare providers to be their most trusted source of information when it comes to vaccines. You play a critical role in helping them understand the importance of COVID-19 vaccination and assuring them that COVID-19 vaccines are safe and effective.

https://www.cdc.gov/vaccines/covid-19/hcp/pediatrician.html

How to Talk with parents about COVID-19 vaccination

Co-administration with other childhood vaccines

- Is allowed
- 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.
- Exception (Monkeypox vaccine)