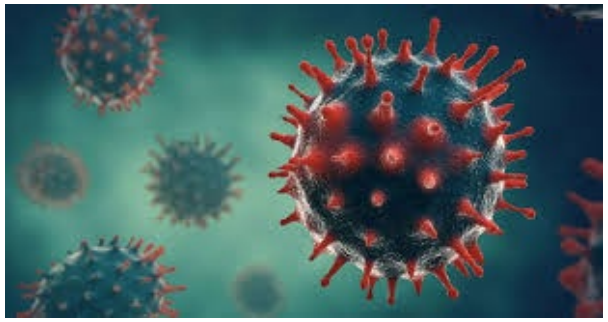


EPIC® Educating Physicians In their Communities & Practices

EPIC Immunization 2023 Update

SARS-CoV-2 (COVID-19)

Reviewed May 4, 2023

Updated May 4, 2023

EPIC® is presented by:

- Georgia Chapter - American Academy of Pediatrics
- Georgia Department. of Public Health/Immunization Program
- *In Cooperation with:*

  Georgia Academy of Family Physicians

  Georgia Chapter - American College of Physicians

  Georgia OB/Gyn Society

Faculty Disclosure Information

- In accordance with ACCME* and ANCC-COA** Standards, all faculty members are required to disclose to the program audience any real or apparent conflict of interest to the content of their presentation.
- This presentation will include the most current ACIP recommendations for frequently used vaccines but is not a comprehensive review of all available vaccines.
- Some ACIP recommendations for the use of vaccines have not currently been approved by the FDA.
- Detailed information regarding all ACIP Recommendations is available at www.cdc.gov/vaccines/acip/recs/index.html

*Accreditation Council for Continuing Medical Education

**American Nurses Credentialing Center Commission on Accreditation

Objectives

At the end of this presentation, you will be able to:

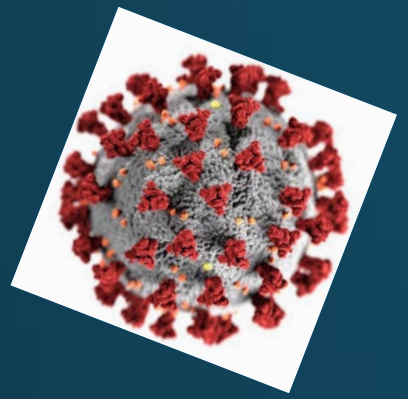
- Name 4 possible symptoms of COVID-19 disease
- Name 3 vaccines approved to prevent COVID-19 disease
- Discuss at least 2 clinical recommendations for use of COVID-19 vaccines and storage, handling, and administration of COVID-19 vaccines
- Name 3 of 5 keys to prevention of COVID-19 disease

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 using 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.



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

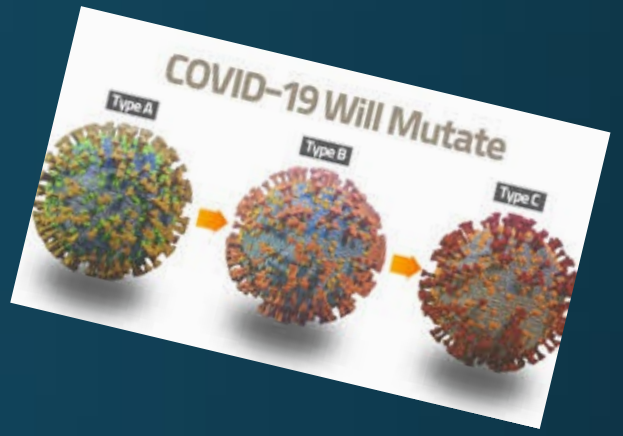
COVID-19 disease

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.

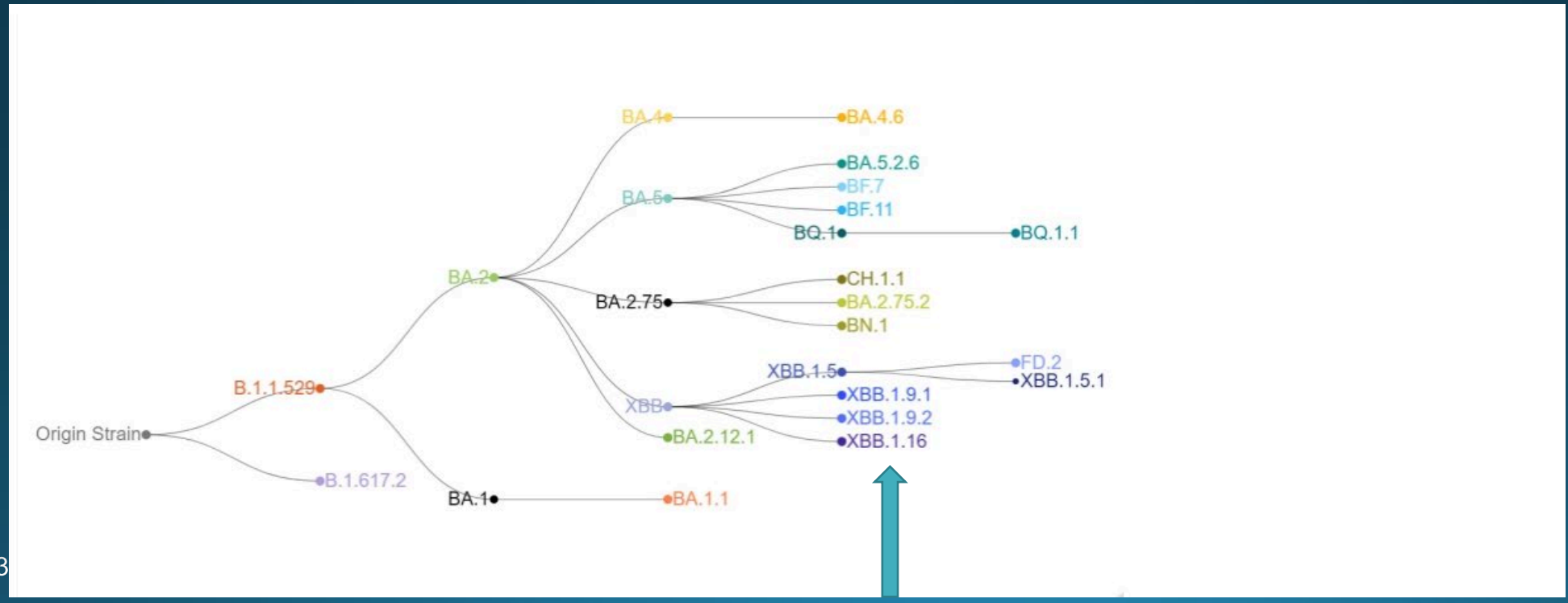
CDC is studying these variants as they appear to understand whether the variants

- 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.

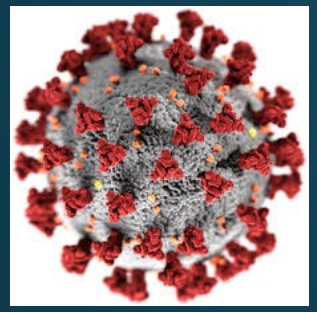
SOURCE: CDC

Newest Variant

- XBB.1.16, Arcturus is a subvariant of Omicron and has been on the World Health Organization's watchlist since the end of March.
- The CDC's most recent update now lists Arcturus as causing 7% of U.S. coronavirus cases, landing it in second place behind the long-predominant Omicron XBB.1.5, which causes 78% of cases.
- Arcturus is more transmissible but not more dangerous than recent variants. Appears to cause conjunctivitis like symptoms in young patients.



Burden of Disease
Children and adolescents



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.

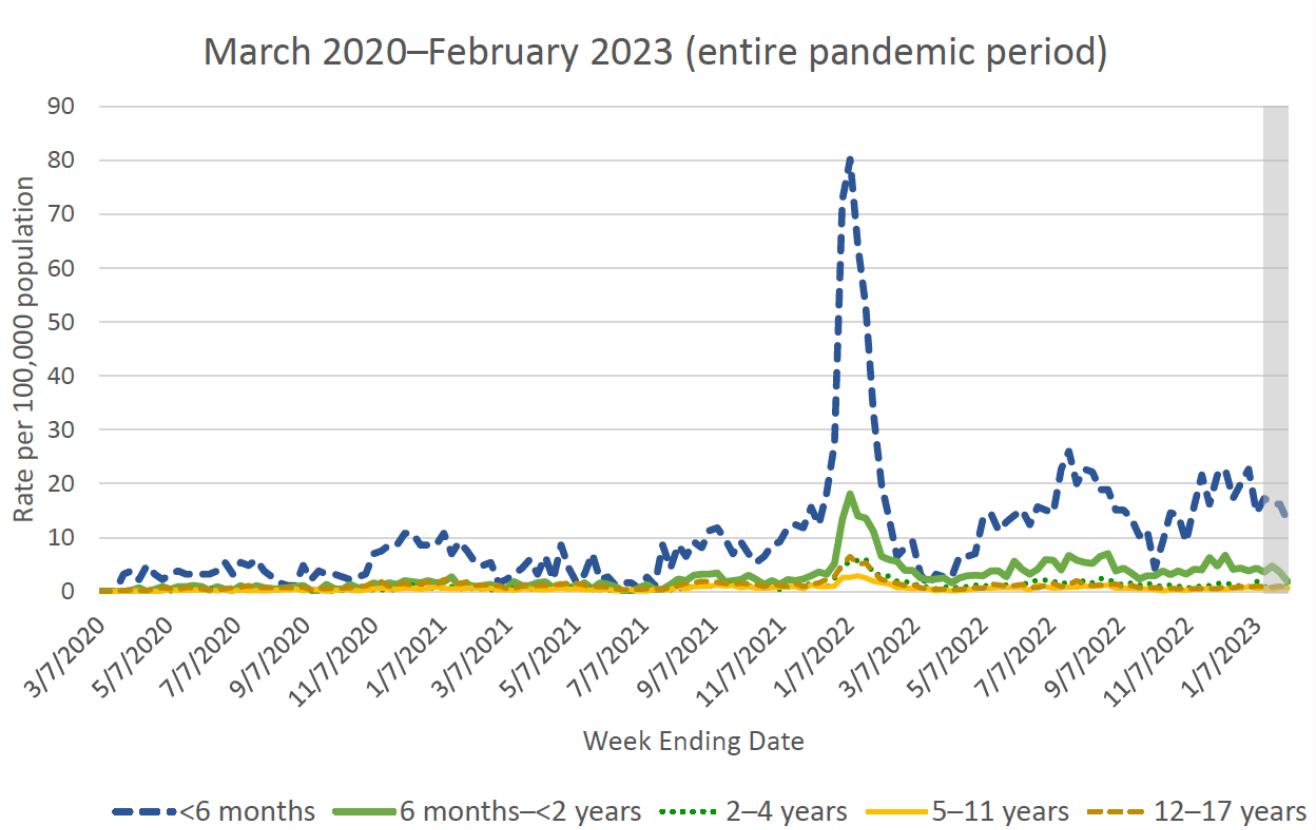
For data on cases in Georgia, visit Georgia data and Georgia data (2)

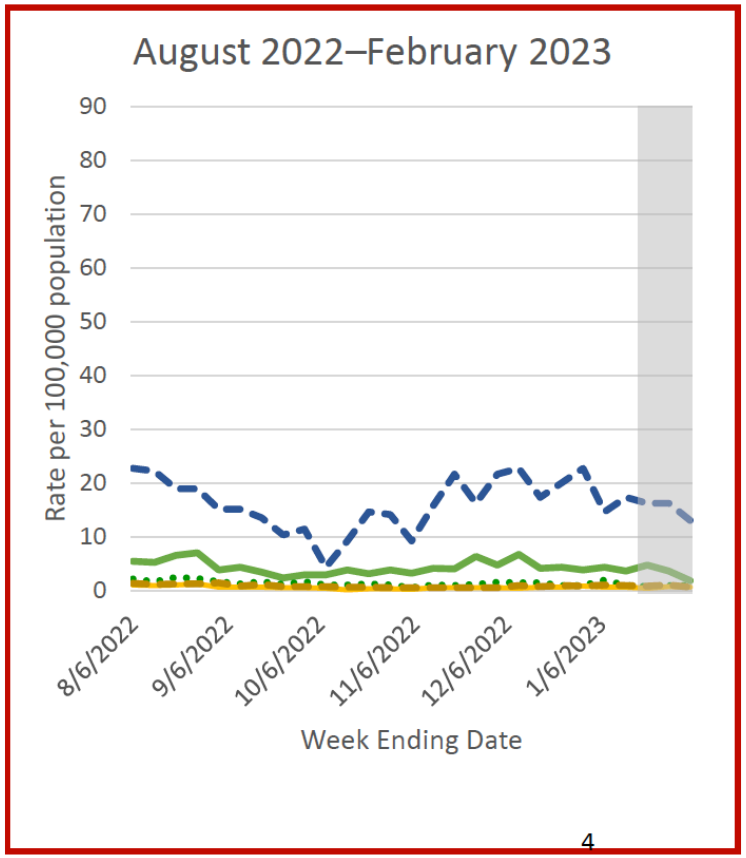
National data

5/4/2023

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





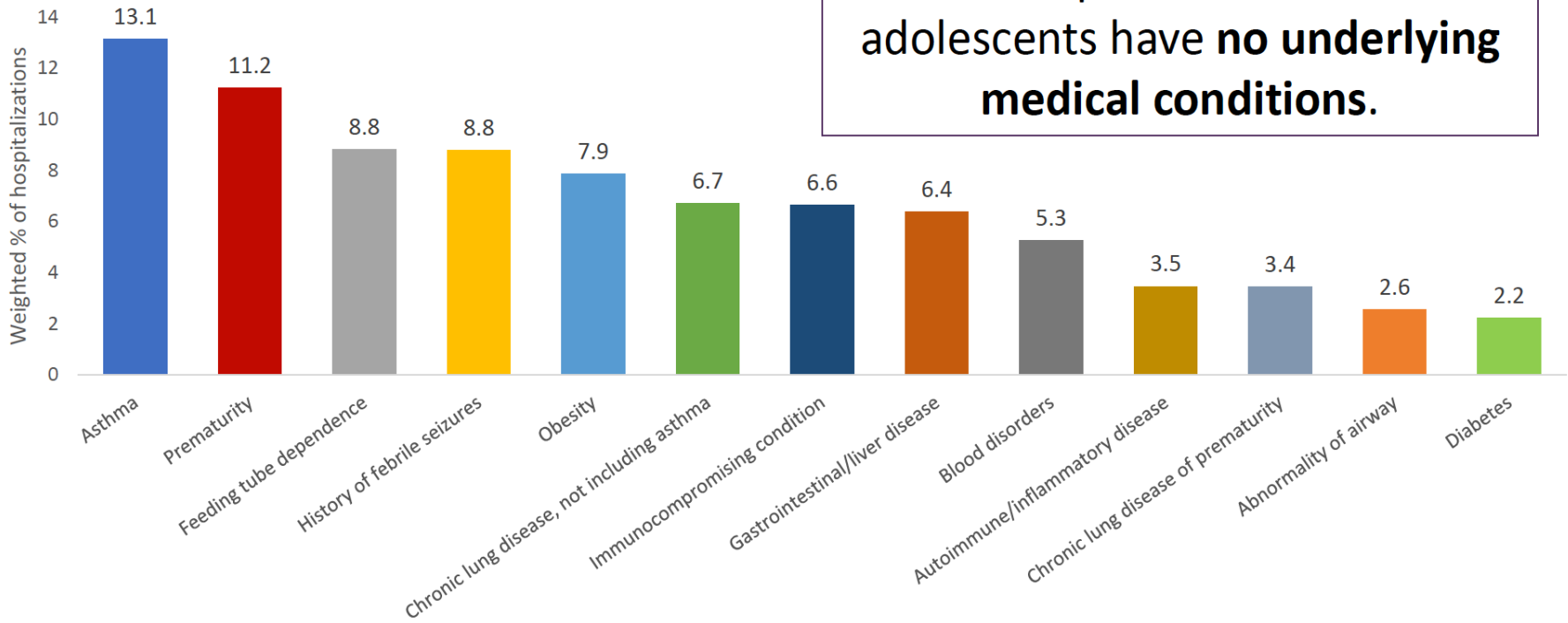
Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

4

Hospitalizations among Children (2)

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

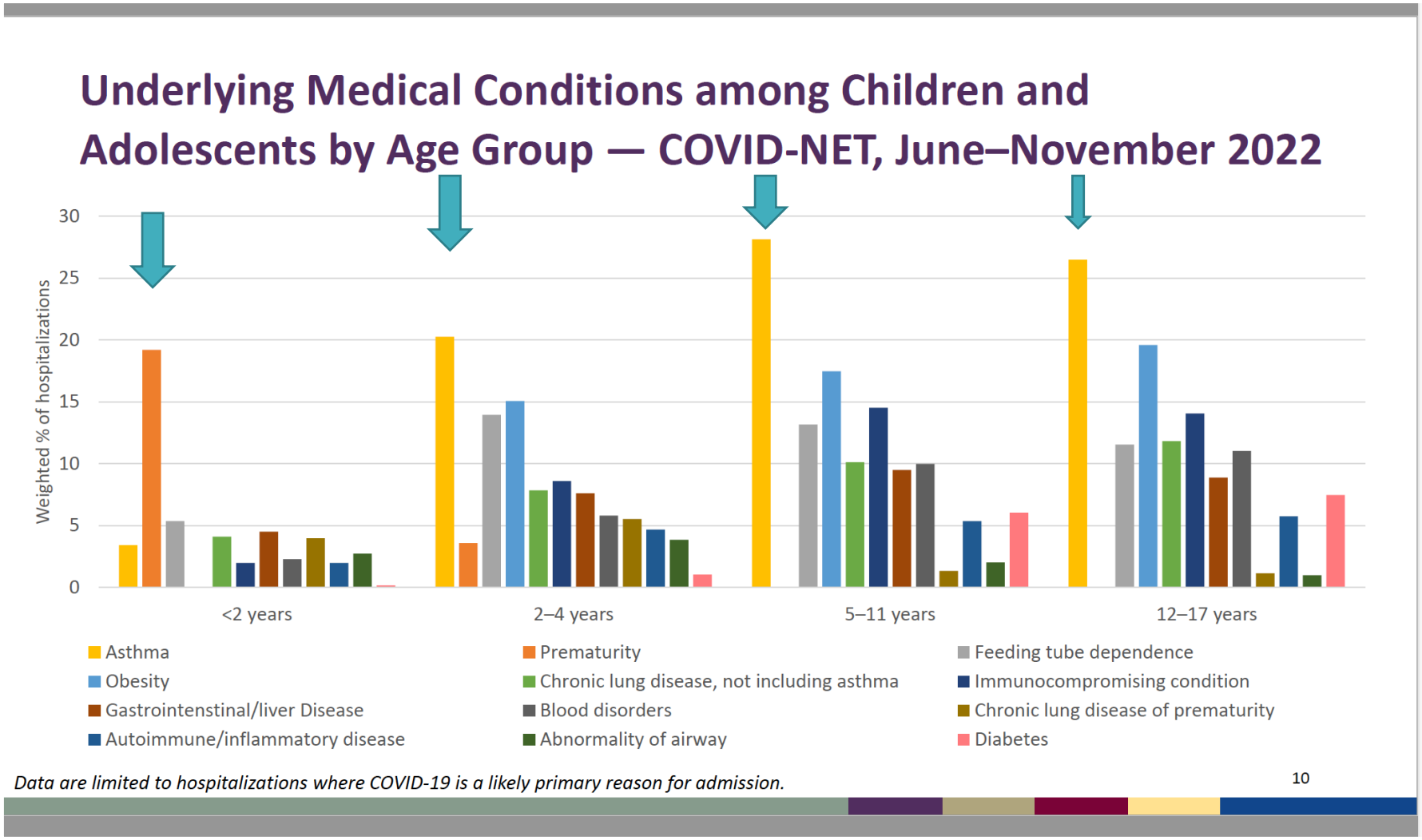
49% of hospitalized children and adolescents have **no underlying medical conditions.**



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

9

Hospitalizations among Children (3)



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	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**

[1]Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8.
[2]National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019.
[3]Meyer 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
[4]Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63.
[5] Glass 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. Accessed 5/14/22

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.

Post COVID conditions

Post-COVID conditions

- Long COVID, Post-COVID, Long Haul COVID
- Most patients appear to recover from acute COVID-19 illness within four weeks. However, some continue to have on-going symptoms or new or recurrent symptoms and conditions after this acute phase. **So at least four weeks after infection** is the start of when Post-COVID Conditions could first be identified.
- Estimates of the proportion of people who had COVID-19 that go on to experience Post-COVID Conditions can vary.
- For the most current data on post-COVID occurrence in the U.S., visit: https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm

Common symptoms of Long COVID in adults

- Dyspnea or increased respiratory effort
- Fatigue
- Post-exertional malaise* and/or poor endurance
- Cognitive impairment or "brain fog"
- Cough
- Chest pain
- Headache
- Palpitations and tachycardia
- Arthralgia
- Myalgia
- Paresthesia
- Abdominal pain
- Diarrhea
- Insomnia and other sleep difficulties
- Fever
- Lightheadedness
- Impaired daily function and mobility
- Pain
- Rash (e.g., urticaria)
- Mood changes
- Anosmia or dysgeusia
- Menstrual cycle irregularities
- Erectile dysfunction

* Post-exertional malaise (PEM) is the worsening of symptoms following even minor physical or mental exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or even weeks.

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%)

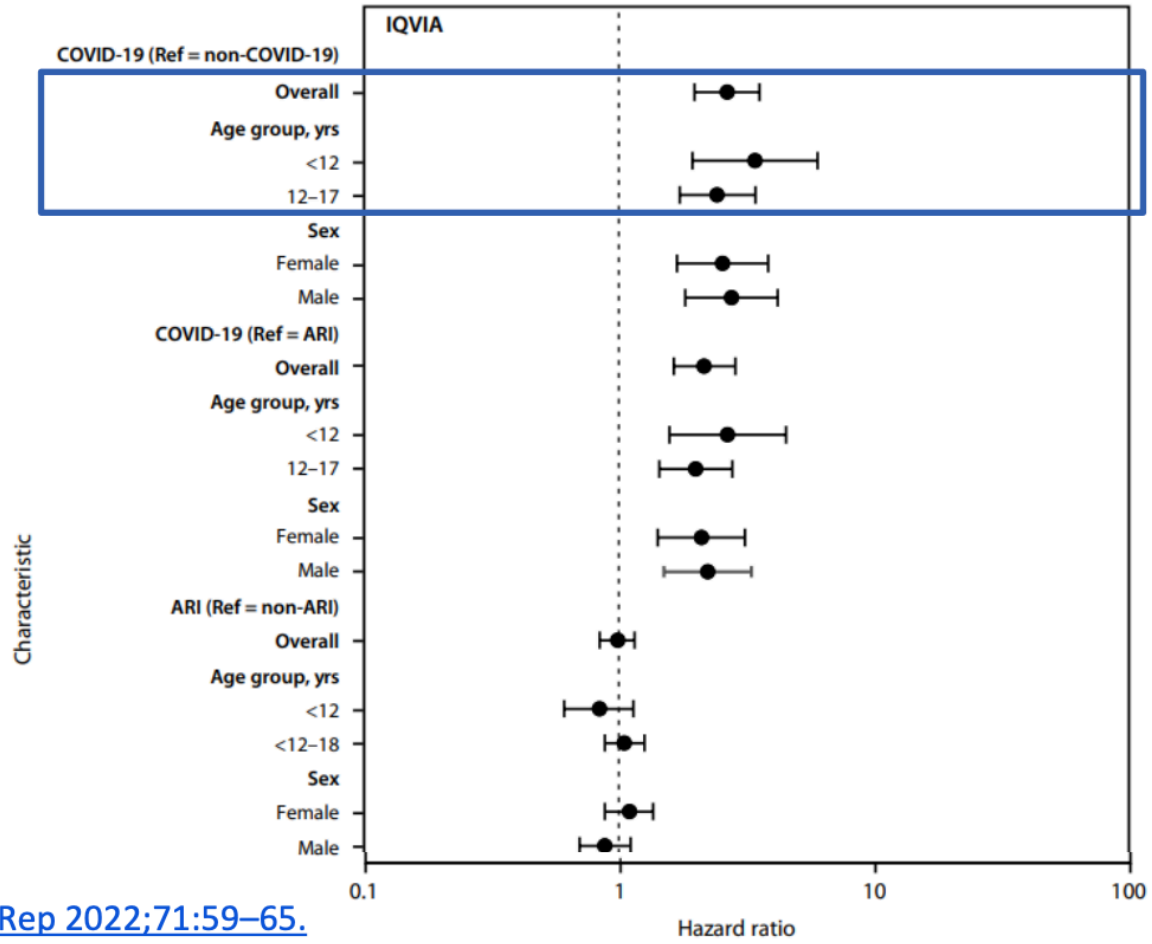
Zimmermann et al. The Challenge of Studying Long COVID: An Updated Review : The Pediatric Infectious Disease Journal (lww.com)
Lopez-Leon et al. Long-COVID in Children and Adolescents: A Systematic Review and Meta-analyses | medRxiv

9

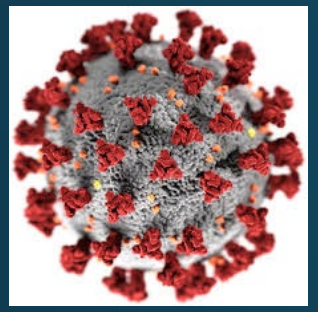
Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 Years — United States, March 1, 2020–June 28, 2021

Centers for Disease Control and Prevention
MMWR

- Retrospective cohorts constructed using IQVIA healthcare claims data from March 1, 2020, through February 26, 2021
- Incidence of new diabetes diagnosis among COVID-19 patients, matched by age and sex, was higher compared to no COVID-19 diagnosis and to pre-pandemic non-COVID acute respiratory infection (ARI)
- Hazard ratio of **2.66** overall



Barrett CE, et al. MMWR Morb Mortal Wkly Rep 2022;71:59–65.



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.

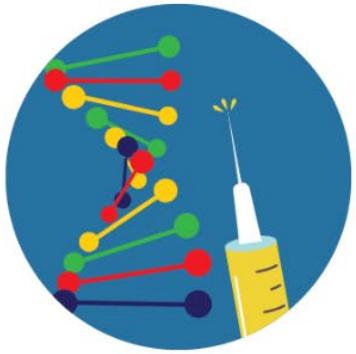
Over 9300 MIS-C cases and over 76 deaths due to MIS-C have been reported in the U.S. as of February 2023. Half of children with MIS-C were between the ages of 5 and 13 years, with a median age of 9 years. MIS-C cases have occurred in children and adolescents from <1 year old to 20 years old.

CDC: MIS-C

COVID-19 vaccines

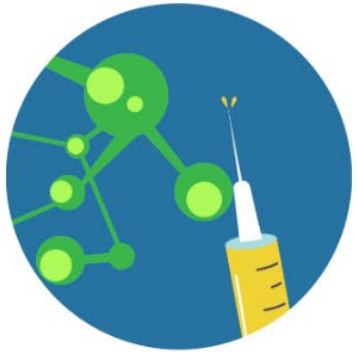
Different Types of COVID-19 Vaccines

THREE MAIN TYPES OF VACCINES



mRNA

mRNA is a molecule that tells our bodies to make proteins. mRNA in the COVID-19 vaccine tells our cells to make harmless proteins just like those on the virus. The Pfizer and Moderna vaccines work this way.



Protein Subunit

Protein subunit vaccines, such as the Novavax vaccine, contain harmless pieces of proteins unique to the COVID-19 virus.

Vector

Vector vaccines, like the J&J vaccine, use another virus that has been made safe to deliver material that tells our cells to make harmless proteins unique to the COVID-19 virus.

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
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: 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dose 2: 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 after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna†	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks after monovalent dose
3 doses monovalent Moderna	Moderna *or* Pfizer BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks after monovalent dose
		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 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 d 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 d
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 d
		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	—	—	—

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

AAP Policy Statement COVID-19 vaccination children and adolescents

- **Children with previous infection or disease with SARS-CoV-2 should receive COVID-19 vaccination, according to CDC guidelines.**
- AAP supports co-administration of routine childhood and adolescent immunizations with COVID-19 vaccines (or vaccination in the days before or after) for children and adolescents who are behind on or due for immunizations

SOURCE: AAP

COVID-19 Vaccination of Pregnant People or Lactating People

- Pregnant and recently pregnant people with COVID-19 are at increased risk for severe illness when compared with non-pregnant people.
- Severe illness includes illness that requires hospitalization, intensive care unit admission, mechanical ventilation, or extracorporeal membrane oxygenation; or illness that results in death.
- Additionally, pregnant people with COVID-19 are at increased risk for preterm birth and might be at increased risk for other adverse pregnancy complications and outcomes, such as preeclampsia, coagulopathy, and stillbirth.

SOURCE:CDC

SOURCE: ACOG

COVID-19 Vaccination of Pregnant People or Lactating People (2)

- COVID-19 vaccination is recommended for all people aged 6 months and older, including people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future.
- There is no evidence that any of the COVID-19 vaccines affect current or future fertility.

SOURCE:CDC

SOURCE: ACOG

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

5/4/2023

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

5/4/2023

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 who are 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

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†	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
		3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2: 3–8 weeks Dose 2 and dose 3: At least 8 weeks
1 dose monovalent Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; gray label border	4-8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent Moderna	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 dose monovalent Pfizer-BioNTech	Pfizer BioNTech†	2	0.2 mL/3 ug	Maroon	Dose 1: 3–8 weeks after monovalent dose Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Children 5 years old

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
2 doses monovalent Moderna	Moderna *or* Pfizer BioNTech	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 or more doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent Pfizer-BioNTech (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Children 6-11 years old

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	1	0.25 mL/25 ug	Dark blue cap; gray label border	—
		1	0.2 mL/10 ug	Orange	—
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna *or* Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	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).					

People 12 years and older

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
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 monovalent Moderna	Moderna†	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks after monovalent dose
3 doses monovalent Moderna	Moderna *or* Pfizer BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks after monovalent dose
		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 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 d 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 d
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 d
		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	—	—	—

Vaccine schedule for people moderately or severely immunocompromised

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

COVID-19 vaccines

People can **self-attest** to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. **Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.**

Factors to consider in assessing a patient's general level of immune competence include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

SOURCE: ACIP Interim Clinical Recommendations

Is this a new vaccine?

- **No.**
  - The Moderna and Pfizer updated bivalent COVID-19 vaccines (also called the Omicron vaccines)provide protection against the original COVID-19 virus strain and the Omicron variants.
  -
  - You may recall that the updated bivalent (Omicron) COVID-19 vaccine was authorized for use as the new booster vaccine in August 2022.
  - This has been the case until now.
  - On April 18, 2023, the FDA authorized this vaccine to be used not only as a booster dose vaccine but also for those getting the vaccine for the first time (as primary series doses). This means the current bivalent vaccines can be used for all doses in persons 6 months and older.

No.

Currently, the recommendation to receive a second updated bivalent vaccine dose only applies to people 65 years and older and people who are immunocompromised.

CDC and ACIP will continue to monitor COVID-19 disease levels and vaccine effectiveness in the months ahead, and additional discussion will take place around potential updates to COVID-19 vaccine recommendations this fall.

What If I am younger than 65 years old and I am not immunocompromised?

Do I need a second updated vaccine dose now?

What about booster vaccines? Do we still need them?

- The CDC continues to recommend that everyone ages 6 years and older get an updated (bivalent) vaccine dose.
- You're up to date on COVID-19 vaccines if you already received an updated bivalent dose since they became available in fall 2022;
- You are **not** currently eligible for **another** dose unless you're 65 and older or immunocompromised.
-

You should receive 1 dose of the bivalent Moderna or Pfizer vaccine now.

CDC recommends that everyone ages 6 years and older receive an updated (bivalent) mRNA COVID-19 vaccine, regardless of whether they previously completed their (monovalent) primary series.

What if I only had 1 dose in the primary series?

I am 36 years old, and I am not immunocompromised. I have only had 1 dose of the mRNA monovalent vaccine; which vaccine should I receive now?

No. You are up to date for now.

People 6 years and older who have already received an updated mRNA vaccine do not need any further doses currently unless they are 65 years or older or immunocompromised.

Guidance may change in the Fall, so stay tuned.

Guidance varies for children, under 6 years old, contact their Healthcare provider.

What if I already had my bivalent booster?

I am 50 years old, am not immunocompromised and I already received my bivalent booster. Do I need anything else?

- mRNA vaccine does not contain any live virus/bacteria.
- It does not interact with our DNA.
- mRNA Vaccine delivers a message only (code) to our body to make the spike protein (outer coat of the COVID-19 virus - not the whole virus).
- So, we can never get COVID-19 disease from the vaccine.
- mRNA does not stay in our bodies. Once it has done its job, it is destroyed and removed from our bodies.

How do mRNA vaccines work again?

Video: https://www.cedars-sinai.org/health-library/video-library/video-detail/h/how-does-a-covid-19-mrna-vaccine-work.html

Novavax Dosing and Formulations

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

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

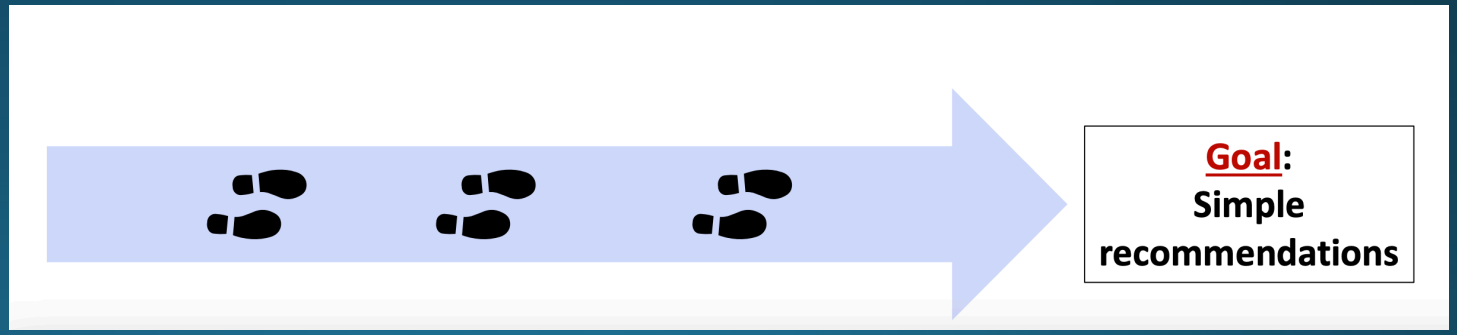
*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

People who received the J and J Janssen Vaccine

- People ages 18 years and older who received the Janssen COVID-19 Vaccine primary series dose are recommended to receive 1 bivalent mRNA vaccine dose (Moderna or Pfizer-BioNTech) at least 2 months after completion of the primary series dose (for people who have not previously received any booster doses), or at least 2 months after the last monovalent booster dose.
- See https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised for guidance on people who are moderately or severely immunocompromised

Are we going to need a booster in the Fall?

- Experts will continue to monitor the spread of the virus and the effectiveness of COVID-19 vaccines and are likely to make additional changes as we move toward to the fall, so expect updates.

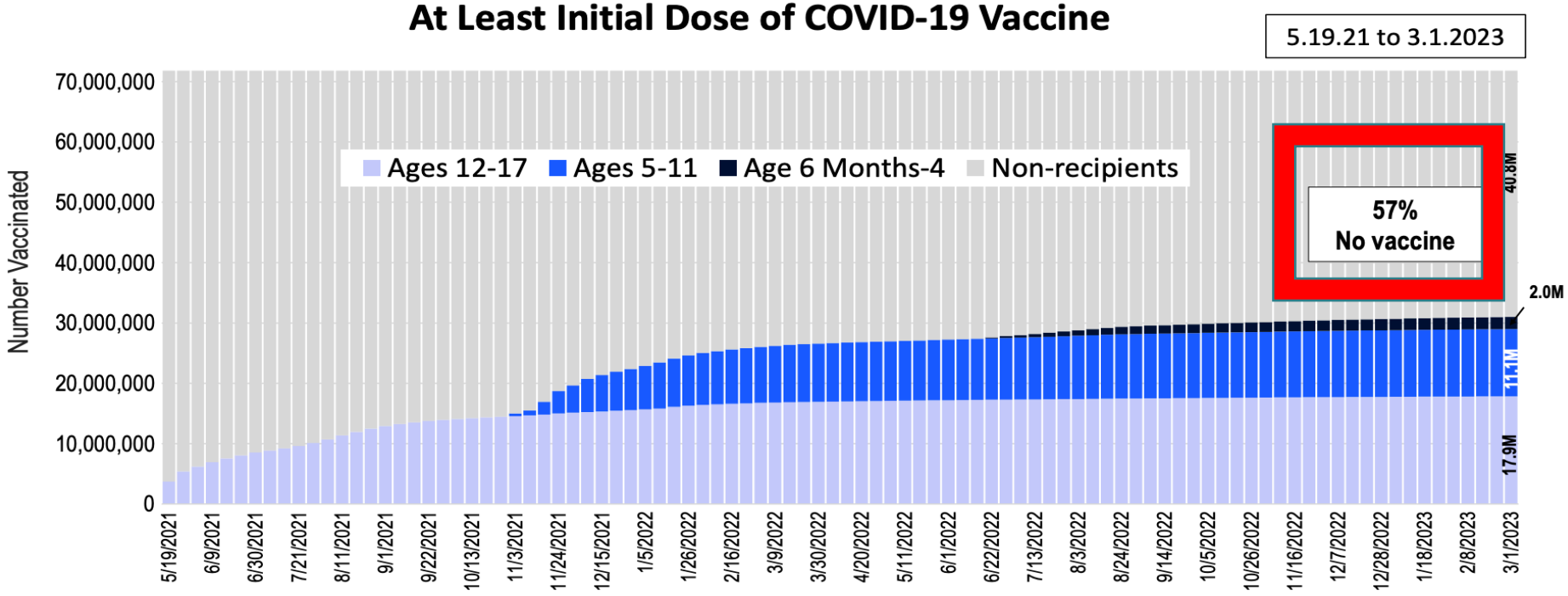


COVID-19 Vaccination Rates

		# vaccinated	Percentage of US population in that age group	# yet to receive 1 dose
Ages 6 mos – 4 years	Vaccinated with at least 1 dose	2 million	12%	15 million
Ages 5-11 years	Vaccinated with at least 1 dose	11.1 million	39%	17.5 million
	Completed 2-dose series	9.2 million	32%	
Ages 12-17 years	Vaccinated with at least 1 dose	17.9 million	68%	8.3 million
	Completed 2-dose series	15.3 million	58%	

Vaccine uptake in U.S. children and adolescents as of March 1, 2023

Cumulative Number of US Children (6 months – 17 years) Receiving At Least Initial Dose of COVID-19 Vaccine



Sources: AAP analysis of data series titled "COVID -19 Vaccinations in the United States, Jurisdiction". CDC COVID -19 Data Tracker. Includes 50 states and DC. (URL: https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc). Population totals are based on 2021 population estimates (SC-EST2021) published by the US Census Bureau (URL: https://www.census.gov/data/datasets/time-series/demo/popest/2020s-state-detail.html).

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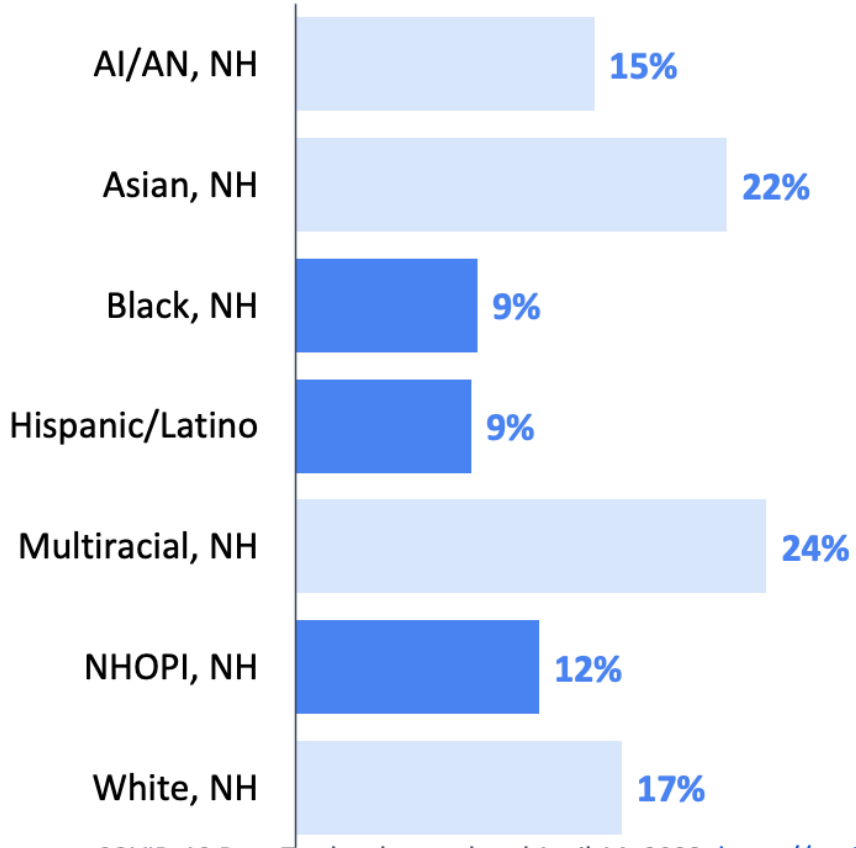
Bivalent COVID-19 vaccine coverage is lower among Black, non-Hispanic, Hispanic/Latino, and Native Hawaiian or Other Pacific Islander.

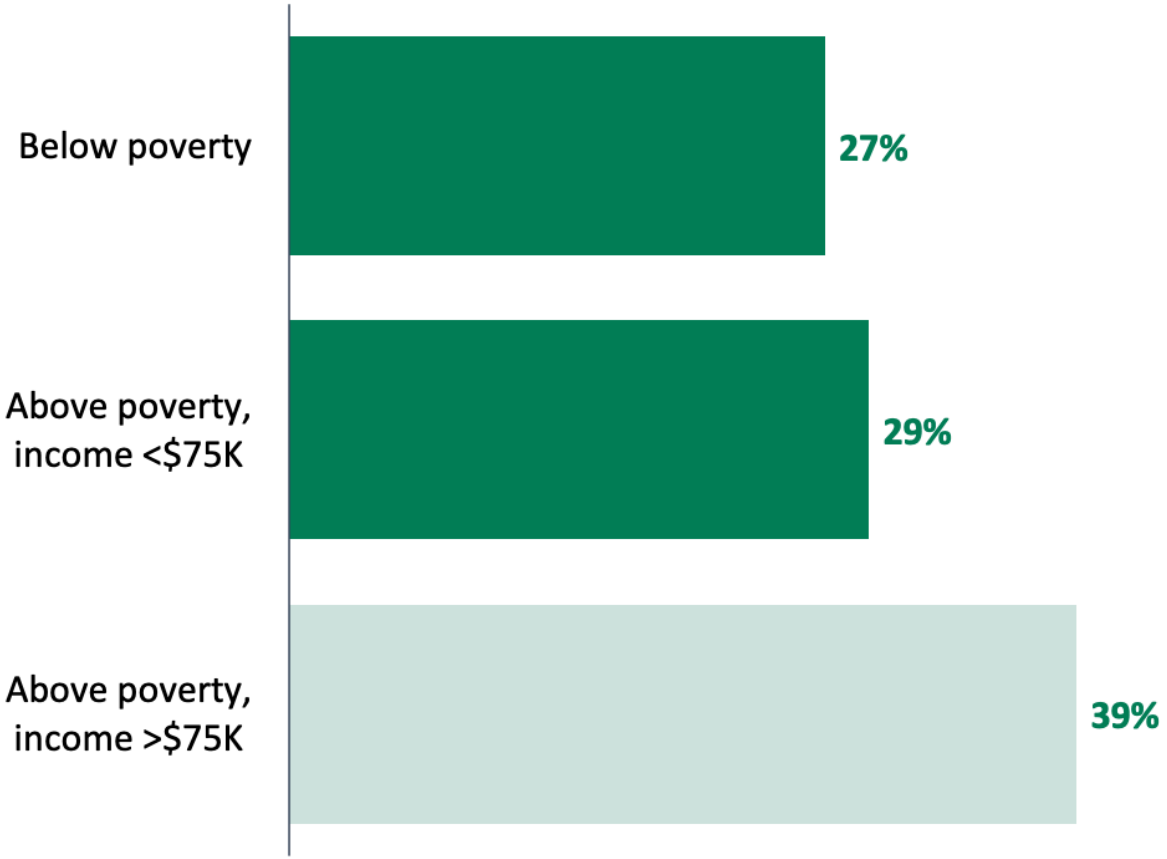
Bivalent COVID-19 Vaccination Coverage by Race/Ethnicity



COVID-19 Data Tracker, last updated April 14, 2023, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends

Bivalent COVID-19 vaccine coverage is lower among those with lower income.

Bivalent COVID-19 vaccine coverage by income among adults aged ≥18 years



COVID-19 Data Tracker, last updated April 14, 2023, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends

Vaccine Safety considerations

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

Vaccine adverse events (3)

- Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:
  - Vaccine administration errors
  - Serious adverse events
  - Cases of Multisystem Inflammatory Syndrome
  - Cases of COVID-19 that result in hospitalization or death

VAERS----https://vaers.hhs.gov/
VSD---https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
V-safe----https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

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.

Can I administer a COVID-19 Vaccine and another vaccine on the same day?

Answer
YES.

- COVID-19 vaccines may **now be administered without regard to timing of other vaccines**.
- **If multiple vaccines are administered at a single visit, administer each injection in a different injection site.**
- **Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.**

- **Exception:** People, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and pericarditis after JYNNEOS. In the setting of an orthopoxvirus (e.g., monkeypox) outbreak, orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine.

Should someone who has had COVID-19 disease get the vaccine?

Should someone who has had COVID-19 disease get the vaccine?

- Yes!!
- People with known current SARS-CoV-2 infection should hold off on any COVID-19 vaccination, including booster vaccination, at least until they have recovered from the acute illness (if symptoms were present) and that they have met criteria to stop isolation.
- People who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).
- Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection.
- Individual factors such as the risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.
- Wear your mask, and follow all precautions if you chose to wait.

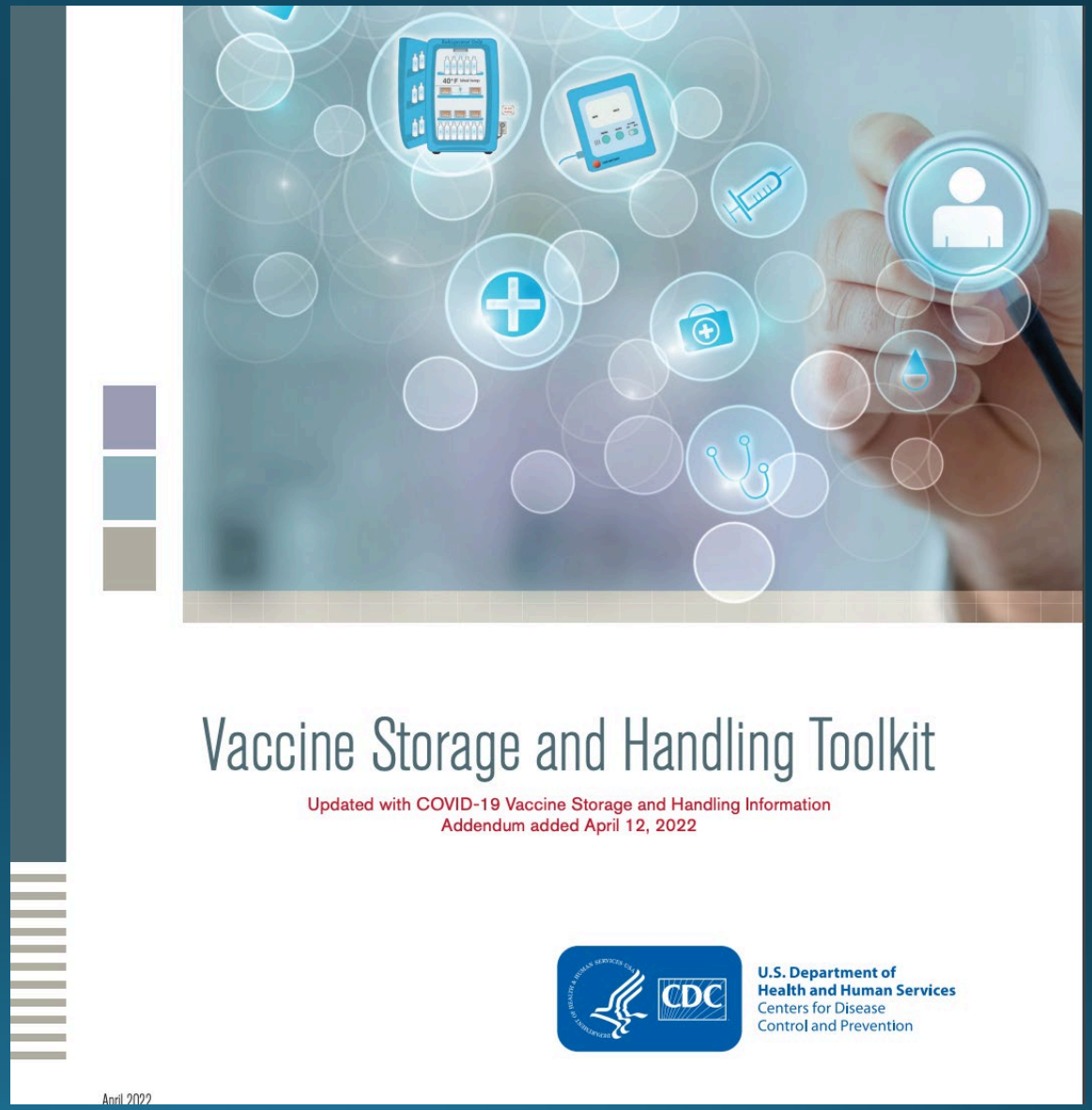
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Critical elements

Vaccine Schedules, Storage and Handling, Administration, Special circumstances

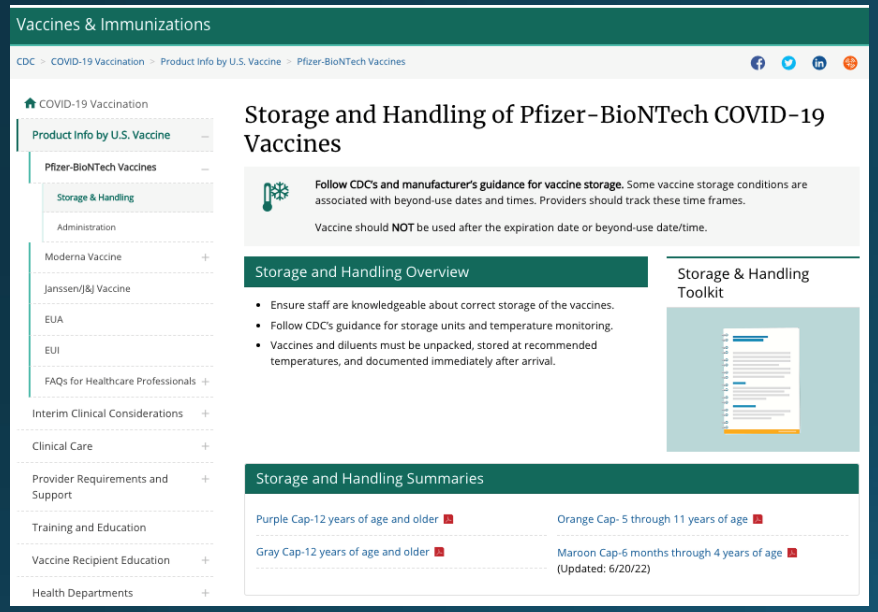
Storage and Handling Guidelines

- **Follow Georgia Department of Health, CDC's and manufacturer's guidance for vaccine storage.** Some vaccine storage conditions are associated with beyond-use dates and times. Providers should track these time frames.
- Vaccine should **NOT** be used after the expiration date or beyond-use date/time.

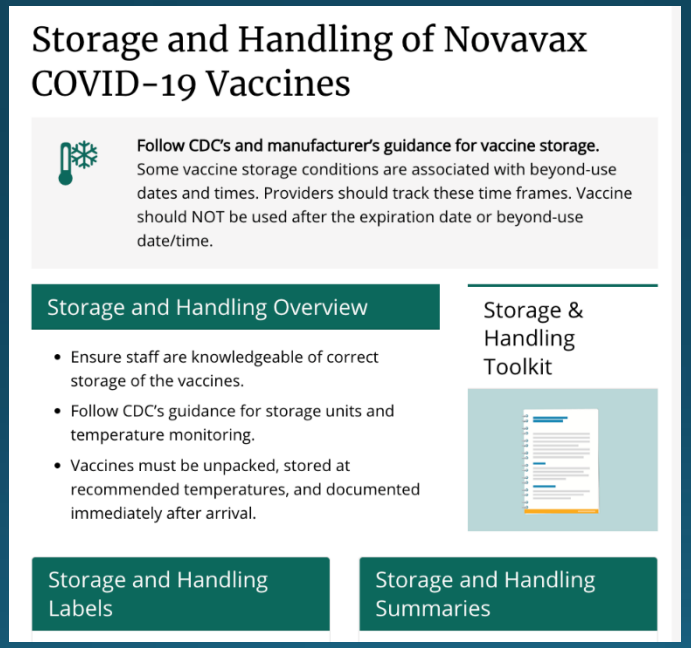


STORAGE AND HANDLING GUIDELINES (See detailed guidelines for each vaccine)

Follow Georgia Department of Health guidelines

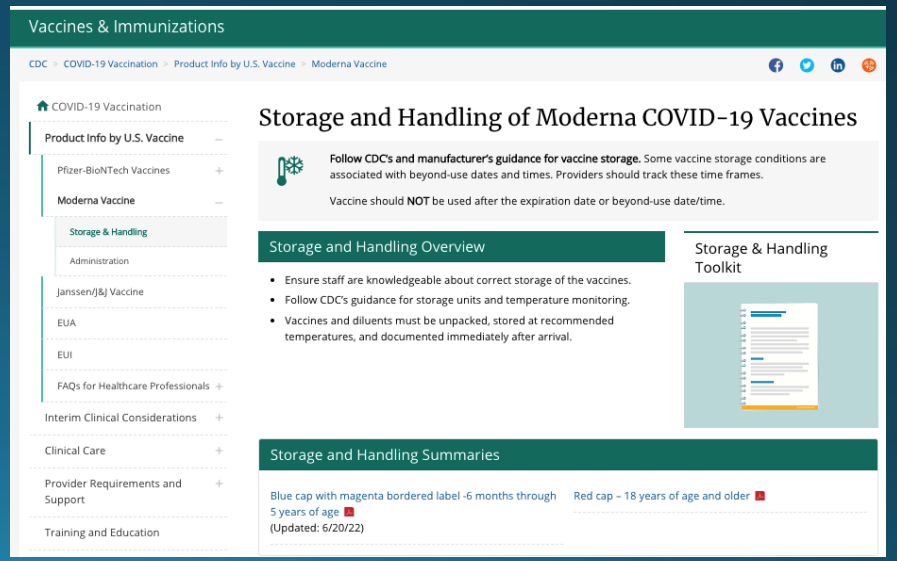


CDC: Pfizer



CDC: Novavax

CDC:Moderna



5/4/2023

Pediatric COVID-19 Vaccine Dosing Quick Reference Guide

For Previously Unvaccinated Individuals

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Pfizer-BioNTech COVID-19 Vaccine Products

Bivalent Products

3 mcg/0.2 ml (dilute before use) | 10 mcg/0.2 ml (dilute before use) | 30 mcg/0.3 ml

Moderna COVID-19 Vaccine Products

Bivalent Product

6 months–11 years: 25 mcg/0.25 ml
≥12 years: 50 mcg/0.5 ml

Age at First Dose	Pfizer-BioNTech COVID-19 Vaccine			Moderna COVID-19 Vaccine	
6 months – 4 years*	**Dose 1** Maroon cap	**Dose 2** 3–8 weeks after dose 1 Maroon cap	**Dose 3** at least 8 weeks after dose 2 Maroon cap	**Dose 1** Blue cap/gray label 25 mcg/0.25 ml	**Dose 2** 4–8 weeks after dose 1 Blue cap/gray label 25 mcg/0.25 ml
5 years*	**Dose 1** Orange cap			**Dose 1** Blue cap/gray label 25 mcg/0.25 ml	**Dose 2** 4–8 weeks after dose 1** Blue cap/gray label 25 mcg/0.25 ml **or Pfizer** Orange cap
6–11 years	**Dose 1** Orange cap			**Dose 1** Blue cap/gray label 25 mcg/0.25 ml	
12 and older	**Dose 1** Gray cap			**Dose 1** Blue cap/gray label 50 mcg/0.5 ml	

*For children receiving Pfizer-BioNTech vaccine who turn 4 to 5 years old during the 3 dose vaccine series, follow dosing recommendations based on age at the start of the vaccine series (3 maroon cap doses).

**Children receiving Moderna vaccine who turn 6 years of age prior to Dose 2 do not require a second dose.

AAP Schedule: Most children

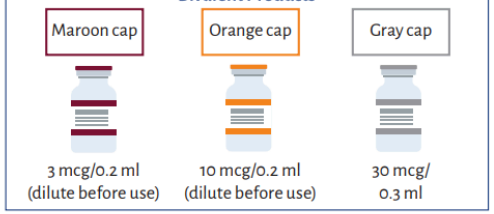
- **Does NOT apply to children who are moderately or severely immunocompromised**

Pediatric COVID-19 Vaccine Dosing Quick Reference Guide

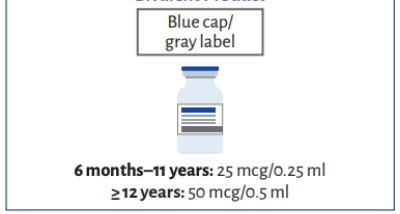
For Previously Unvaccinated Individuals who are Moderately to Severely Immunocompromised

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Pfizer-BioNTech COVID-19 Vaccine Products
Bivalent Products



Moderna COVID-19 Vaccine Products
Bivalent Product



Age at First Dose	Pfizer-BioNTech COVID-19 Vaccine				Moderna COVID-19 Vaccine			
	Dose 1	Dose 2	Dose 3	Additional dose	Dose 1	Dose 2	Dose 3	Additional dose
6 months – 4 years*	Maroon cap	3 weeks after dose 1 Maroon cap	at least 8 weeks after dose 2 Maroon cap	at least 8 weeks after dose 3† Maroon cap	Blue cap/gray label 25 mcg/0.25 ml	4 weeks after dose 1 Blue cap/gray label 25 mcg/0.25 ml	at least 4 weeks after last dose Blue cap/gray label 25 mcg/0.25 ml	at least 8 weeks after dose 3† Blue cap/gray label 25 mcg/0.25 ml
5 years*	Orange cap	3 weeks after dose 1 Orange cap	at least 4 weeks after dose 2 Orange cap	at least 8 weeks after dose 3† Orange cap	Blue cap/gray label 25 mcg/0.25 ml	4 weeks after dose 1** Blue cap/gray label 25 mcg/0.25 ml	at least 4 weeks after last dose Blue cap/gray label 25 mcg/0.25 ml	at least 8 weeks after dose 3‡ Blue cap/gray label 25 mcg/0.25 ml or Pfizer Orange cap
6–11 years	Orange cap	3 weeks after dose 1 Orange cap	at least 4 weeks after dose 2 Orange cap	at least 8 weeks after dose 3‡ Orange cap or Moderna Blue cap/gray label 25 mcg/0.25 ml	Blue cap/gray label 25 mcg/0.25 ml	4 weeks after dose 1 Blue cap/gray label 25 mcg/0.25 ml	at least 4 weeks after dose 2 Blue cap/gray label 25 mcg/0.25 ml	at least 8 weeks after dose 3‡ Blue cap/gray label 25 mcg/0.25 ml or Pfizer Orange cap
12 and older	Gray cap	3 weeks after dose 1 Gray cap	at least 4 weeks after dose 2 Gray cap	at least 8 weeks after dose 3‡ Gray cap or Moderna Blue cap/gray label 50 mcg/0.5 ml	Blue cap/gray label 50 mcg/0.5 ml	4 weeks after dose 1 Blue cap/gray label 50 mcg/0.5 ml	at least 4 weeks after dose 2 Blue cap/gray label 50 mcg/0.5 ml	at least 8 weeks after dose 3‡ Blue cap/gray label 50 mcg/0.5 ml or Pfizer Gray cap

†Further additional homologous bivalent doses may be administered at least 8 weeks after the last dose, informed by clinical judgment of the healthcare provider and person preference and circumstances.

*For children receiving Pfizer-BioNTech vaccine who turn 4 to 5 years old during the 3 dose vaccine series, follow dosing recommendations based on age at the start of the vaccine series (3 maroon cap doses).

**Children receiving Moderna vaccine who turn 6 years of age prior to dose 2 do not require a second dose.

AAP schedule: moderately to severely immunocompromised children

https://downloads.aap.org/AAP/PDF/COVID%20Vaccine%20Dosing_Quick%20Reference.pdf?_ga=2.99648926.1009274042.1683237721-1257560788.1649785296

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
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 monovalent Moderna	Moderna†	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks after monovalent dose
3 doses monovalent Moderna	Moderna —or— Pfizer BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks after monovalent dose
		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 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	—	—	—

Vaccine Schedule for people moderately or severely immunocompromised

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

CDC considers COVID-19 vaccination to be contraindicated or a precaution in the following situations:

Table 4. Contraindications and precautions to COVID-19 vaccination

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine*	Contraindication	Do not vaccinate with the same type of COVID-19 vaccine.*
History of a known diagnosed allergy to a component of the COVID-19 vaccine†	Contraindication	Do not vaccinate with a COVID-19 vaccine that contains that component.*
History of anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])*	Precaution	The benefit of vaccination outweighs the risks for most people.*
People with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the **same type of COVID-19 vaccine.***	Precaution	
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the **other types of COVID-19 vaccines.** **Special situation**: People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines.*†	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis after a dose of an **mRNA or Novavax COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis for additional considerations.

Abbreviations: MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

Contraindications and Precautions (1)

- SOURCE: CDC

Can you interchange mRNA COVID-19 vaccine products

- People ages 6 months–4 years who are unvaccinated or previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive only bivalent mRNA vaccine dose(s) from the same vaccine manufacturer.
- People age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
- People age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
- People ages 6 years and older who are unvaccinated or previously received 1 or more doses of any monovalent COVID-19 vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
- Consult the COVID vaccination schedules for age-specific information.

Co-administration with other 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 (Mpox vaccine)

Best practices for multiple injections

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable.
- Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible. (e.g. High dose flu vaccine and COVID-19 vaccine)
- See ACIP's general best practices and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book) for further information.

COVID-19 Vaccines when Transitioning from a younger to older age group

- In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination (See Table 1 and Table 2 at the reference below).
- If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group for all subsequent doses with the following exception: FDA EUA requires that children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 years to 5 years during the 3-dose vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).
- Additionally, children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border).

COVID-19 Vaccine Interim Clinical Considerations
Vaccine counseling

- Before vaccination, counsel patients about expected local and systemic reactions and the availability of the v-safe program
- CDC VIS is available for FDA approved COVID-19 vaccines
- Give appropriate EUA Fact sheets/VIS to vaccine recipients

SOURCE: CDC

- **Observation after COVID-19 vaccination**

30 minutes:

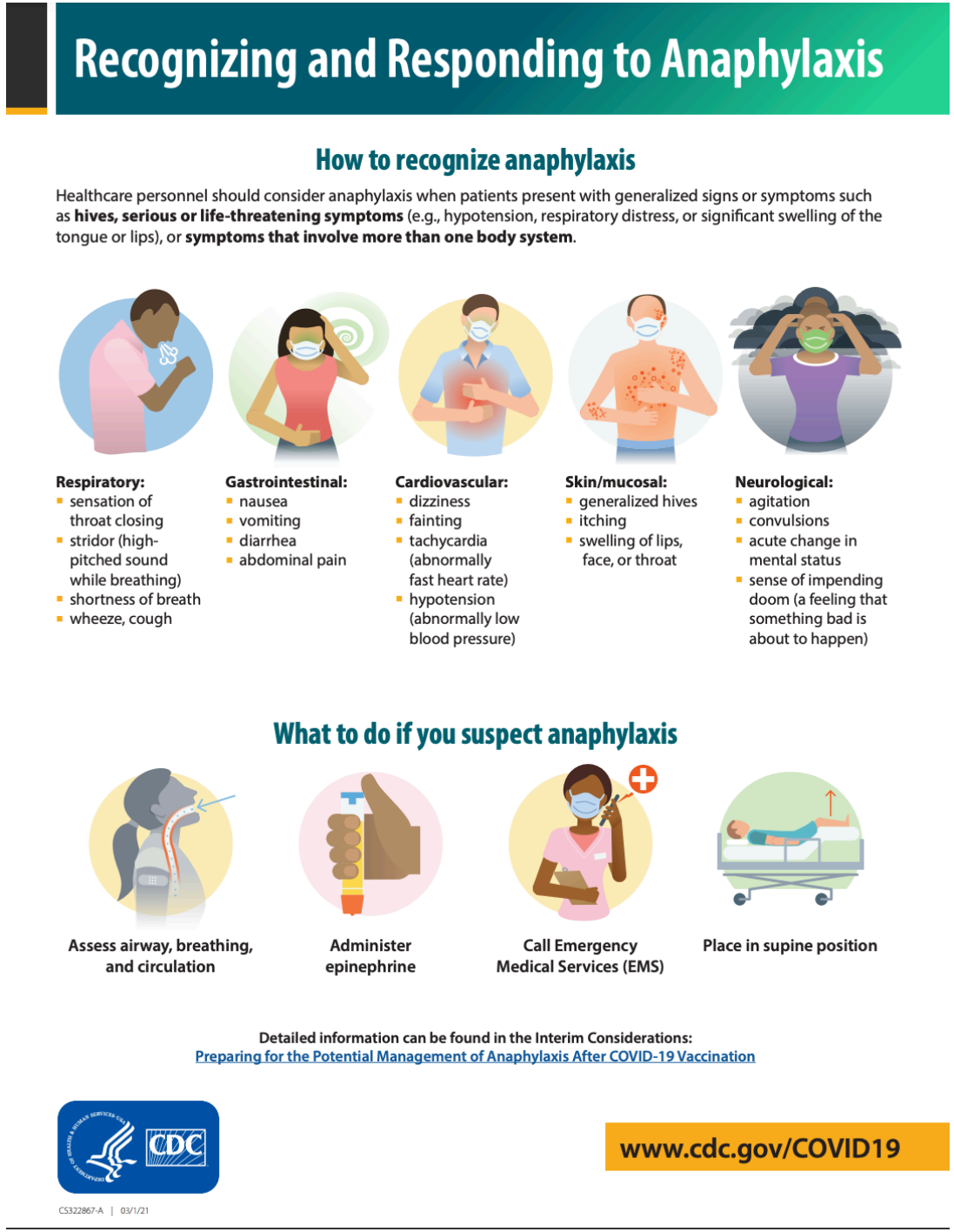
-An allergy-related contraindication to a different type of COVID-19 vaccine

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

-Anaphylaxis after non-COVID-19 vaccines or injectable therapies

15 minutes:

All other people



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

COVID-19 Vaccine Errors

Dilution Errors

- If an incorrect amount of diluent is used, the patient may get too much or too little vaccine. Using the wrong diluent.

Administering vaccine vial contents WITHOUT adding diluent first

Product Packaging and Labeling Issues

- Vials of vaccine and Regeneron antibodies have been mixed up, partially due to similar packaging and inattention to the vial label

Waste of Vaccine Doses

- Doses wasted due to canceled appointments or leftovers at the end of the clinic day
- Use of certain syringes that contain a dead space between the hub and needle, thus wasting small amounts of vaccine

Errors with Scheduling the 2nd Dose

SOURCE: ISMP and SOURCE: CDC

COVID-19 Vaccine Administration errors

- Appendix D. Vaccine administration errors and deviations
- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html

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.

Improper Immunization Administration Practices with Any Vaccine

SOURCE: CDC
SOURCE: IMMUNIZATION ACTION COALITION

DO NOT re-use needles or syringes, due to the possibility of:

- Transmission of blood-borne viruses (HCV, HBV, HIV)
- Referral of providers to licensing boards for disciplinary action
- Malpractice suits filed by patients

Never use partial doses from 2 or more vials to obtain a dose of vaccine.

Per OSHA and the CDC, you MAY use the same needle to withdraw a diluent, inject this into a lyophilized vaccine vial, and then administer to a patient, providing the needle or syringe has not otherwise been contaminated or damaged.

Vaccine Administration Best practices – Route, Dose, Site, Needle Size

Administering Vaccines: Dose, Route, Site, and Needle Size

Vaccine	Dose	Route
COVID-19	Pfizer-BioNTech •age 5 to <12 yrs: 0.2 mL pediatric formulation ("orange cap") •age ≥12 yrs: 0.3 mL adult/adolescent formulation for primary and booster doses Moderna; ≥18 yrs: 0.5 mL primary series*; 0.25 mL booster Janssen: ≥18 yrs: 0.5 mL for primary & booster doses	IM
Diphtheria, Tetanus, Pertussis (DTaP, DT, Tdap, Td)	0.5 mL	IM
***Haemophilus influenzae* type b** (Hib)	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL ≥19 yrs: 1.0 mL	IM
Hepatitis B (HepB) *Persons 11–15 yrs may be given Recombivax HB (Merck) 1.0 mL adult formulation on a 2-dose schedule.*	Engerix-B; Recombivax HB ≤19 yrs: 0.5 mL ≥20 yrs: 1.0 mL Heplisav-B ≥18 yrs: 0.5 mL	IM
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL (0.1 mL in each nostril)	Intranasal spray
Influenza, inactivated (IIV); for ages 6–35 months	Afluria: 0.25 mL Fluzone: 0.25 or 0.5 mL Fluarix, Flucelvax, FluLaval: 0.5 mL	IM
Influenza, inactivated (IIV), ≥3 yrs; **recombinant** (RIV), ≥18 yrs; **high-dose** (HD-IIV) ≥65 yrs	0.5 mL FluZone HD: 0.7 mL	IM
Measles, Mumps, Rubella (MMR)	0.5 mL	Subcut
Meningococcal serogroups A, C, W, Y (MenACWY)	0.5 mL	IM
Meningococcal serogroup B (MenB)	0.5 mL	IM
Pneumococcal conjugate (PCV)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM or Subcut
Polio, inactivated (IPV)	0.5 mL	IM or Subcut
Rotavirus (RV)	Rotarix: 1.0 mL Rotateq: 2.0 mL	Oral
Varicella (VAR)	0.5 mL	Subcut
Zoster (Zos)	Shingrix: 0.5† mL	IM
Combination Vaccines		
DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix; Quadracel) DTaP-IPV-Hib-HepB (Vaxelis)	0.5 mL	IM
MMRV (ProQuad)	≤12 yrs: 0.5 mL	Subcut
HepA-HepB (Twinrix)	≥18 yrs: 1.0 mL	IM

* If immunocompromised, Moderna 0.5 mL for 3-dose primary series, then 0.25 mL for booster dose.

† The Shingrix vial might contain more than 0.5 mL. Do not administer more than 0.5 mL.

Injection Site and Needle Size

Subcutaneous (Subcut) injection
Use a 23–25 gauge needle. Choose the injection site that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Infants (1–12 mos)	5/8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps

Intramuscular (IM) injection
Use a 22–25 gauge needle. Choose the injection site and needle length that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	5/8"[1]	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 years)	1–1¼"	Anterolateral thigh muscle[2]
	5/8–1"[1]	Deltoid muscle of arm
Children (3–10 years)	5/8–1"[1]	Deltoid muscle of arm[2]
	1–1¼"	Anterolateral thigh muscle
Adolescents and teens (11–18 years)	5/8–1"[1]	Deltoid muscle of arm[2]
	1–1½"	Anterolateral thigh muscle
Adults 19 years or older		
Female or male <130 lbs	5/8–1"[1]	Deltoid muscle of arm
Female or male 130–152 lbs	1"	Deltoid muscle of arm
Female 153–200 lbs Male 153–260 lbs	1–1½"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½"	Deltoid muscle of arm
Female or male, any weight	1½"	Anterolateral thigh muscle

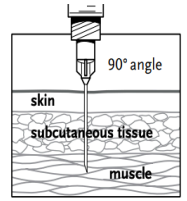
[1] A 5/8" needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

[2] Preferred site

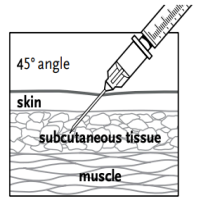
NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.

Intranasal (NAS) administration of Flumist (LAIV) vaccine

Intramuscular (IM) injection



Subcutaneous (Subcut) injection



IMMUNIZATION ACTION COALITION Saint Paul, Minnesota · 651-647-9009 · www.immunize.org · www.vaccineinformation.org
www.immunize.org/catg.d/p3085.pdf . Item #P3085 (11/21)

https://www.immunize.org/catg.d/p3085.pdf

How to administer IM and SC vaccine injections

How to Administer Intramuscular and Subcutaneous Vaccine Injections

Administration by the Intramuscular (IM) Route

Administer these vaccines via IM route

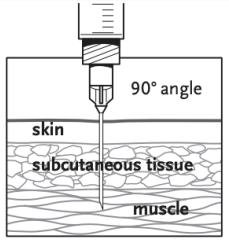
- Diphtheria-tetanus-pertussis (DTaP, Tdap)
- Diphtheria-tetanus (DT, Td)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Human papillomavirus (HPV)
- Inactivated influenza (IIV)
- Meningococcal serogroups A,C,W, Y (MenACWY)
- Meningococcal serogroup B (MenB)
- Pneumococcal conjugate (PCV13)
- Zoster, recombinant (RZV)

Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) vaccines either IM or subcutaneously (Subcut).

PATIENT AGE	INJECTION SITE	NEEDLE SIZE
Newborn (0–28 days)	Anterolateral thigh muscle	5/8"* (22–25 gauge)
Infant (1–12 mos)	Anterolateral thigh muscle	1" (22–25 gauge)
Toddler (1–2 years)	Anterolateral thigh muscle	1–1¼" (22–25 gauge)
	Alternate site: Deltoid muscle of arm if muscle mass is adequate	5/8*–1" (22–25 gauge)
Children (3–10 years)	Deltoid muscle (upper arm)	5/8*–1" (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1¼" (22–25 gauge)
Children and adults (11 years and older)	Deltoid muscle (upper arm)	5/8†–1" (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1½" (22–25 gauge)

* A 5/8" needle usually is adequate for neonates (first 28 days of life), preterm infants, and children ages 1 through 18 years if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90° angle to the skin.

† A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90° angle to the skin; a 1" needle is sufficient in patients weighing 130–152 lbs (60–70 kg); a 1–1½" needle is recommended in women weighing 153–200 lbs (70–90 kg) and men weighing 153–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing more than 200 lbs (91 kg) or men weighing more than 260 lbs (118 kg).



Needle insertion

Use a needle long enough to reach deep into the muscle.

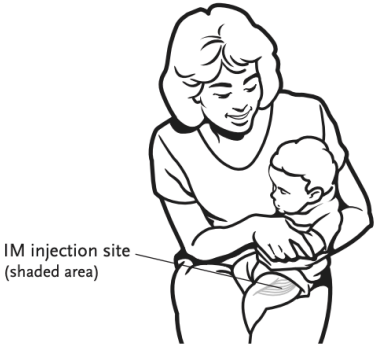
Insert needle at a 90° angle to the skin with a quick thrust.

(Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.¶)

Multiple injections given in the same extremity should be separated by a minimum of 1", if possible.

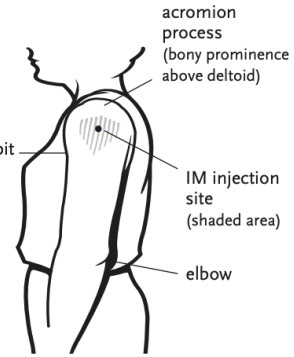
¶ CDC. "General Best Practices Guidelines for Immunization: Best Practices Guidance of the ACIP" at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

Intramuscular (IM) injection site for infants and toddlers



Insert needle at a 90° angle into the anterolateral thigh muscle.

Intramuscular (IM) injection site for children and adults



Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2") below the acromion process. See the diagram. To avoid causing an injury, do not inject too high (near the acromion process) or too low.

CONTINUED ON THE NEXT PAGE ▶

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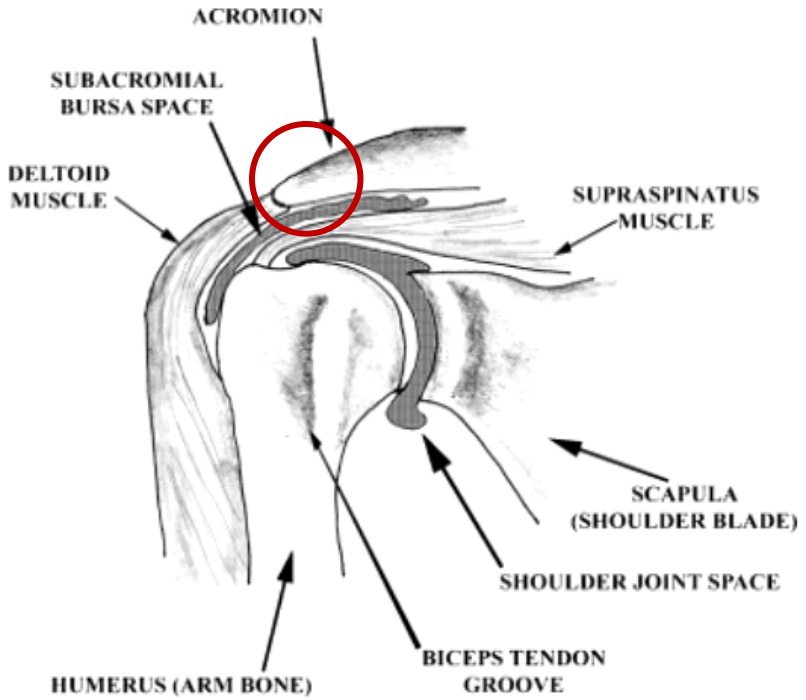
www.immunize.org/catg.d/p2020.pdf • Item #P2020 (1/18)

https://www.immunize.org/catg.d/p2020.pdf

SIRVA

Shoulder anatomy



HRSA Healthcare Systems

4

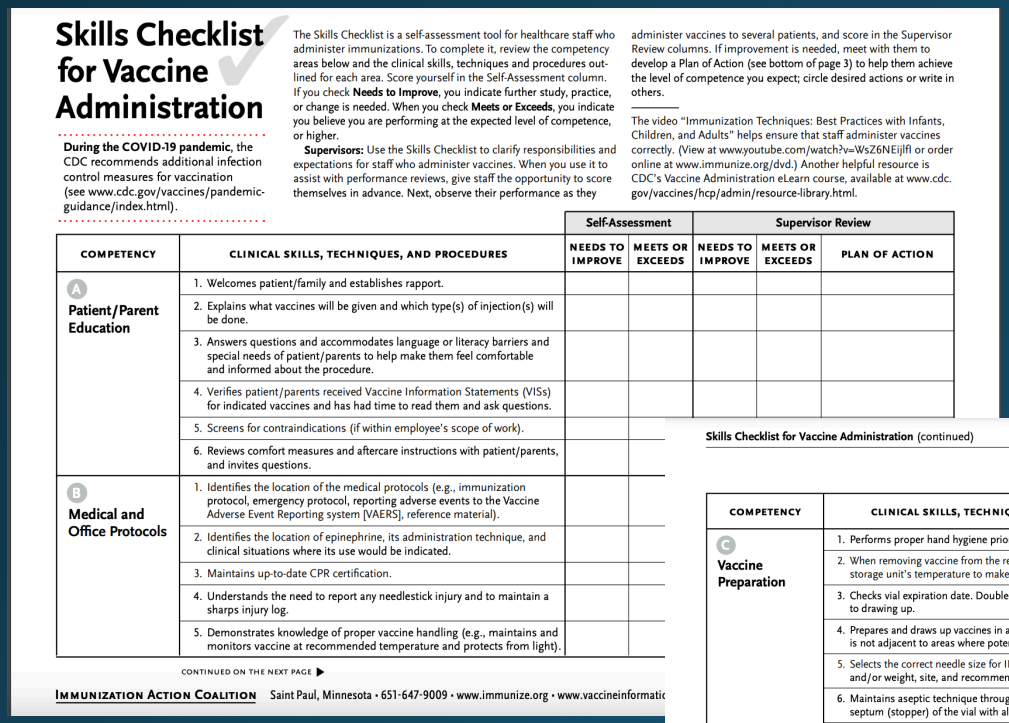
SIRVA = Shoulder Injury Related to Vaccine Administration

TIPS TO AVOID THIS INJURY

- **Landmark the site---don't "eyeball" it**
- **If possible, be seated to vaccinate a seated pt.**
- **Expose the shoulder completely**
- **Roll the sleeve up---don't pull the shirt over the neck**
- **REMEMBER!**
  2-3 FINGERS DOWN FROM THE ACROMION

SOURCE: HHS

Training Tools: Skills Checklist for Vaccine Administration



Skills Checklist for Vaccine Administration

During the COVID-19 pandemic, the CDC recommends additional infection control measures for vaccination (see www.cdc.gov/vaccines/pandemic-guidance/index.html).

The Skills Checklist is a self-assessment tool for healthcare staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each area. Score yourself in the Self-Assessment column. If you check **Needs to Improve**, you indicate further study, practice, or change is needed. When you check **Meets or Exceeds**, you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it to assist with performance reviews, give staff the opportunity to score themselves in advance. Next, observe their performance as they administer vaccines to several patients, and score in the Supervisor Review columns. If improvement is needed, meet with them to develop a Plan of Action (see bottom of page 3) to help them achieve the level of competence you expect; circle desired actions or write in others.

The video "Immunization Techniques: Best Practices with Infants, Children, and Adults" helps ensure that staff administer vaccines correctly. (View at www.youtube.com/watch?v=WsZ6NEijlfI or order online at www.immunize.org/dvd.) Another helpful resource is CDC's Vaccine Administration eLearn course, available at www.cdc.gov/vaccines/hcp/admin/resource-library.html.

COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	Self-Assessment: NEEDS TO IMPROVE	Self-Assessment: MEETS OR EXCEEDS	Supervisor Review: NEEDS TO IMPROVE	Supervisor Review: MEETS OR EXCEEDS	Supervisor Review: PLAN OF ACTION
A Patient/Parent Education	1. Welcomes patient/family and establishes rapport.					
	2. Explains what vaccines will be given and which type(s) of injection(s) will be done.					
	3. Answers questions and accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received Vaccine Information Statements (VISs) for indicated vaccines and has had time to read them and ask questions.					
	5. Screens for contraindications (if within employee's scope of work).					
	6. Reviews comfort measures and aftercare instructions with patient/parents, and invites questions.					
B Medical and Office Protocols	1. Identifies the location of the medical protocols (e.g., immunization protocol, emergency protocol, reporting adverse events to the Vaccine Adverse Event Reporting system [VAERS], reference material).					
	2. Identifies the location of epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
	5. Demonstrates knowledge of proper vaccine handling (e.g., maintains and monitors vaccine at recommended temperature and protects from light).					

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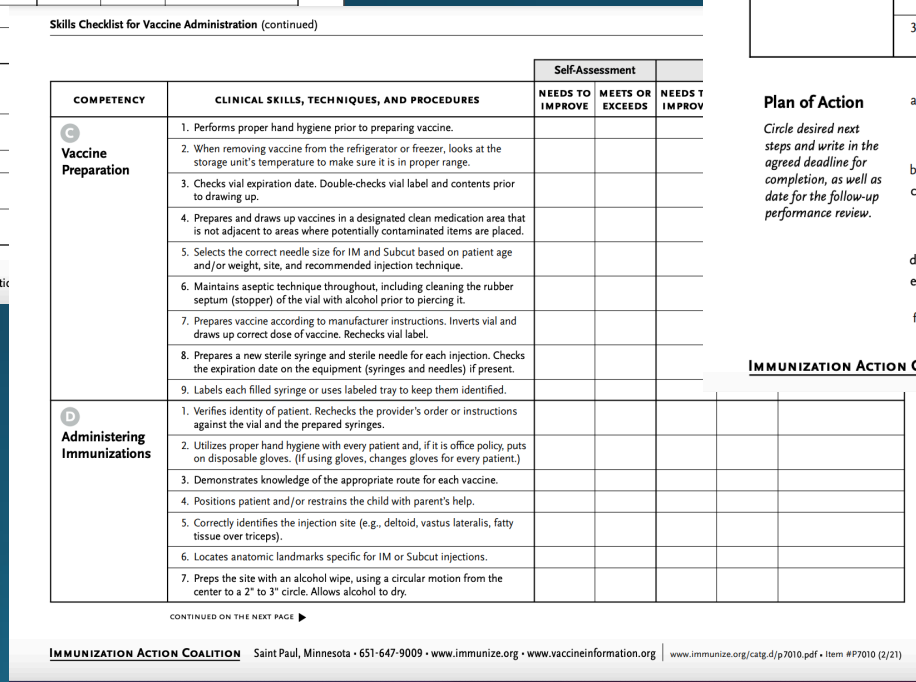

COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	Self-Assessment: NEEDS TO IMPROVE	Self-Assessment: MEETS OR EXCEEDS	Supervisor Review: NEEDS TO IMPROV
C Vaccine Preparation	1. Performs proper hand hygiene prior to preparing vaccine.			
	2. When removing vaccine from the refrigerator or freezer, looks at the storage unit's temperature to make sure it is in proper range.			
	3. Checks vial expiration date. Double-checks vial label and contents prior to drawing up.			
	4. Prepares and draws up vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.			
	5. Selects the correct needle size for IM and Subcut based on patient age and/or weight, site, and recommended injection technique.			
	6. Maintains aseptic technique throughout, including cleaning the rubber septum (stopper) of the vial with alcohol prior to piercing it.			
	7. Prepares vaccine according to manufacturer instructions. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.			
	8. Prepares a new sterile syringe and sterile needle for each injection. Checks the expiration date on the equipment (syringes and needles) if present.			
	9. Labels each filled syringe or uses labeled tray to keep them identified.			
D Administering Immunizations	1. Verifies identity of patient. Rechecks the provider's order or instructions against the vial and the prepared syringes.			
	2. Utilizes proper hand hygiene with every patient and, if it is office policy, puts on disposable gloves. (If using gloves, changes gloves for every patient.)			
	3. Demonstrates knowledge of the appropriate route for each vaccine.			
	4. Positions patient and/or restrains the child with parent's help.			
	5. Correctly identifies the injection site (e.g., deltoid, vastus lateralis, fatty tissue over triceps).			
	6. Locates anatomic landmarks specific for IM or Subcut injections.			
	7. Preps the site with an alcohol wipe, using a circular motion from the center to a 2" to 3" circle. Allows alcohol to dry.			

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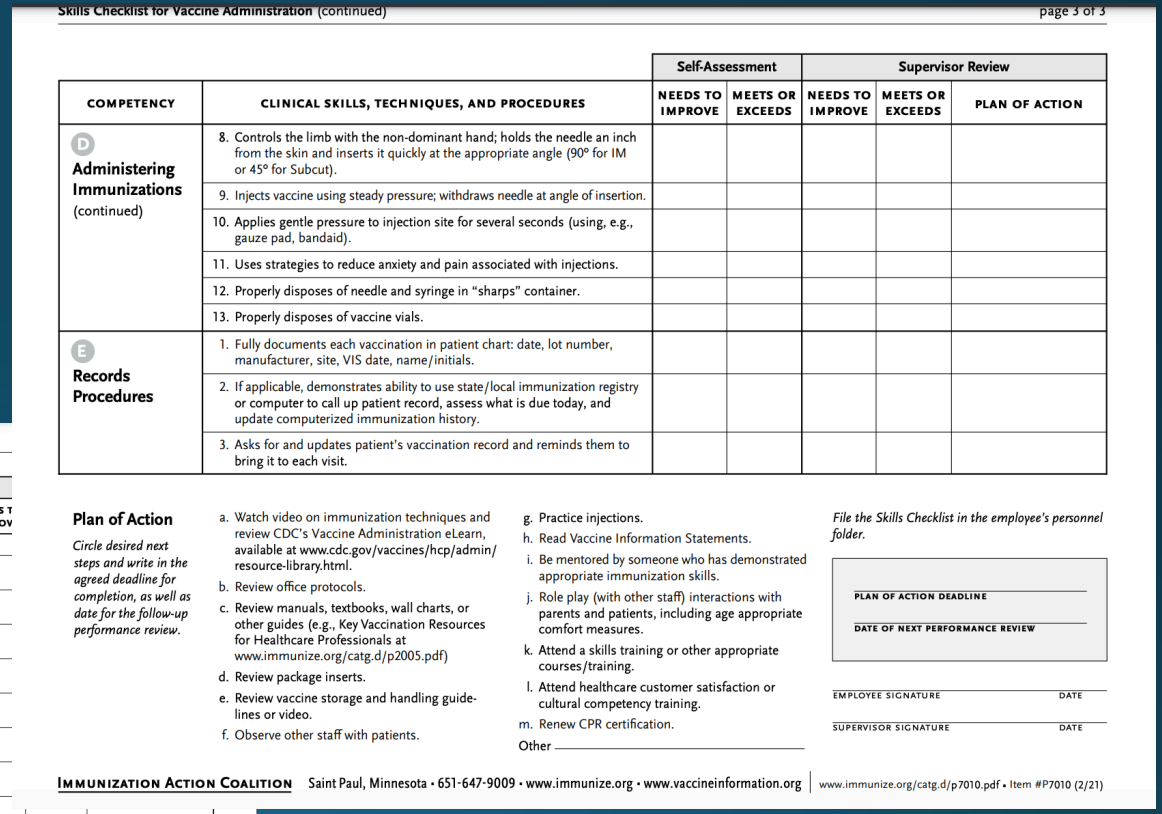


COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	Self-Assessment: NEEDS TO IMPROVE	Self-Assessment: MEETS OR EXCEEDS	Supervisor Review: NEEDS TO IMPROVE	Supervisor Review: MEETS OR EXCEEDS	Supervisor Review: PLAN OF ACTION
D Administering Immunizations (continued)	8. Controls the limb with the non-dominant hand; holds the needle an inch from the skin and inserts it quickly at the appropriate angle (90° for IM or 45° for Subcut).					
	9. Injects vaccine using steady pressure; withdraws needle at angle of insertion.					
	10. Applies gentle pressure to injection site for several seconds (using, e.g., gauze pad, bandaid).					
	11. Uses strategies to reduce anxiety and pain associated with injections.					
	12. Properly disposes of needle and syringe in "sharps" container.					
	13. Properly disposes of vaccine vials.					
E Records Procedures	1. Fully documents each vaccination in patient chart: date, lot number, manufacturer, site, VIS date, name/initials.					
	2. If applicable, demonstrates ability to use state/local immunization registry or computer to call up patient record, assess what is due today, and update computerized immunization history.					
	3. Asks for and updates patient's vaccination record and reminds them to bring it to each visit.					

Plan of Action

Circle desired next steps and write in the agreed deadline for completion, as well as date for the follow-up performance review.

a. Watch video on immunization techniques and review CDC's Vaccine Administration eLearn, available at www.cdc.gov/vaccines/hcp/admin/resource-library.html.
b. Review office protocols.
c. Review manuals, textbooks, wall charts, or other guides (e.g., Key Vaccination Resources for Healthcare Professionals at www.immunize.org/catg.d/p2005.pdf)
d. Review package inserts.
e. Review vaccine storage and handling guidelines or video.
f. Observe other staff with patients.
g. Practice injections.
h. Read Vaccine Information Statements.
i. Be mentored by someone who has demonstrated appropriate immunization skills.
j. Role play (with other staff) interactions with parents and patients, including age appropriate comfort measures.
k. Attend a skills training or other appropriate courses/training.
l. Attend healthcare customer satisfaction or cultural competency training.
m. Renew CPR certification.

Other _____

File the Skills Checklist in the employee's personnel folder.

PLAN OF ACTION DEADLINE _____

DATE OF NEXT PERFORMANCE REVIEW _____

EMPLOYEE SIGNATURE _____ DATE _____

SUPERVISOR SIGNATURE _____ DATE _____

https://www.immunize.org/catg.d/p7010.pdf

Administration

Age	Needle gauge	Needle length	Injection Site
6 months through 2 years	22- to 25-gauge needle	1-inch (25mm) needle*	Vastus lateralis in the anterolateral thigh
3 years and older	22- to 25-gauge needle	5/8- to 1-inch (25mm) needle†	Deltoid muscle

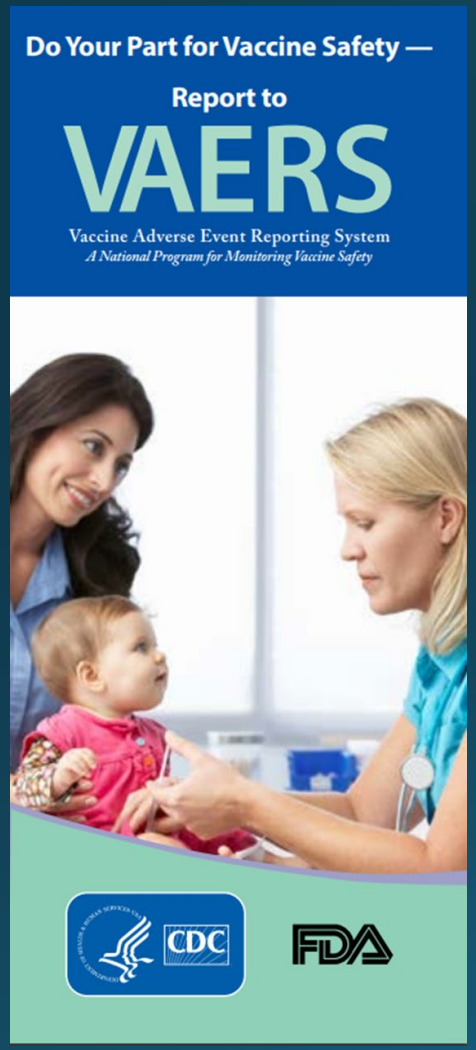
*Use a 5/8- to 1-inch (16 to 5 mm) if using the deltoid muscle. A 5/8-inch needle may be used only if the skin is stretched tightly and the subcutaneous tissue is not bunched.
† Use a 1- to 1.25-inch (25–32 mm) needle if administering vaccine in the vastus lateralis muscle in the anterolateral thigh

- Intramuscular (IM) Injection Infants 11 months of age and younger: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM -Injection-Infants-508.pdf
- Intramuscular (IM) Injection Children 1 through 2 years of age: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM -Injection-1-2-Years-508.pdf
- Intramuscular (IM) Injection Children 3 through 6 years of age: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM -Injection-3-6-Years.pdf

Vaccine administration

- Intramuscular (IM) Injection Infants 11 months of age and younger: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-Infants-508.pdf
- Intramuscular (IM) Injection Children 1 through 2 years of age: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-1-2-Years-508.pdf
- • Intramuscular (IM) Injection Children 3 through 6 years of age: https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-3-6-Years.pdf

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**

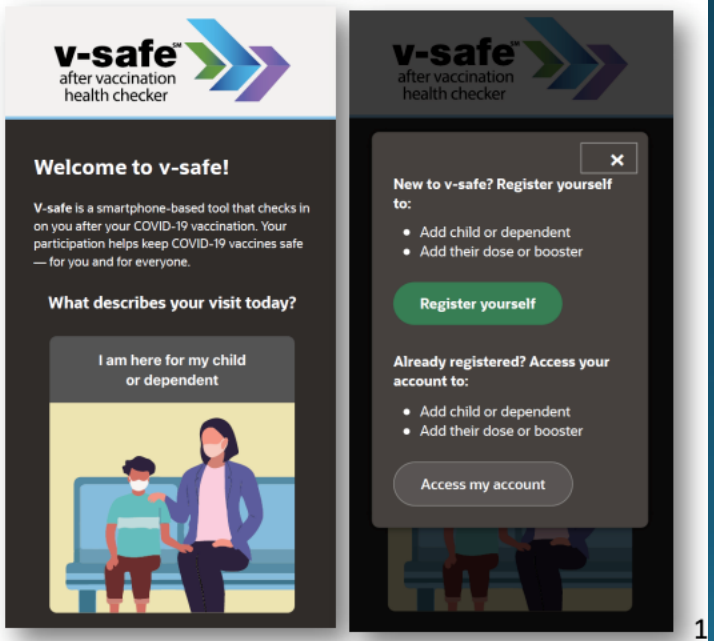
  ✓ On-line reporting at http://verp.ismp.org/
  ✓ Report even if no adverse events associated with incident
  ✓ Will help identify sources of errors to help develop prevention strategies

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/



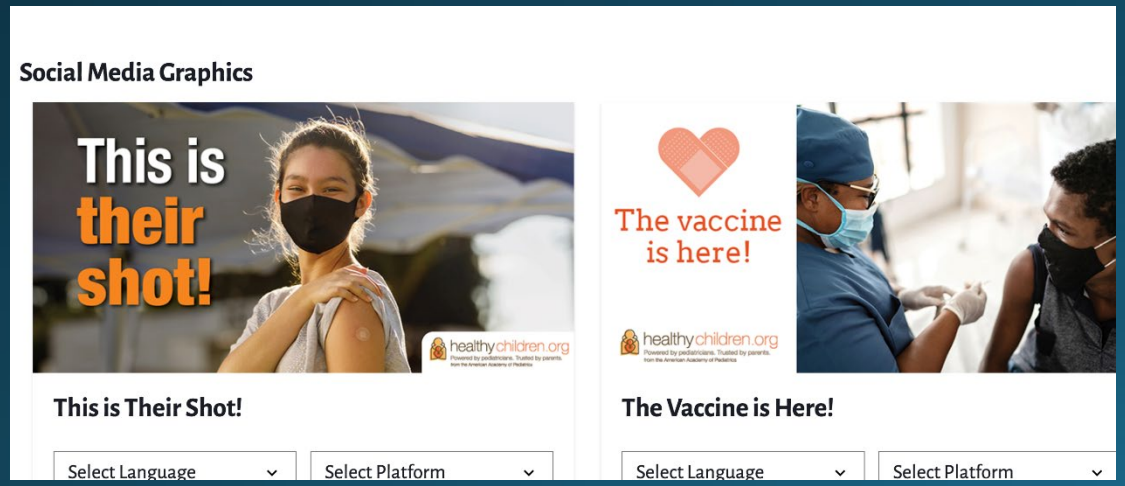
There may be changes after June 30, 2023

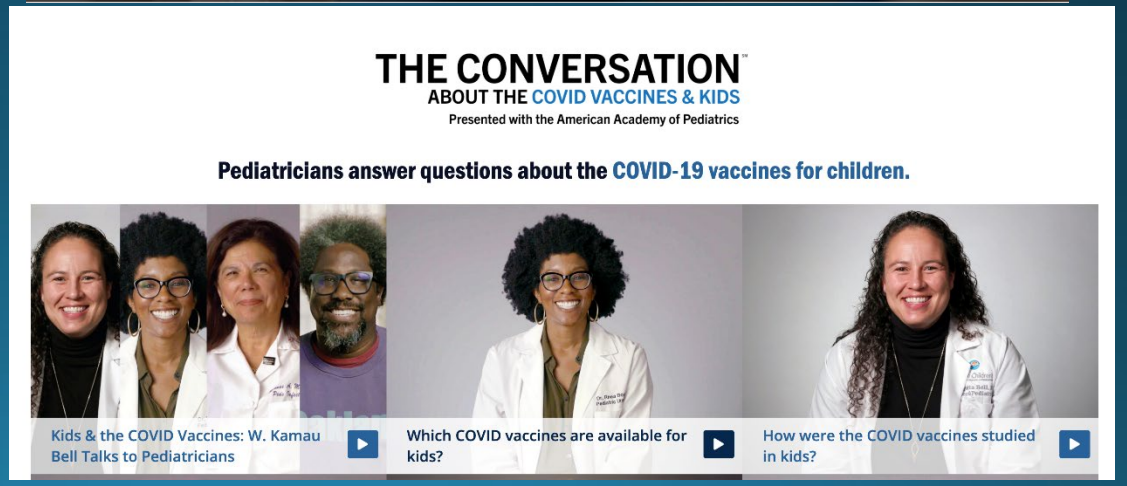
Health Care Provider Role

- Set a good example. Get vaccinated yourself!
- Recommend the vaccine (Engage in effective COVID-19 vaccine conversations)
  - Start from a place of empathy and understanding
  - Assume patients will want to be vaccinated but may not know what to expect
  - Discuss anticipated side effects
  - Give a strong recommendation! Listen to and respond to patient questions
- Encourage registration in v-safe
- Document the vaccine in GRITS and on a personal record for the patient

SOURCE:CDC

AAP Resources for Providers and Parents (Vaccine Campaign Toolkit)





SOURCE:AAP

5/4/2023

Vaccine Administration

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

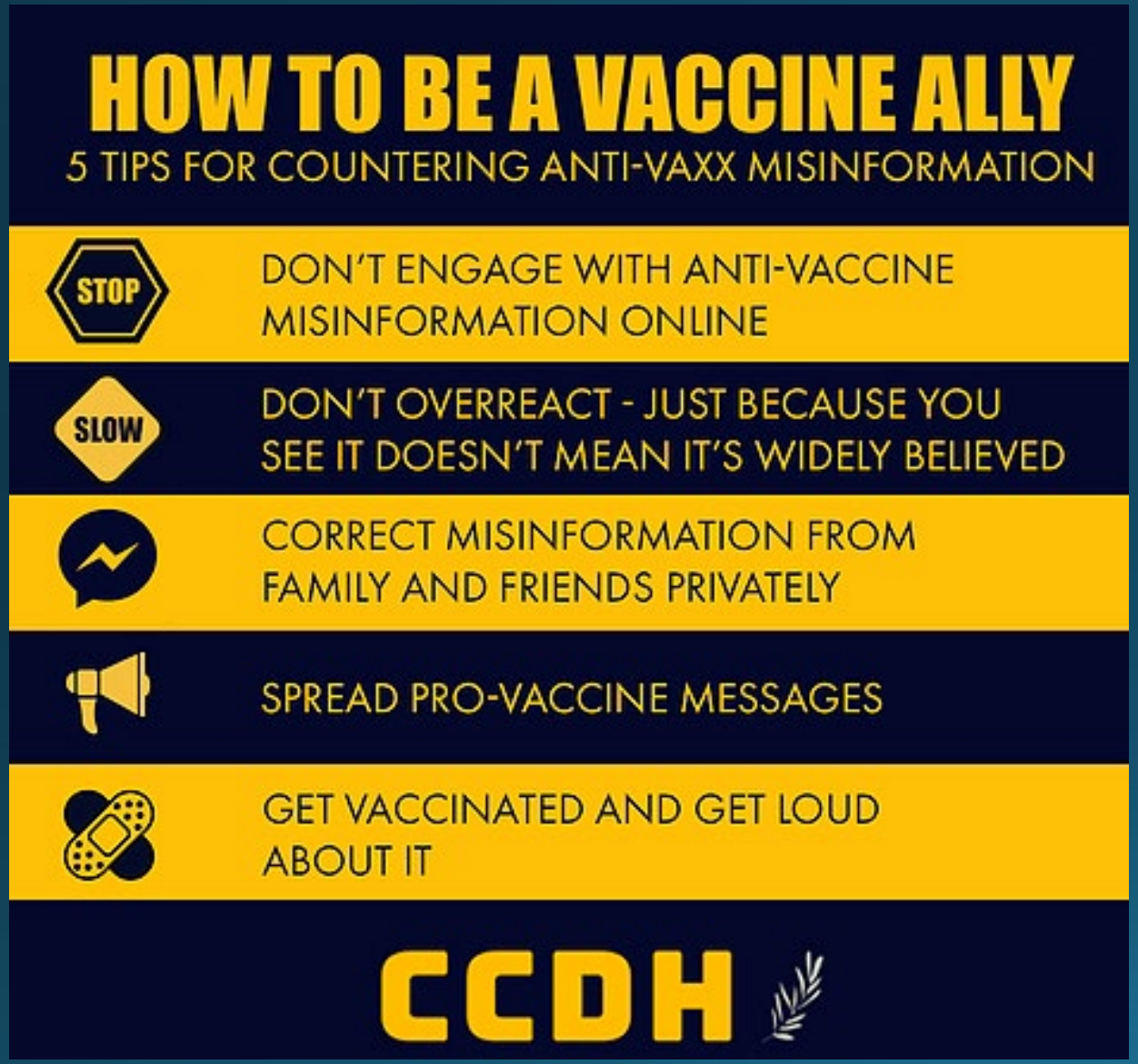
AAP and Greater Than COVID

GREATER THAN COVID

NEW VIDEOS EXPAND THE CONVERSATION: Pediatricians Answer Questions about Children and the COVID-19 Vaccines

THE CONVERSATION / LA CONVERSACIÓN expands to address information needs about the COVID-19 vaccines available to children 12 and older and the status of vaccines for younger children. Produced by KFF under its **Greater Than COVID** public information response, this campaign is presented with the American Academy of Pediatrics. The new videos join the expansive living video library featuring Black and Latinx health care workers answering common questions on the COVID vaccines (available in English and Spanish). YouTube/Google, Facebook, Twitter and Pinterest are supporting distribution.

THE CONVERSATION℠
ABOUT THE COVID VACCINES & KIDS
Presented with the American Academy of Pediatrics



How to Stop the Spread of Misinformation about COVID-19 Vaccines

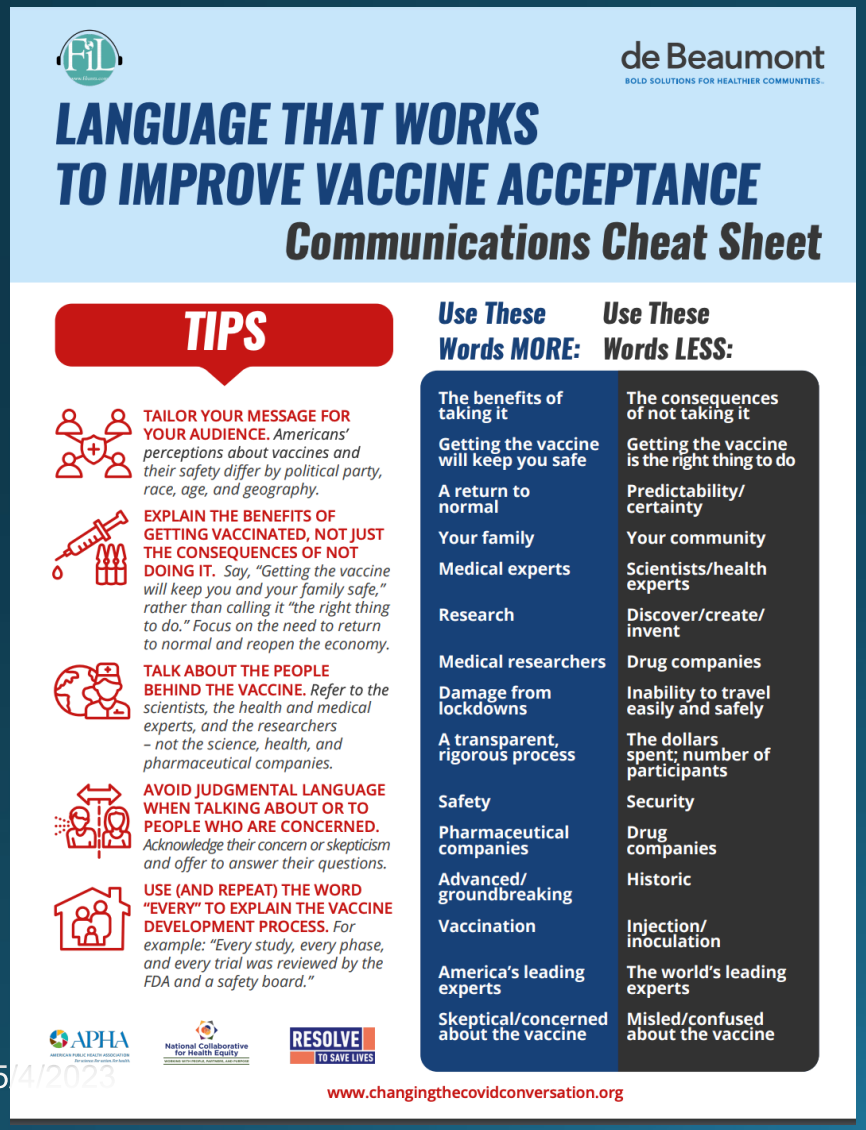
SOURCE:COUNTERHATE

VitalTalk COVID-Ready Communication Playbook

- Persons holding extreme negative views on vaccines are unlikely to be swayed
- These skills outlined here are designed to address people who are not sure or are deciding
  - Start with open-ended questions that do not assume vaccine acceptance
  - Acknowledge patient concerns without judging
  - Avoid criticizing the patient's information sources; cite your experience and/or point them to high quality sources
  - Show awareness of your status as a messenger
  - Link vaccine acceptance to the patient's hopes and goals

SOURCE:VITALTALK

Changing the Covid Conversation



de Beaumont
BOLD SOLUTIONS FOR HEALTHIER COMMUNITIES

LANGUAGE THAT WORKS TO IMPROVE VACCINE ACCEPTANCE

Communications Cheat Sheet

TIPS

TAILOR YOUR MESSAGE FOR YOUR AUDIENCE. *Americans' perceptions about vaccines and their safety differ by political party, race, age, and geography.*

EXPLAIN THE BENEFITS OF GETTING VACCINATED, NOT JUST THE CONSEQUENCES OF NOT DOING IT. *Say, "Getting the vaccine will keep you and your family safe," rather than calling it "the right thing to do." Focus on the need to return to normal and reopen the economy.*

TALK ABOUT THE PEOPLE BEHIND THE VACCINE. *Refer to the scientists, the health and medical experts, and the researchers – not the science, health, and pharmaceutical companies.*

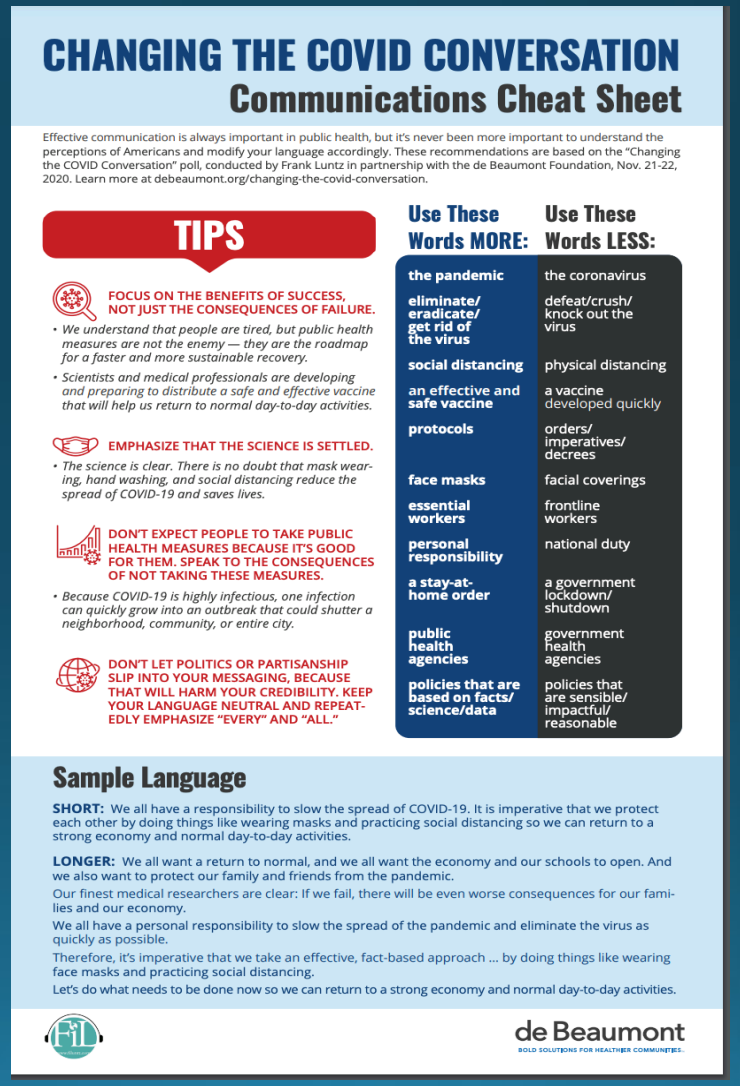
AVOID JUDGMENTAL LANGUAGE WHEN TALKING ABOUT OR TO PEOPLE WHO ARE CONCERNED. *Acknowledge their concern or skepticism and offer to answer their questions.*

USE (AND REPEAT) THE WORD "EVERY" TO EXPLAIN THE VACCINE DEVELOPMENT PROCESS. *For example: "Every study, every phase, and every trial was reviewed by the FDA and a safety board."*

Use These Words MORE:	Use These Words LESS:
The benefits of taking it	The consequences of not taking it
Getting the vaccine will keep you safe	Getting the vaccine is the right thing to do
A return to normal	Predictability/ certainty
Your family	Your community
Medical experts	Scientists/health experts
Research	Discover/create/ invent
Medical researchers	Drug companies
Damage from lockdowns	Inability to travel easily and safely
A transparent, rigorous process	The dollars spent; number of participants
Safety	Security
Pharmaceutical companies	Drug companies
Advanced/ groundbreaking	Historic
Vaccination	Injection/ inoculation
America's leading experts	The world's leading experts
Skeptical/concerned about the vaccine	Misled/confused about the vaccine

APHA · National Collaborative for Health Equity · RESOLVE TO SAVE LIVES

www.changingthecovidconversation.org



CHANGING THE COVID CONVERSATION

Communications Cheat Sheet

Effective communication is always important in public health, but it's never been more important to understand the perceptions of Americans and modify your language accordingly. These recommendations are based on the "Changing the COVID Conversation" poll, conducted by Frank Luntz in partnership with the de Beaumont Foundation, Nov. 21-22, 2020. Learn more at debeaumont.org/changing-the-covid-conversation.

TIPS

FOCUS ON THE BENEFITS OF SUCCESS, NOT JUST THE CONSEQUENCES OF FAILURE.

- *We understand that people are tired, but public health measures are not the enemy — they are the roadmap for a faster and more sustainable recovery.*
- *Scientists and medical professionals are developing and preparing to distribute a safe and effective vaccine that will help us return to normal day-to-day activities.*

EMPHASIZE THAT THE SCIENCE IS SETTLED.

- *The science is clear. There is no doubt that mask wearing, hand washing, and social distancing reduce the spread of COVID-19 and saves lives.*

DON'T EXPECT PEOPLE TO TAKE PUBLIC HEALTH MEASURES BECAUSE IT'S GOOD FOR THEM. SPEAK TO THE CONSEQUENCES OF NOT TAKING THESE MEASURES.

- *Because COVID-19 is highly infectious, one infection can quickly grow into an outbreak that could shutter a neighborhood, community, or entire city.*

DON'T LET POLITICS OR PARTISANSHIP SLIP INTO YOUR MESSAGING, BECAUSE THAT WILL HARM YOUR CREDIBILITY. KEEP YOUR LANGUAGE NEUTRAL AND REPEATEDLY EMPHASIZE "EVERY" AND "ALL."

Use These Words MORE:	Use These Words LESS:
the pandemic	the coronavirus
eliminate/ eradicate/ get rid of the virus	defeat/crush/ knock out the virus
social distancing	physical distancing
an effective and safe vaccine	a vaccine developed quickly
protocols	orders/ imperatives/ decrees
face masks	facial coverings
essential workers	frontline workers
personal responsibility	national duty
a stay-at-home order	a government lockdown/ shutdown
public health agencies	government health agencies
policies that are based on facts/ science/data	policies that are sensible/ impactful/ reasonable

Sample Language

SHORT: We all have a responsibility to slow the spread of COVID-19. It is imperative that we protect each other by doing things like wearing masks and practicing social distancing so we can return to a strong economy and normal day-to-day activities.

LONGER: We all want a return to normal, and we all want the economy and our schools to open. And we also want to protect our family and friends from the pandemic.

Our finest medical researchers are clear: If we fail, there will be even worse consequences for our families and our economy.

We all have a personal responsibility to slow the spread of the pandemic and eliminate the virus as quickly as possible.

Therefore, it's imperative that we take an effective, fact-based approach ... by doing things like wearing face masks and practicing social distancing.

Let's do what needs to be done now so we can return to a strong economy and normal day-to-day activities.

de Beaumont
BOLD SOLUTIONS FOR HEALTHIER COMMUNITIES

SOURCE: de Beaumont

Reframing the Conversation

1. Talk about the benefits of vaccination for the common good.
2. Talk about improving vaccination access as a preventive public health measure.
3. Focus on how vaccines are beneficial to children's and adolescents' long-term health and wellbeing.
4. Use a computer updates metaphor to explain how the immune system improves its performance through vaccination.
5. Use a literacy metaphor to explain how the immune system learns how to respond to viruses through vaccination.

Anti-Vaccine Movement

- Sends confusing & conflicting information
- Uses stories, personal statements, and books to play on the emotional side of concerned parents/patients

Encourage parents/patients to:

- Get the facts
- Consider the source
- Discuss their concerns with you

Global Vaccine Awareness League

Resources for Factual & Responsible Vaccine Information

Allied Vaccine Group
MEMBER

ACP-ASIM online
American College of Physicians
American Society of Internal Medicine

American Academy of Family Physicians

vaccine safety net

www.vaccinesafetynet.org

National Foundation for Infectious Diseases

WHO OMS

NNii

immunization action coalition
IAC
immunize.org

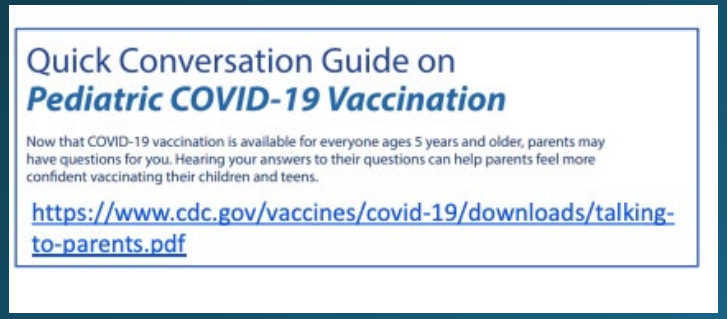
Georgia public health

Gavi
The Vaccine Alliance

CDC
SAFER • HEALTHIER • PEOPLE™

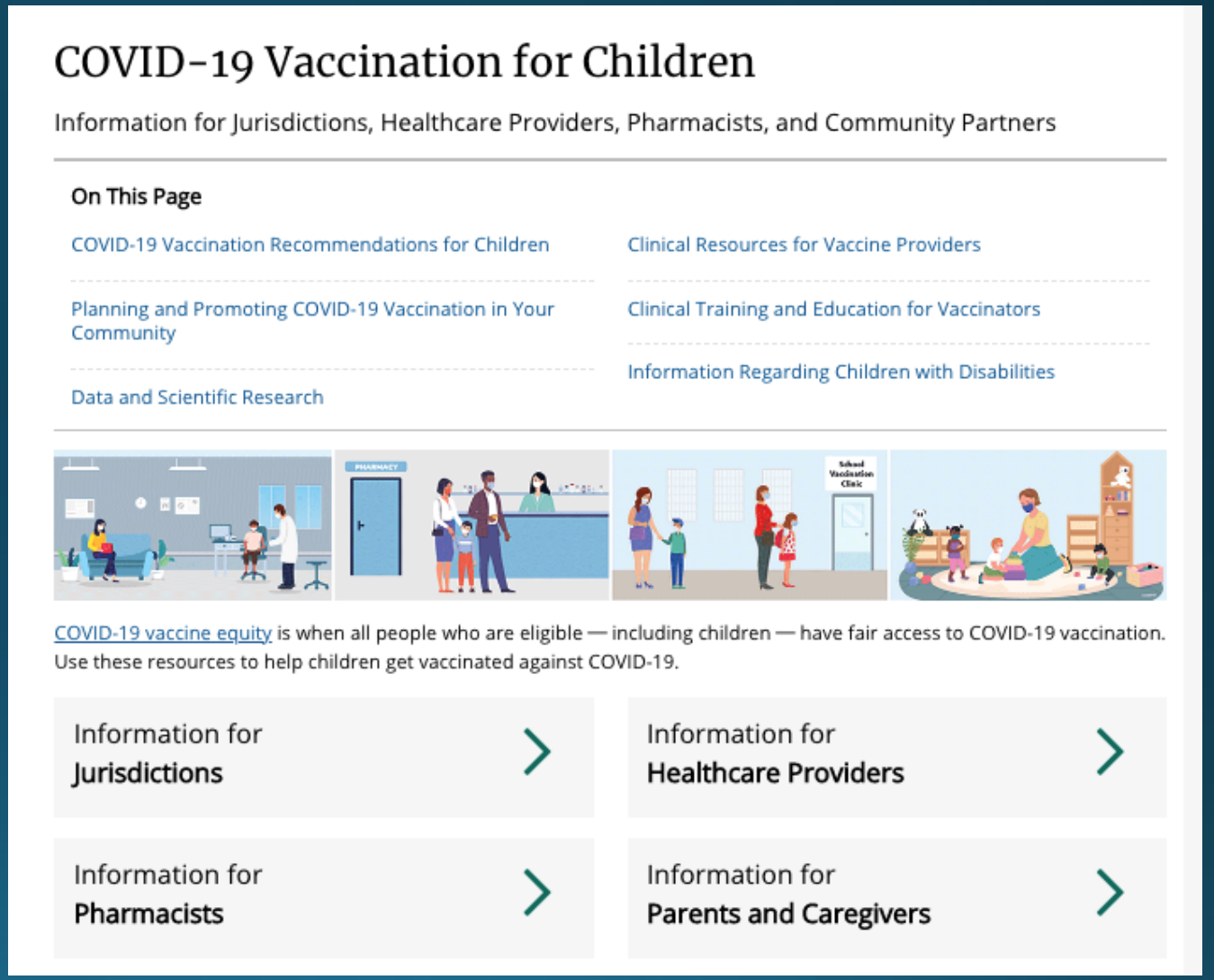
Resources for parents and providers

- Recipient Education:
  - https://www.cdc.gov/vaccines /covid-19/hcp/index.html
- COVID-19 Vaccination for Children:
  - https://www.cdc.gov/vaccines /covid19/planning/children.html


Quick Conversation Guide on
Pediatric COVID-19 Vaccination

Now that COVID-19 vaccination is available for everyone ages 5 years and older, parents may have questions for you. Hearing your answers to their questions can help parents feel more confident vaccinating their children and teens.

https://www.cdc.gov/vaccines/covid-19/downloads/talking-to-parents.pdf


COVID-19 Vaccination for Children

Information for Jurisdictions, Healthcare Providers, Pharmacists, and Community Partners

On This Page

COVID-19 Vaccination Recommendations for Children
Planning and Promoting COVID-19 Vaccination in Your Community
Data and Scientific Research
Clinical Resources for Vaccine Providers
Clinical Training and Education for Vaccinators
Information Regarding Children with Disabilities

COVID-19 vaccine equity is when all people who are eligible — including children — have fair access to COVID-19 vaccination. Use these resources to help children get vaccinated against COVID-19.

Information for **Jurisdictions**
Information for **Healthcare Providers**
Information for **Pharmacists**
Information for **Parents and Caregivers**

Patient and Health Care Provider Resources

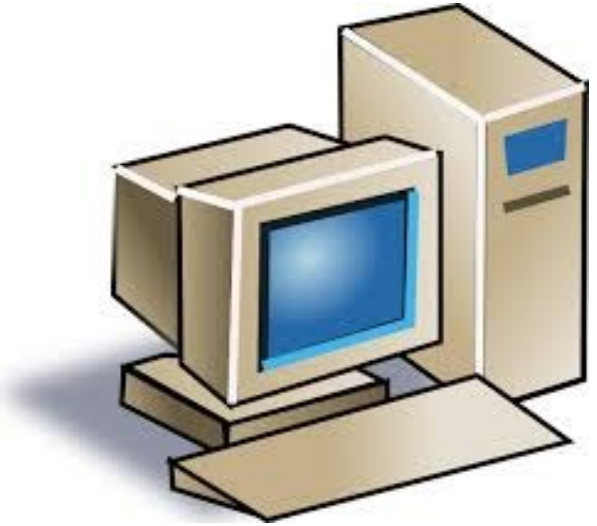
Vaccine Package Inserts

- Pfizer---https://www.fda.gov/media/144413/download (for providers)
- Moderna---https://www.fda.gov/media/144637/download (for providers)
- Janssen---https://www.fda.gov/media/146304/download (for providers)

VIS/Emergency Use Authorization (EUA) – Fact sheets for recipients

- Pfizer---https://www.fda.gov/media/144414/download (for vaccine recipients and caregivers)
- Moderna---https://www.fda.gov/media/144638/download (for vaccine recipients and caregivers)
- Janssen--- https://www.fda.gov/media/146305/download (for vaccine recipients and caregivers)

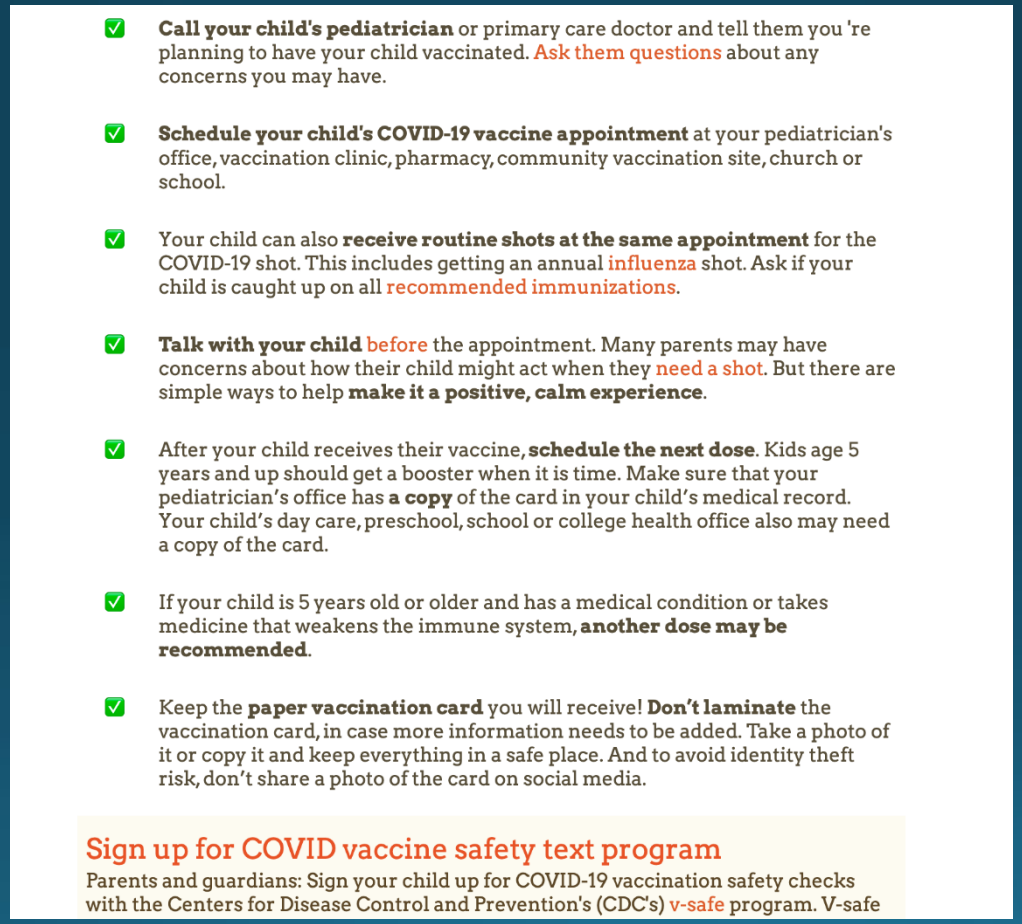
CDC resources for healthcare providers and vaccine recipients---https://www.cdc.gov/vaccines/



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

Checklist for getting kids vaccinated



- ✅ **Call your child's pediatrician** or primary care doctor and tell them you 're planning to have your child vaccinated. Ask them questions about any concerns you may have.
- ✅ **Schedule your child's COVID-19 vaccine appointment** at your pediatrician's office, vaccination clinic, pharmacy, community vaccination site, church or school.
- ✅ Your child can also **receive routine shots at the same appointment** for the COVID-19 shot. This includes getting an annual influenza shot. Ask if your child is caught up on all recommended immunizations.
- ✅ **Talk with your child** before the appointment. Many parents may have concerns about how their child might act when they need a shot. But there are simple ways to help **make it a positive, calm experience**.
- ✅ After your child receives their vaccine, **schedule the next dose**. Kids age 5 years and up should get a booster when it is time. Make sure that your pediatrician's office has **a copy** of the card in your child's medical record. Your child's day care, preschool, school or college health office also may need a copy of the card.
- ✅ If your child is 5 years old or older and has a medical condition or takes medicine that weakens the immune system, **another dose may be recommended**.
- ✅ Keep the **paper vaccination card** you will receive! **Don't laminate** the vaccination card, in case more information needs to be added. Take a photo of it or copy it and keep everything in a safe place. And to avoid identity theft risk, don't share a photo of the card on social media.

Sign up for COVID vaccine safety text program

Parents and guardians: Sign your child up for COVID-19 vaccination safety checks with the Centers for Disease Control and Prevention's (CDC's) v-safe program. V-safe

Test Your Knowledge and FAQs EPIC 2023

Can I administer a COVID-19 Vaccine and another vaccine on the same day?

Answer
YES.

- COVID-19 vaccines may **now be administered without regard to timing of other vaccines**.
- **If multiple vaccines are administered at a single visit, administer each injection in a different injection site.**
- **Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.**

•**Exception:**People who previously received a dose of any COVID-19 vaccine may be given orthopoxvirus vaccine (either JYNNEOS or ACAM2000) without a minimum interval between vaccinations.

•People who previously received orthopoxvirus vaccination (either JYNNEOS or ACAM2000), particularly adolescent or young adult males, might consider waiting 4 weeks before receiving a dose of any COVID-19 vaccine because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and the unknown risk for myocarditis and pericarditis after JYNNEOS administration.

Should someone who has had COVID-19 disease get the vaccine?

Should someone who has had COVID-19 disease get the vaccine?

- Yes!!
- People with known current SARS-CoV-2 infection should hold off on any COVID-19 vaccination, including booster vaccination, at least until they have recovered from the acute illness (if symptoms were present) and that they have met criteria to stop isolation.
- People who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).
- Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection.
- Individual factors such as the risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.
- Wear your mask, and follow all precautions if you chose to wait.

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

FAQS

What is mRNA?

Messenger RNA---found in all living cells; teaches cells to make a protein to help trigger an immune response. Cannot alter our DNA.

How do we know the vaccines are safe?

All vaccines must undergo extensive safety testing, which is reviewed by the FDA before the vaccine is licensed for widespread use.

Can a person receive the vaccine if they are taking antibiotics?

Yes, there is no interaction between the two.

Will persons be required to show proof of vaccination at work or school?

Some employers may require this.

SOURCE: CHOP SOURCE: AAP SOURCE: NFID and SOURCE: CDC

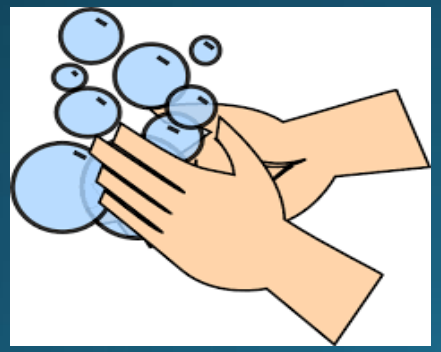
FAQS (2)

Can you get the disease from the vaccine?

No, but it may take a few weeks for the body to develop immunity so if exposed to the virus during that period of time, the person could become infected.

SOURCE: NFID and SOURCE: CDC

KEYS TO PREVENTION



Questions?

Contacts for more immunization information and resources!

National Center for Immunization and Respiratory Diseases, CDC

E-mail ▶ **NIPInfo@cdc.gov**

Hotline 800.CDC.INFO

Website **http://www.cdc.gov/vaccines**

Georgia Immunization Program

E-mail **DPH-Immunization@dph.ga.gov**

Hotline 404-657-3158

Website **http://dph.georgia.gov/immunization-section**

Immunization Action Coalition

E-mail **admin@immunize.org**

Phone 651.647.9009

Website **www.immunize.org**

Extra slides

Efficacy/Safety in Clinical Trials – Moderna (make resource)

Moderna vaccine:

- Efficacy seen after two doses of Moderna COVID-19 vaccine in children ages 6 months–5 years of age consistent with real-world vaccine effectiveness in all other ages during Omicron predominance
- Antibody levels after 2 doses in children ages 6 months–5 years produces similar antibody levels after 2 doses in individuals ages 18–24 years
- Reactogenicity post-vaccine consistent with other recommended vaccines in this age group

Clinical trial structure

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- Trial conducted from December 2021 through February 2022
- Children ages 6 months–5 years in the United States randomized **3:1** vaccine to saline placebo
  - Analyses performed separately for ages 6–23 months and 2–5 years
  - Results pooled for a combined estimate for ages 6 months–5 years
- Two doses of 25µg separated by **28 days**
- Median follow-up time post-dose 2: **2.5 months**

Efficacy/Safety in Clinical Trials - Pfizer

- Antibody levels after 3 doses in children ages 6 months–4 years produces similar antibody levels after 2 doses in individuals ages 16–24 years
- Reactogenicity post-vaccine similar after each of the 3 vaccine doses, and similar to reactions seen in placebo recipients
- Efficacy estimates difficult to interpret given small numbers and limited follow-up time – Impact of longer interval in the trial between dose 2 and dose 3 on efficacy, reactogenicity or safety are unknown

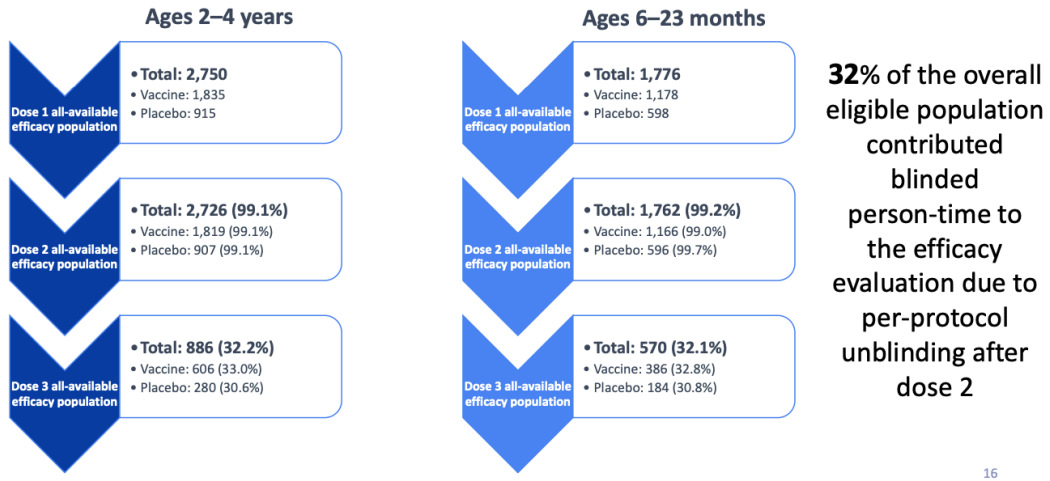
Clinical trial structure

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- Trial conducted from June 2021 through April 2022
- Children ages 6 months–4 years in the United States randomized **2:1** vaccine to saline placebo
  - Analyses performed separately for 6–23 months and 2–5 years
  - Results pooled for a combined estimate for 6 months–5 years
- Three doses, 3µg each: Dose 1 and dose 2 separated by **21 days**
  Dose 2 and dose 3 separated by at least **8 weeks**
  - Interval between dose 2 and dose 3 in the trial longer than authorized interval:
    ~16 weeks (range 8–32 weeks) for children ages 6–23 months
    ~11 weeks (range 8–34 weeks) for children ages 2–4 years
- Median follow-up time post-dose 3: **1.3 months**

13

Number of children contributed *blinded* person-time to efficacy evaluation, by age group



32% of the overall eligible population contributed blinded person-time to the efficacy evaluation due to per-protocol unblinding after dose 2

16

Moderna COVID-19 vaccine clinical trials (6 to 17-year-olds)

- Study on 6-11-year-olds (2 doses, 50 mcg, IM)
- Study on 12–17-year-olds (2 doses, 100 mcg, IM)
- Efficacy seen after two doses of Moderna COVID-19 vaccine in children and adolescents ages 6–17 years of age consistent with real-world vaccine effectiveness seen with SARS-CoV-2 variants at that time
- Antibody levels after 2 doses in children and adolescents ages 6–17 years produces similar antibody levels after 2 doses in individuals ages 18–25 years
- Reactogenicity post-vaccine consistent with what has been seen with Moderna COVID-19 vaccine in other age groups

COVID-19 VACCINE OVERVIEW

In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.

	Pfizer-BioNTech	Moderna	Novavax	Janssen
Vaccine Type	mRNA	mRNA	Protein subunit	Non-replicating Human adenovirus 26 vector
EUA granted/ Approval	EUA 6 months-15 years Approved 12 and older	EUA 6 months – 17 years Approved 18 yrs and older	EUA 12 yrs and older	EUA 18 yrs and older

5/4/2023

SOURCE: CDC Pfizer SOURCE: CDC Janssen SOURCE: CDC Moderna

Protein subunit vaccines

Novavax is the only protein subunit COVID-19 vaccine authorized for use in the U.S. under an EUA. It is authorized for persons 18 years and older

The vaccine works by:

- Instead of using the whole virus, subunit vaccines use just small pieces of a virus. These pieces can't give you the disease. They can be the protein, sugar, or casing around the virus. This kind of vaccine teaches your body how to recognize the actual virus and attack it when needed.
- Scientists created the first subunit vaccine in the 1980s to help prevent hepatitis B. This technology has been used for many other vaccines as well, including shingles and human papillomavirus (HPV). Novavax is using the same well-established technology.

Myths and facts about protein subunit vaccines:

- It cannot give someone COVID-19.
- Protein subunit vaccines do not use the live virus that causes COVID-19.
- They do not affect or interact with our DNA in any way.

SOURCE: CDC

Non-replicating Viral Vector Vaccines

Janssen is the one non-replicating viral vector vaccine currently authorized for use in the U.S. under an EUA for people 18 years and older

The vaccines work by:

- Using a modified version of a different virus to deliver instructions via a gene to a cell. Our cells are taught 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 non-replicating viral vector vaccines:

- Viral vector vaccines do not cause infection with either COVID-19 or the virus that is used as the vector.
- The genetic material does not enter the cell nucleus and does not change a person's DNA.
- Viral vector vaccines have been well-studied in clinical trials.
- Viral vector vaccines have been used to respond to recent Ebola outbreaks.
- Viral vector vaccines for COVID-19 will be rigorously tested for safety before being authorized or approved for use in the United States.

SOURCE: CDC

Novavax COVID-19 vaccine

- Authorized by FDA
- Recommended by ACIP for people 12 years and older
- **Manufacturer:** Novavax, Inc.
- **Number of Shots:** 2 doses in the primary series, given 3–8 weeks apart.
- People who are moderately or severely immunocompromised should also receive 2 doses, given 3 weeks apart (a 3rd primary dose is NOT currently authorized in people who receive 2 doses of Novavax vaccine).
- **Booster Shot: As of October 19, 2022,** Novavax COVID-19 vaccine is now authorized for use as a booster dose in adults 18 years and older. It is now an option for booster doses.
- **Type of Vaccine:** Protein subunit
- **How Given:** Shot in the muscle of the upper arm
- **Does NOT Contain:** Eggs, preservatives, latex, metals

FDA Fact sheets: https://www.fda.gov/media/159897/download

COVID-19 non-replicating viral vector vaccines **In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.**

	Janssen (J and J)
Vaccine Type	Non-replicating human adenovirus Efficacy ≈ 85% in preventing severe disease 93% in preventing hospitalizations
Age Indication	≥ 18 years of age (EUA)
Recipient EUA (Emergency Use Authorization) factsheet	FDA Fact sheet for Recipients
Vaccine Presentation	• Multi-dose vial, 5 doses per vial
Dose	0.5 mL (IM)
Dosing Regimen	1 dose

SOURCE: CDC

Use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people (3)

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.

NIH COVID-19 treatment guidelines as of 10/14/2022

- Therapeutics are available for preventing and treating COVID-19 in specific at-risk populations.
- Certain Monoclonal antibodies
- Antivirals
  - Paxlovid
  - Remdesivir
- **Pre-exposure** prophylaxis for highest risk immunocompromised patients
  - Evusheld (**tixagevimab 300 mg plus cilgavimab 300 mg)**(ages ≥12 years and weighing ≥40 kg)
  - Not for treatment of patients with COVID-19
- Resistance to some monoclonal antibodies noted with certain Omicron subvariants.
- For most up to date guidance, visit: NIH https://www.covid19treatmentguidelines.nih.gov/therapies/

Benefits of vaccinating older children and teens (5-18 years)

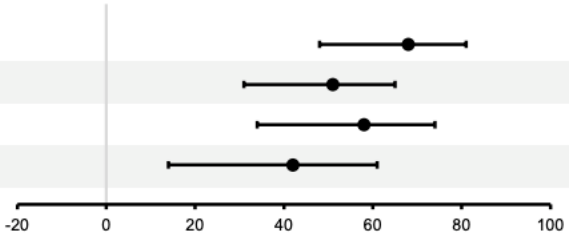
Post-authorization vaccine effectiveness

Overcoming COVID-19 platform

2 doses of Pfizer-BioNTech vaccine against hospitalization, Dec 19, 2021-Apr 27, 2022

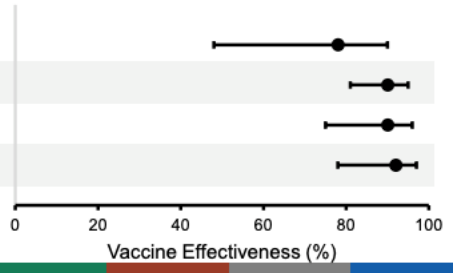
	No. vaccinated COVID-19 patients/Total COVID-19 patients (%)	Adjusted VE % (95% CI)
5–11 years*	25/325 (8)	68 (48-81)
12–18 years	109/286 (38)	51 (31-65)
2–22 weeks since vaccination	42/219 (19)	58 (34-74)
23–45 weeks since vaccination	67/244 (27)	42 (14-61)

*median time from vaccination to hospitalization is 37 days



2 doses of Pfizer-BioNTech vaccine against MIS-C, Jul 1, 2021-Apr 7, 2022

	No. vaccinated MIS-C patients/Total no. MIS-C patients (%)	Median (IQR) days from 2nd dose to MIS-C	Adjusted VE (95% CI)
5–11 years	10/144 (7)	44 (32-56)	78 (48-90)
12–18 years	14/160 (9)	120 (57-169)	90 (81-95)
28-120 days since vaccination	7/153 (5)	60 (42-89)	90 (75-96)
≥121 days since vaccination	7/131 (5)	172 (138-215)	92 (78-97)



COVID-19 vaccination and Evushield™

- In addition to following the recommended COVID-19 vaccination schedule, tixagevimab/cilgavimab (EVUSHELD™), a combination of two monoclonal antibodies, should be administered to people who are moderately or severely immunocompromised every 6 months for pre-exposure prophylaxis to supplement vaccine protection.
- Per the product EUA, EVUSHELD™ is given at least 2 weeks after COVID-19 vaccine. People may initiate EVUSHELD™ at any time after this interval, including between doses in the primary series and primary and booster doses.
- Providers should consult CDC's EVUSHELD™ guidance and current treatment guidelines for more information on the use of EVUSHELD™ as pre-exposure prophylaxis.
- Such use of monoclonal antibodies, however, is not a substitute for COVID-19 vaccination.

Preterm infants

- In accordance with general best practices, preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the same schedule and guidance as for full-term infants and children.

Infants born to mothers with COVID-19 immunity

- Infants of mothers who were vaccinated and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy should be vaccinated according to the recommended schedule (see Table 2) of Interim Clinical Considerations.

COVID-19 Vaccine Interim Clinical Considerations
History of prior SARS-CoV-2 infection

CDC recommends COVID-19 vaccination for all people ages 6 months and older, including people with a history of SARS-CoV-2 infection.

Prior infection: Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection, including to people with prolonged post-COVID-19 symptoms and people who experienced SARS-CoV-2 infection (symptomatic or asymptomatic) after vaccination. People who recently had SARS-CoV-2 infection may consider delaying their primary or booster COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

Current infection: Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until criteria have been met for them to discontinue isolation.

Laboratory testing is not recommended for the purpose of vaccine decision-making.
For more information, see COVID-19 vaccination and SARS-CoV-2 infection.

SOURCE: CDC

COVID-19 Vaccine Interim Clinical Considerations
History of MIS-C or MIS-A

History of MIS-C or MIS-A

- Experts consider the benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for those who meet the following three criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been at least 90 days after the diagnosis of MIS-C; and

SOURCE: CDC

COVID-19 Vaccine Interim Clinical Considerations
Recommendations for those vaccinated outside the US – (move to resource)

- The recommendations for people vaccinated outside of the United States depend on the number and type of vaccine(s) received for the primary series and/or booster dose(s). People who initiated vaccination outside of the United States are considered to be up to date with their COVID-19 vaccines when they have completed the recommended actions described at:
  - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-b
- Age-appropriate Pfizer-BioNTech, Novavax and Moderna COVID-19 Vaccine products can be used in people ages 6 months and older to initiate or complete vaccination.

SOURCE: CDC

Vaccination of people with certain underlying medical conditions with COVID-19 Vaccine (move to resource section)

SOURCE:CDC

Clinicians should consult current CDC guidance for:

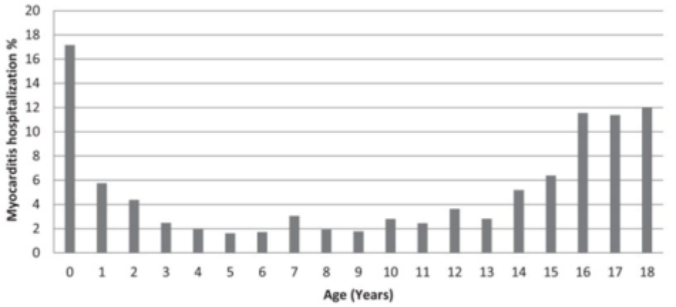
- People with autoimmune conditions
- People with a history of Bells' Palsy
- People with a history of dermal filler use
- People receiving antiviral therapy
- People with a history of myocarditis/pericarditis
- People with a history of thrombosis or risk factors for thrombosis
- People with a history of Guillain-Barre` Syndrome

Myocarditis in young children

Background rates

- Before the COVID-19 pandemic, peaks in myocarditis hospitalizations seen in infants and adolescents
  - In adolescents, typically **viral** in etiology
  - In infants, many cases can represent cardiomyopathy with **genetic** component

- Children
  - Annual incidence 0.8 per 100,000
    - In 15-18yo, 1.8 per 100,000 in 2015-2016
  - 66% male
  - Median LOS 6.1 days



Vasudeva et al. *American J Cardiology.* 2021.

LOS = Length of hospital stay

Vasudeva et al. Am J Cardiology 2021 https://www.sciencedirect.com/science/article/pii/S0002914921002617

Previously presented: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf

59

COVID-19 Vaccine Interim Clinical Considerations
TB Skin testing

TB skin tests and COVID-19 vaccines

- COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon-gamma release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination.

SOURCE: CDC

Immunity after COVID-19 vaccination

- We are still learning about COVID-19 vaccines. COVID-19 vaccines work well to prevent severe illness, hospitalization, and death. However, public health experts are seeing decreases in the protection COVID-19 vaccines provide over time, especially for certain groups of people.
- We don't know how long protection lasts for those who are vaccinated. But we do know that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice.
- People who have a condition or are taking medications that weaken their immune system may not be completely protected even if they are fully vaccinated. They should continue to take all precautions recommended for unvaccinated people, including wearing a well-fitted mask, until advised otherwise by their healthcare provider.
- CDC recommends an additional primary shot for moderate to severely immunocompromised people and booster shots for certain groups of people.

For continued protection, follow CDC guidelines re: wearing masks, social distancing, avoiding large crowds, and hand washing after receiving your vaccine. Visit: COVID-19 Community Levels Tool from CDC

CDC: boosters

SOURCE:CDC

SOURCE: NFID

Is COVID-19 vaccine immunity better than immunity from the disease? If I already had COVID-19 and recovered, am I protected by natural immunity, or do I still need to get a COVID-19 vaccine?

- Evidence is emerging that people **get better protection by being fully vaccinated** compared with previously having a COVID-19 infection. One study showed that unvaccinated people who already had COVID-19 are more than two times as likely than fully vaccinated people to get COVID-19 again.
- Children who get COVID-19 can develop serious complications like MIS-C—a condition where different body parts become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. Children with underlying medical conditions are more at risk for severe illness from COVID-19 compared with healthy children.
- COVID-19 is still a threat to people who are unvaccinated. Some people – including children – who get COVID-19 can become severely ill, which could result in hospitalization, and some have ongoing health problems several weeks or even longer after getting infected. Even people who did not have symptoms when they were infected can have these ongoing health problems.

Vaccine effectiveness in real-world studies

- COVID-19 vaccines are protecting people in the real world
- Two doses are better than one for mRNA vaccines: If you are getting the Pfizer-BioNTech or Moderna vaccine, be sure to get both doses and booster doses when eligible.
- While COVID-19 vaccines are effective, studies have shown some declines in vaccine effectiveness against infections over time, especially when the Delta and Omicron variants are circulating widely.
- Research shows that the COVID-19 vaccines used in the United States protect against severe disease, hospitalization, and death from known variants of concern; they may not be as effective in preventing asymptomatic infection
- Most people who get COVID-19 are unvaccinated. However, since vaccines are not 100% effective at preventing infection, some people who are fully vaccinated will still get COVID-19. This is called a breakthrough infection. Even when people who are fully vaccinated develop symptoms of COVID-19, they tend to be less severe than in people who are unvaccinated.

Laboratory Testing and COVID-19 vaccines)

- Antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result
- Unvaccinated people who are being screened for SARS-CoV-2 infection (e.g., work, school, travel requirement) may be vaccinated at the time of screening if they do not have symptoms consistent with COVID-19.
- Prior receipt of a COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests).
- FDA has reported that falsely reactive Rapid Plasma Reagin (RPR; non-treponemal) test results can occur with certain RPR tests for at least five months following COVID-19 vaccination in some people. Treponemal testing for syphilis such as *Treponema pallidum* particle agglutination (TP-PA) and treponemal immunoassays do not appear to be impacted by this issue.

TTS and J and J COVID-19 vaccine

- **Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare** and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS.
- Cases of TTS, including deaths, following administration of the Janssen COVID-19 Vaccine have been reported in males and females, with the highest risk in females ages 30-49 years.
- **Based on an updated risk-benefit analysis, COVID-19 vaccine recipients should be informed that mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine. Due to the risk of TTS, the Janssen COVID-19 Vaccine should only be used in limited situations:**
- **It is contraindicated to administer Janssen COVID-19 Vaccine to people with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca's COVID-19 Vaccine, which is not authorized or approved in the United States).**

SOURCE: CDC

Seek medical care right away if you develop any of the symptoms below after receiving the J and J vaccine

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision
- Easy bruising or tiny blood spots under the skin beyond the site of the injection

- If you have any questions or concerns, call your doctor, nurse, or clinic.

5/4/2023

SOURCE: CDC

What should providers do?

- Clinicians should consult the Health Alert Network (HAN) notification and guidance from the American Society of Hematology for information on the diagnosis and treatment of suspected cases of TTS.
- Any occurrence of TTS following COVID-19 vaccination should be reported to VAERS.
- CDC and FDA will continue to monitor and review cases of TTS among people who receive any currently FDA-approved or FDA-authorized COVID-19 vaccine in the United States and may update this guidance in the future.

SOURCE: HEMATOLOGY

SOURCE: CDC

Guillain-Barre Syndrome (GBS) and Janssen COVID-19 vaccine

- Guillain-Barré syndrome (GBS) is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis.
- Vaccine safety monitoring suggests an elevated risk of GBS after Janssen COVID-19 vaccination with proportionally more GBS cases observed after Janssen COVID-19 vaccination compared with mRNA COVID-19 vaccination. The highest risk has been observed in people ages 40-64 years, with symptoms of GBS beginning within 42 days after Janssen COVID-19 vaccination; most GBS reports have been in males.
- Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

SOURCE: FDA SOURCE: CDC

Guillain-Barre Syndrome (GBS) and Janssen COVID-19 vaccine (2)

People should seek medical attention immediately if they develop any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that is worsening and spreading to other parts of the body
- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function

SOURCE: CDC

COVID-19 Disease: testing and quarantine

COVID-19 TESTS

Diagnostic Tests

- Determines whether someone is currently infected
- Two types:
  - RT-PCR tests: detect virus genetic materials
  - Antigen tests: detect specific proteins from the virus
- Collected by nasal or nasopharyngeal swab, throat swab, or saliva specimen

Antibody Tests

- Determines whether someone was previously infected
- Important for studies related to
  - Reinfection
  - Markers for protection
  - Understanding COVID-19 treatments

SOURCE: CHOP
And SOURCE: FDA

Testing After Vaccination

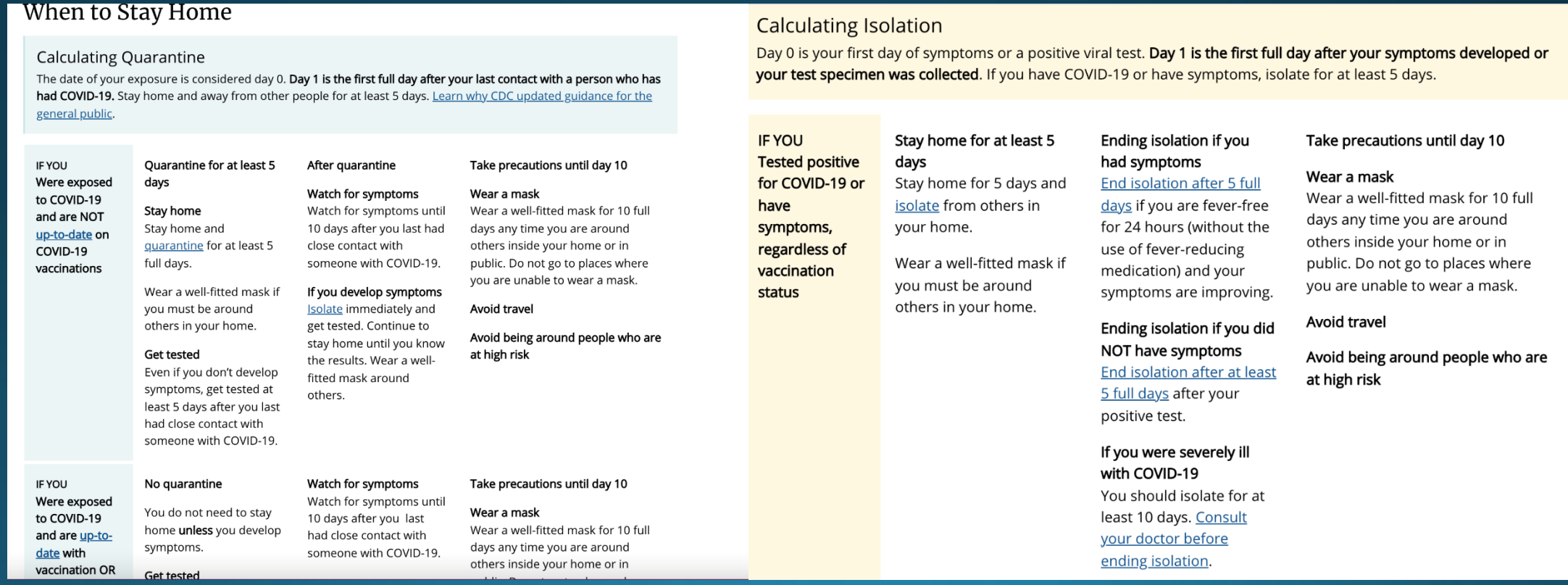
- Antibody testing is not currently recommended to assess for immunity to COVID-19 following COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person or to determine the need to quarantine after a close contact with someone who has COVID-19. Some antibody tests will not detect the antibodies generated by COVID-19 vaccines.
- Infectious virus is never produced by vaccine
- Vaccination does not interfere with the viral testing used to evaluate someone for current infection
- Vaccination will cause the generation of antibodies, so this needs to be considered when planning antibody testing
- Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid. Because COVID-19 vaccines are constructed to encode the spike protein, a positive test for spike protein IgM/IgG could indicate prior infection and/or vaccination.
- To evaluate for evidence of prior infection in an individual with a history of COVID-19 vaccination, a specific test evaluating IgM/IgG to the nucleocapsid protein should be used

SOURCE: CHOP and SOURCE: CDC

QUARANTINE RECOMMENDATIONS (COVID-19 DISEASE)

For the most up-to-date guidance for healthcare workers and for the general public, please review CDC guidance*

- You **quarantine** when you might have been exposed to the virus.
- You **isolate** when you have been infected with the virus, even if you don't have symptoms.



When to Stay Home

Calculating Quarantine

The date of your exposure is considered day 0. **Day 1 is the first full day after your last contact with a person who has had COVID-19.** Stay home and away from other people for at least 5 days. Learn why CDC updated guidance for the general public.

IF YOU	Quarantine for at least 5 days	After quarantine	Take precautions until day 10
Were exposed to COVID-19 and are NOT up-to-date on COVID-19 vaccinations	**Stay home** Stay home and quarantine for at least 5 full days. Wear a well-fitted mask if you must be around others in your home. **Get tested** Even if you don't develop symptoms, get tested at least 5 days after you last had close contact with someone with COVID-19.	**Watch for symptoms** Watch for symptoms until 10 days after you last had close contact with someone with COVID-19. **If you develop symptoms** Isolate immediately and get tested. Continue to stay home until you know the results. Wear a well-fitted mask around others.	**Wear a mask** Wear a well-fitted mask for 10 full days any time you are around others inside your home or in public. Do not go to places where you are unable to wear a mask. **Avoid travel** **Avoid being around people who are at high risk**
Were exposed to COVID-19 and are up-to-date with vaccination OR	**No quarantine** You do not need to stay home **unless** you develop symptoms. **Get tested**	**Watch for symptoms** Watch for symptoms until 10 days after you last had close contact with someone with COVID-19.	**Take precautions until day 10** **Wear a mask** Wear a well-fitted mask for 10 full days any time you are around others inside your home or in

Calculating Isolation

Day 0 is your first day of symptoms or a positive viral test. **Day 1 is the first full day after your symptoms developed or your test specimen was collected**. If you have COVID-19 or have symptoms, isolate for at least 5 days.

IF YOU	Stay home for at least 5 days	Ending isolation if you had symptoms	Take precautions until day 10
Tested positive for COVID-19 or have symptoms, regardless of vaccination status	Stay home for 5 days and isolate from others in your home. Wear a well-fitted mask if you must be around others in your home.	**Ending isolation if you had symptoms** End isolation after 5 full days if you are fever-free for 24 hours (without the use of fever-reducing medication) and your symptoms are improving. **Ending isolation if you did NOT have symptoms** End isolation after at least 5 full days after your positive test. **If you were severely ill with COVID-19** You should isolate for at least 10 days. Consult your doctor before ending isolation.	**Wear a mask** Wear a well-fitted mask for 10 full days any time you are around others inside your home or in public. Do not go to places where you are unable to wear a mask. **Avoid travel** **Avoid being around people who are at high risk**

CDC: HCP's

Source: CDC

Preparing for COVID-19 vaccination in Pediatric practices

Prepare for COVID-19 vaccines

Pediatricians and their teams can begin preparing by:

- Enrolling to become a COVID-19 vaccine site
- Encourage and administer catch-up vaccines to children
- Consider and learn about providing COVID-19 vaccines to adults
- Review AAP's #CallYourPediatrician campaign

Things to consider as you prepare your office for COVID-19 vaccines

- Who will you vaccinate? Patients only, adults, community?
- Define your vaccination hours, visits
- Promoting/marketing to your patients that vaccine is available
- Plan for avoiding vaccine wastage
- Where will you vaccinate: inside, outside, car?
- Staffing needs
- How much vaccine should you order at one time?

Things to consider as you prepare your office for COVID-19 vaccines (2)

Identify a vaccine champion/coordinator:

- discuss pre-drawing and labeling vaccine syringes
- monitoring time to ensure that vaccine is used within 6 hours once drawn up
- filling out vaccine cards
- scheduling the second dose

Pandemic Provider Enrollment

1. Complete Pandemic Enrollment application in GRITS
2. Complete required training and upload completion certificates
3. Enrollment team reviews applications for completeness
4. Immunization Regional Consultant (IRC) schedules a site visit
5. Enrollment is finalized and provider is assigned a Pandemic PIN
6. Providers register in Vaccine Management System
    - Ordering
    - Inventory
    - Administration process

Vaccine Ordering

- For questions about orders or access to the Vaccine Management System:
- email **DPH-COVID19vaccine@dph.ga.gov** or call **(888) 920-0165**
- **Provider Technical Support**
- **GRITS Hotline** (Technical/IT questions): 866-483-2958 or email at dph-gaimmreg@dph.ga.gov
- **Provider Support** (VMS functional/IT questions and provider enrollment questions): 888-920-0165 or email DPH-COVID19vaccine@dph.ga.gov
-

COVID-19 Vaccine Reporting

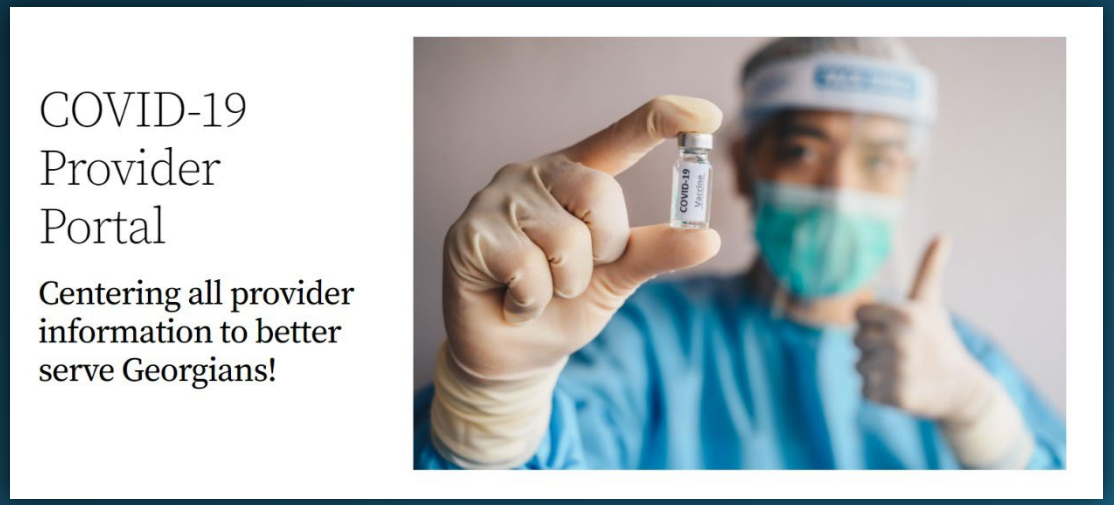
- COVID vaccination records must be submitted to the Vaccine Management System **within 24 hours** of administration
- Submit daily inventory totals to CDC VaccineFinder.org

- **3231 forms will not populate COVID-19 vaccines as they are not a school requirement.**

- **Please Note:** If facility submits vaccination records through EMR system, all records must be submitted using the eligibility code "COVID Specific." COVID Specific is coded as V07 for electronic interfaces.

Vaccine Communications – Provider Portal, GA DPH

When new information is available, the DPH Immunization team will send out communication to all Pandemic Providers



- The COVID-19 Provider Portal contains:
  - ✓ Latest Updates
  - ✓ Provider reminders
  - ✓ Vaccine Logistics
  - ✓ Storage and Shipping
  - ✓ Additional Resources
  - ✓ Learning and Education

http://dph.Georgia.gov/covid-19-provider-portal

Pandemic Provider Enrollment Contact Information

Contact	Email
General COVID-19 vaccine questions VMS access/reporting questions	DPH-COVID19Vaccine@dph.ga.gov
Office of Immunization Sheila Lovett, Immunization Program Director	Sheila.Lovett@dph.ga.gov
GRITS/Reporting Questions Nikki Griffin, Immunization Registry Manager	Nikki.Griffin@dph.ga.gov
Preparation/Administration Questions Tracy Dabbs, Emergency Preparedness Pharmacist	Tracy.Dabbs@dph.ga.gov
Preparation/Administration Questions; *Addressing vaccine hesitant patients* Alexander Millman, Chief Medical Officer	Alexander.Millman@dph.ga.gov

Coding for COVID-19 Services

- New ICD-10-CM COVID-19 Diagnosis Codes:
  - Effective January 1, 2021
  - Eligible codes: Z11.52, Z20.822, Z86.16, M35.81, M35.89, and J12.82

SOURCE: GA AAP

Billing for COVID-19 Services

Billing:

- You may bill for vaccine administration (Commercial, Medicaid, Medicare, HRSA uninsured fund)
- Differentiate Pediatric from Adult (6 months and up) doses
- Never bill patient, no balance billing
- What demographic information is needed to bill the vaccine administration fee?

- Check with your insurance carrier if you have questions. HRSA for uninsured claims.

SOURCE: GA AAP

AAP COVID-19 Vaccine Coding Chart

Vaccine Manufacturer	Patient Age	Cap Color	Vaccine Product	1st Dose Admin	2nd Dose Admin	3rd Dose Admin	Booster Admin	Vaccine Product	Dosing Interval	NDC
Pfizer	≥12 years	Purple	91300	0001A	0002A	0003A	0004A	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 30mcg/0.3mL dosage, diluent reconstituted, for IM use	1st to 2nd Dose: 21 d 2nd to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days Booster*	59267-1000-1 59267-1000-01
Pfizer	≥12 years	Gray	91305	0051A	0052A	0053A	0054A	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 30mcg/0.3 mL dosage, tris-sucrose formulation, for IM use	1st to 2nd Dose: 21 d 2nd to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days Booster*	59267-1025-1 59267-1025-01
Pfizer	5-11 years	Orange	91307	0071A	0072A	0073A	0074A	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 10mcg /0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for IM use	1st to 2nd Dose: 21 d 2nd to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days Booster*	59267-1055-1 59267-1055-01
Pfizer	6 months-4 years	Maroon	91308	0081A	0082A	0083A	N/A	COVID-19 vaccine, mRNA, spike protein, LNP, PF, 3mcg/0.2 mL dose, tris-sucrose formulation	1st to 2nd Dose: 21 d 2nd to 3rd Dose*	59267-0078-1 59267-0078-01 59267-0078-4 59267-0078-04
Moderna	≥18 years	Red	91301	0011A	0012A	0013A	N/A	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 100 mcg/0.5mL dosage, for IM use	1st to 2nd Dose: 28 d 2nd to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days	80777-273-10 80777-0273-10
Moderna	≥18 years	Red	91306	N/A	N/A	N/A	0064A (Low Dose)	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 50mcg/0.25 mL dosage, for IM use	Booster*	80777-273-10 80777-0273-10
Moderna	≥18 years	Blue	91309	N/A	N/A	N/A	0094A	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 50mcg/0.5 mL dosage, for IM use	Booster*	80777-275-05 80777-0275-05
Moderna	6 months-5 years	Blue Cap Magenta Label Border	91311	0111A	0112A	N/A	N/A	COVID-19 vaccine, mRNA-LNP, spike protein, PF, 25mcg/0.25 mL dosage, for IM use	1st to 2nd Dose: 1 month	80777-279-05 80777-0279-05

Janssen	≥18 years	91303	0031A	N/A	N/A	0034A	COVID-19 vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, PF, $5x10^{10}$viral particles/0.5mL dosage, for IM use	Booster*	59676-580-05 59676-0580-05
Sanofi-GSK	≥18 years	91310	N/A	N/A	N/A	0104A	COVID-19 vaccine, monovalent, PF, 5mcg/0.5 mL dosage, adjuvant AS03 emulsion, for IM use	Booster*	49281-618-20 49281-0618-20

*Refer to FDA/CDC Guidance

COVID-19 vaccine, Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease); d, days; IM, intramuscular; PF, preservative-free

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#covid19-vaccines

- The CPT code for the new 5-11 yo Pfizer BiValent booster is 91315
- The CPT code for the new 6-11 yo bivalent Moderna booster is 91314
- The vaccine administration fee for COVID-19 vaccines is $40.

COVID-19 Vaccines & Administration Codes

Revised: *October 1, 2022*

Submit claim for administration fee with the appropriate vaccine CPT Code (See NOTE tab for additional instructions)

#	CPT HCPCS	Vaccine Code Description, Dose	Vaccine Administration Code(s)	Labeler Name	Drug Name	Patient's Age	NDC	Max Allow	Max Units/Day	GAMMIS Effective Date	NOTE
1	91300	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use	0001A (First Dose) 0002A (Second Dose) 0003A (Third Dose) 0004A (Booster Dose)	Pfizer, Inc.	PFIZER-BIONTECH COVID-19 VACC 30MCG/0.3ML Suspension	12 Years & Older	59267-1000-01 59267-1000-02 59267-1000-03	$0.00 - Vaccine $40.00 - Admin	1	12/11/2020	Report 91300 with administration codes 0001A, 0002A, 0003A, 0004A
2	91301	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use	0011A (First Dose) 0012A (Second Dose) 0013A (Third Dose)	Moderna, Inc	MODERNA COVID-19 VACCINE 100MCG/0.5ML Solution	12 Years & Older	80777-0273-10 80777-0273-15 80777-0273-98 80777-0273-99	$0.00 - Vaccine $40.00 - Admin	1	12/18/2020	Report 91301 with administration codes 0011A, 0012A, 0013A
3	91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5 mL dosage, for intramuscular use	0013A (Single Dose) 0034A (Booster Dose)	Janssen	JANSSEN COVID-19 VACCINE 0.5ML Suspension	18 Years & Older	59676-0580-05 59676-0580-15	$0.00 - Vaccine $40.00 - Admin	1	2/27/2021	Report 91303 with administration codes 0031A, 0034A
4	91304	severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use	0041A (1st Dose) 0042A (2nd Dose)	Novavax	Novavax Covid-19 Vaccine, Adjuvanted	18 Years & Older	80631-1000-01	$0.00 - Vaccine $40.00 - Admin	1	7/13/2022	Report 91304 with administration codes 0041A, 0042A
5	91305	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use	0051A (First Dose) 0052A (Second Dose) 0053A (Third Dose) 0054A (Booster Dose)	Pfizer, Inc.	PFIZER-BIONT COVID-19 VAC-TRIS 30MCG/0.3ML Suspension	12 Years & Older	59267-1025-01 59267-1025-02 59267-1025-03 59267-1025-04	$0.00 - Vaccine $40.00 - Admin	1	11/1/2021	Report 91305 with administration codes 0051A, 0052A, 0053A, 0054A
6	91306	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use	0064A (Booster Dose)	Moderna	MODERNA COVID-19 VACCINE 100MCG/0.5ML Solution	18 Years & Older	80777-0273-10 80777-0273-15 80777-0273-98 80777-0273-99	$0.00 - Vaccine $40.00 - Admin	1	10/20/2021	Report 91306 with administration code 0064A
7	91307	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	0071A (First Dose) 0072A (Second Dose) 0073A (Third Dose) 0074A (Booster Dose)	Pfizer, Inc.	PFIZER COVID-19 VAC-TRIS 5-11Y 10MCG/0.2ML Suspension	5-11 Years Old	59267-1055-01 59267-1055-02 59267-1055-04	$0.00 - Vaccine $40.00 - Admin	1	10/29/2021	Report 91307 with administration codes 0071A, 0072A
8	91308	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	0081A (1st Dose) 0082A (2nd Dose) 0083A (3rd Dose	Pfizer, Inc.	Pfizer-BioNTech Covid-19 Pediatric Vaccine	6 Months - 4 Years	59267-0078-01 59267-0078-04	$0.00 - Vaccine $40.00 - Admin	1	6/17/2022	Report 91308 with administration codes 0081A, 0082A, 0083A
9	91309	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use	0091A (1st Dose) 0092A (2nd Dose) 0093A (3rd Dose	Moderna, Inc	Moderna COVID-19 Vaccine	6 - 11 Years	80777-0275-05	$0.00 - Vaccine $40.00 - Admin	1	6/17/2022	Report 91309 with administration codes 0091A, 0092A, 0093A, 0094A
			0094A (Booster)			18 Years & older				3/29/2022	
10	91311	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use	0111A (1st Dose) 0112A (2nd Dose) 0113A (3rd Dose)	Moderna, Inc	Moderna COVID -19 Vaccine	6 Months - 5 Years	80777 -0279 -05	$0.00 - Vaccine $40.00 - Admin	1	6/17/2022	Report 91311 with administration codes 0111A, 0112A, 0113A
11	91312	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, trissucrose formulation, for intramuscular use	0124A (Booster)	Pfizer, Inc.	Pfizer-BioNTech COVID-19 Bivalent	12 Years & older	59267-0304-01 59267-1404-01	$0.00 - Vaccine $40.00 - Admin	1	8/31/2022	Report 91312 with administration code 00124A
12	91313	Severe acute respiratory syndrome coronavirus 2 (SARS -CoV -2) (coronavirus disease [COVID -19]) vaccine, mRNA -LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use	0134A (Booster)	Moderna, Inc	Moderna COVID-19 Vaccine, Bivalent Product	18 Years & older	80777 -0282 -05	$0.00 - Vaccine $40.00 - Admin	1	8/31/2022	Report 91313 with administration code 00134A
13	91314	Severe acute respiratory syndrome coronavirus 2 (SARS -CoV -2) (coronavirus disease [COVID -19]) vaccine, mRNA -LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use	0144A (Booster)	Moderna, Inc	Moderna COVID -19 Vaccine, Bivalent	6 - 11 Years	80777 -0282 -05	$0.00 - Vaccine $40.00 - Admin	1	8/31/2022	Report 91314 with administration code 00144A
14	91315	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	0154A (Booster)	Pfizer, Inc.	Pfizer-BioNTech COVID-19 Bivale	5 - 11 Years	59267-0565-01	$0.00 - Vaccine $40.00 - Admin	1	8/31/2002	Report 91315 with administration code 00154A
15	M0201	Covid-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only covid-19 vaccine administration is performed at the patient's home	N/A	N/A	N/A		N/A	$35.50	1	6/8/2021	Report M0201 with any combination of vaccine & administration code

Bivalent Booster coding

13	91314	Severe acute respiratory syndrome coronavirus 2 (SARS -CoV -2) (coronavirus disease [COVID -19]) vaccine, mRNA -LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use	0144A **(Booster)**	Moderna, Inc	Moderna COVID -19 Vaccine, Bivalent	6 - 11 Years	80777 -0282 -05	$0.00 - Vaccine $40.00 - Admin	1	8/31/2022	Report 91314 with administration code 00144A
14	91315	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	0154A **(Booster)**	Pfizer, Inc.	Pfizer-BioNTech COVID-19 Bivale	5 - 11 Years	59267-0565-01	$0.00 - Vaccine $40.00 - Admin	1	8/31/2002	Report 91315 with administration code 00154A

Preventive Medicine Counseling Code

Subject Preventive Medicine Counseling Code 99401

Message

Dear Providers:

Effective July 1, 2021, the Department of Community Health (DCH) updated the Georgia Medicaid Management Information System (GAMMIS), with the following procedure code 99401: Preventive Medicine Counseling. Opening of code 99401 will allow existing providers to counsel patients on the benefits of COVID-19 vaccination.

If you billed claims with procedure code 99401 that were affected by this implementation and your claims denied, the Department of Community Health (DCH) and Gainwell Technologies will reprocess these claims automatically.

Procedure Code	Description	Reimbursement
99401	Preventive Medicine Counseling	$28.29

For other questions, please contact the Gainwell Technologies Call Center at (770) 325-9600 or contact us at www.mmis.geogia.gov.

We apologize for any inconvenience this may have caused your facility. Thank you for your continued participation in the Georgia Medicaid program.

Effective Date 09/24/2021

Sent Date 09/24/2021

Medicaid Fee Schedules & Opened Codes

- CMS approves State Plan Amendments (SPA) submitted by Ga Dept. of Community Health. While the CMOs have been paying these increases, Medicaid Fee for Service (FFS) has not; impacted claims will now be reprocessed by FFS:
  - E&M codes 1% increase
  - Increase to Medicare 2020 rates on select codes
- Additionally, Medicaid opened three codes within its fee schedule related to COVID-19
  - CPT 99401 – counseling COVID-19 vaccination; pays $28.29
  - CPT 87428 – antigen detection by immunoassay COVID-19 & flu A & B; pays $67.08
  - CPT 87811 – immunoassay for COVID-19 using visual observation; pays $41.38
- Medicaid is working on loading COVID-19 vaccine and vaccine administration codes for children ages 5-11 years of age: 91307 is reported for the vaccine product authorized for use in children aged 5 through 11 years; vaccine administration is 0071A for the 1st dose and 0072A for 2nd dose.