EPIC Immunization 2022 Update

SARS-CoV-2 (COVID-19)

July 2022

1

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

2

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

3

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

4

Disclaimer

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

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

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

5

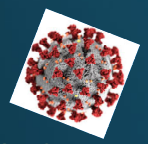
Table of Contents

6

Overview COVID-19 disease

7

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

8

COVID-19 disease

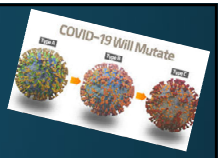
Symptoms can be mild to severe and can develop 2-14 days after exposure

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

Source: CDC

9

COVID-19 VARIANTS



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

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

CDC is studying these variants quickly to understand whether the variants

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

SOURCE: CDC

10

Omicron variant

As of 6/1/2022, Omicron is responsible for over 98% of positive SARS-CoV-2 in the United States.

- The Omicron variant, like other variants, is comprised of subvariants, lineages and sublineages. Three of the more common ones are BA.1, BA.1.1 and BA.2.
- Spread/contagiousness: The Omicron variant spreads more easily than the original virus that causes COVID-19 and the Delta variant. CDC expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms
- Disease severity: Omicron infection generally causes less severe disease than infection with prior variants. Preliminary data suggest that Omicron may cause more mild disease, although some people may still have severe disease, need hospitalization, and could die from the infection with this variant. Even if only a small percentage of people with Omicron infection need hospitalization, a large volume of cases in a community could overwhelm the healthcare system which is why it's important to take steps to protect yourself.

SOURCE: CDC Omicron variant

11

Omicron variant 2

- Vaccine effectiveness: Current vaccines protect against severe illness, hospitalizations, and deaths due to infection with the Omicron variant. However, breakthrough infections in people who are vaccinated can occur. People who are up to date with their COVID-19 vaccines and get COVID-19 are less likely to develop serious illness than those who are unvaccinated and get COVID-19.
- COVID-19 vaccines remain the best public health measure to protect people from COVID-19 and reduce the likelihood of new variants emerging. This includes primary series, booster shots, and additional doses for those who need them.
- Treatments: Scientists are working to determine how well existing treatments for COVID-19 work. Some, but not all, monoclonal antibody treatments remain effective against Omicron. Other non-monoclonal antibody treatments remain effective against Omicron. Public health agencies work with healthcare providers to ensure that effective treatments are used appropriately to treat patients.

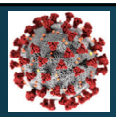
12

NIH COVID-19 treatment guidelines as of 6/1/2022

- 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 (not for treatment of patients with COVID-19)
- For more details, visit: NIH https://www.covid19treatmentguidelines.nih.gov/therapies/

6/24/22 13

13



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.

(6/20/2022) Over 13.5million 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 19% of total cumulated cases since the pandemic began. Among states reporting, children were 0.00%-0.32% of all COVID-19 deaths.

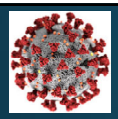
Access current pediatric data on COVID-19 cases, hospitalizations and deaths at AAP's site.

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

National data

6/24/22 14

14



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 8525 MIS-C cases and 69 deaths due to MIS-C have been reported in the U.S. as of May 31, 2022. 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

6/24/22 15

15

ACIP Meeting COVID vaccines June 17-18/22 and 22-23/22

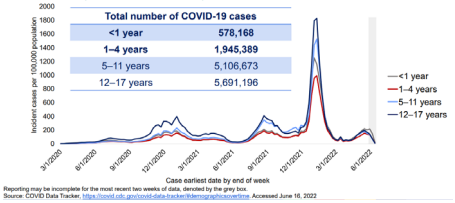
https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-18.html and also https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-22-23.html

6/24/22 16

16

Cases among Children

COVID-19 weekly cases per 100,000 population among children ages 0–17 years by age group — United States
March 1, 2020 – June 12, 2022

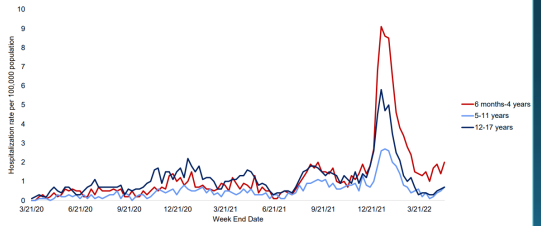


Reporting may be incomplete for the most recent two weeks of data, denoted by the grey box.
Source: COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Accessed June 16, 2022

17

Hospitalizations among Children

COVID-19-associated hospitalizations among children and adolescents 6 months–17 years, COVID-NET
March 2020 – March 2022

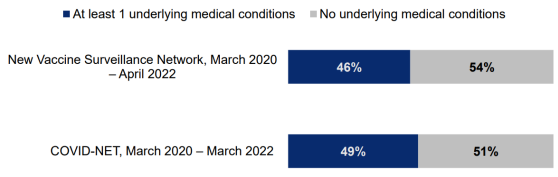


Source: COVID-NET, https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html. Accessed May 21, 2022.

18

Hospitalizations among Children (2)

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

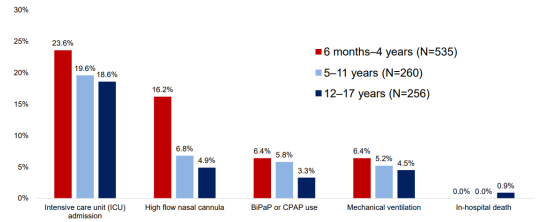


Source: 1. New Vaccine Surveillance Network. Preliminary data as of May 25, 2022, reflecting data from March 2020–April 2022
2. COVID-NET data. Accessed May 21, 2022, reflecting data from March 2020–March 2022

19

Severity of Hospitalizations

Severity of COVID-19-associated hospitalizations among children and adolescents 6 months–17 years, COVID-NET,
December 19, 2021 – March 31, 2022 (Omicron period)



BiPAP: bilevel positive pressure, CPAP: continuous positive pressure
Source: COVID-NET data. Accessed May 21, 2022.

20

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

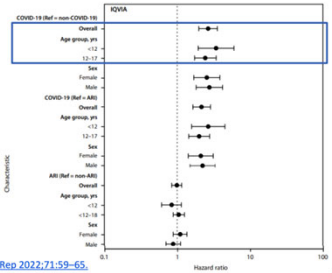
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/02-COVID-Briggs-Hagan-508.pdf

21

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

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.

14

22

Deaths among Children

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

March 1, 2020–April 30, 2022

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

Based on death certificate data from the National Center for Health Statistics. COVID-19 based on cumulative total incidence of COVID-19 deaths from March 1, 2020-April 30, 2022.
Source: Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; doi: https://doi.org/10.1101/2022.05.23.22275458

23

Pediatric vaccine preventable diseases: Deaths per year in the United States prior to recommended vaccines

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

[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

24

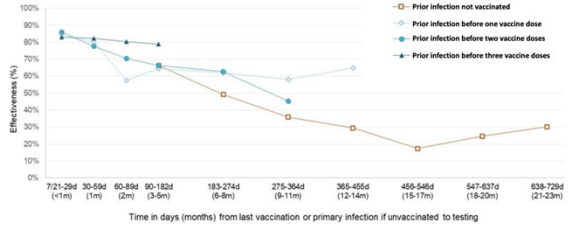
Seroprevalence of infection-induced SARS-CoV-2 antibodies among children ages 6 months–17 years — National Commercial Lab Seroprevalence Study

September 2021– April 2022

Shading indicates confidence intervals for each trend line.
Data updated for March/April 2022, based on Clarke K, Kim Y, Jones J et al. Pediatric Infection-Induced SARS-CoV-2 Seroprevalence Estimation Using Commercial Laboratory Specimens: How Representative Is It of the General U.S. Pediatric Population? (April 26, 2022).
SSRN: https://ssrn.com/abstract=4092074 or http://dx.doi.org/10.2139/ssrn.4092074

25

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



Carazo S, Skowronski DM, Brisson M, et al. "Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination" *medRxiv*, May 2022. Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination | medRxiv

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

26

Improved antibody response after vaccination

- Among children, COVID-19 vaccine induces a **broader neutralizing antibody** response compared with infection induced immunity:
  - From a U.S. multicenter cohort, antibody profiles of unvaccinated pediatric patients hospitalized for COVID-19 were compared to profiles of vaccinated children.
  - In contrast to those with SARS-CoV-2 infection, **children vaccinated with two doses demonstrated higher titers** against Alpha, Beta, Gamma, Delta and Omicron.
  - The findings suggest that antibodies produced by prior SARS-CoV-2 infection (pre-Omicron) may not neutralize the currently circulating Omicron variant.
  - This builds on evidence among adults that previous infection provides poor protection from infection with Omicron.
- Highlights the importance of vaccinating **children with prior infection** to prevent both severe disease and future infections.

Tang J, Novak T, Hecker J, et al. "Cross-reactive immunity against the SARS-CoV-2 Omicron variant is low in pediatrics patients with prior COVID-19 or MIS-C." *Nature Communications*. (2022) 13:2979. https://doi.org/10.1038/s41467-022-30649-1

27

Summary
U.S. COVID-19 epidemiology in children 6 months–4 years

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

28

Subject to change based on 6/23/22 meeting

Vaccination of children and adolescents

- Persons 6 months and older are now eligible to receive the Pfizer-BioNTech COVID-19 vaccine or the Moderna COVID-19 vaccine.
- Children and adolescents younger than 18 years of age are not authorized to receive the Janssen COVID-19 vaccines at this time.
- A Pfizer COVID-19 Booster dose is now recommended for all persons 5 years to 17 years, 5 months after completion of dose 2 of their primary series
- A Pfizer additional dose is recommended for some children and adolescents 5 years and older who are moderately or severely immunocompromised to complete the primary series (total of 3 primary doses). A booster dose is also recommended 3 months after the 3rd dose and a second booster dose 4 months after the first booster dose for moderately or severely immunocompromised people 12 years and older

FDA: Second Booster 3 2022
SOURCE: CDC

6/24/22 29

29

AAP Policy Statement COVID-19 vaccination children and adolescents

- The AAP recommends COVID-19 vaccination for all children and adolescents 6 months of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age.
- Any COVID-19 vaccine authorized through Emergency Use Authorization or approved by the FDA, recommended by the CDC, and appropriate by age and health status can be used for COVID-19 vaccination in children and adolescents.
- Children with previous infection or disease with SARS-CoV-2 should receive COVID-19 vaccination, according to CDC guidelines.
- AAP supports coadministration 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

6/24/22 SOURCE: AAP 30

30

UPDATES CLINICAL TRIALS Vaccination of children and adolescents (6/1/2022)

- At this time, The safety and efficacy of the Janssen COVID-19 Vaccine have **not been established in individuals younger than 18 years of age.**
- Clinical trials ongoing

6/24/22 Update as information received 31

31

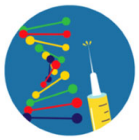
Overview of COVID-19 vaccines

mRNA Vaccines
Non replicating Viral vector vaccines
Vaccine Storage and Handling, Dosing, Ingredients
Interim Clinical Recommendations from the CDC

6/24/22 32

32

Different Types of COVID-19 Vaccines



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

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

Vector vaccines, like the AstraZeneca vaccine, use another virus that has been made safe. Material from the COVID-19 virus has been inserted inside of it. The material tells our cells to make harmless proteins unique to the COVID-19 virus.

https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/coronavirus-vaccines-infographic

6/24/22 33

33

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. (Table Subject to change as other vaccines are authorized)

	Pfizer-BioNTech	Moderna	Janssen
Vaccine Type	mRNA	mRNA	Non-replicating Human adenovirus 26 vector
EUA granted	EUA 6 months-15 years Approved 16 and older	EUA 6 months – 17 years Approved 18 yrs and older	EUA 18 yrs and older

6/24/22

SOURCE: CDC Pfizer SOURCE: CDC Janssen SOURCE: CDC Moderna 34

34

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 16 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.

6/24/22 SOURCE: CDC 35

35

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

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..

6/24/22 SOURCE: CDC 36

36

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

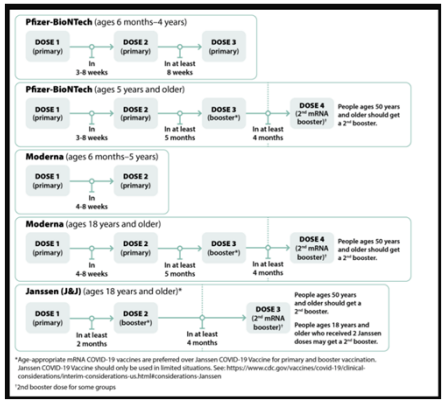
SOURCE: CDC

6/24/22

37

COVID-19 vaccination schedule for most people

- COVID-19 vaccination schedule for most people



6/24/22 38

38

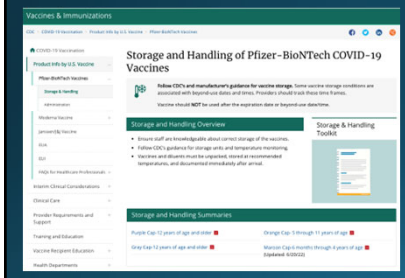
COVID-19 Vaccine ingredients

Description	Pfizer-BioNTech (mRNA) For persons aged 5-11 years (10µg dose) formulation	Pfizer-BioNTech (mRNA) For persons aged ≥12 years (30µg dose) formulation	Moderna (mRNA) For persons aged ≥18 years	Janssen (viral vector) For persons aged ≥18 years
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG:1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102:heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

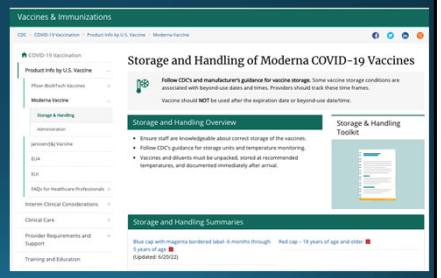
6/24/22 39

39

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



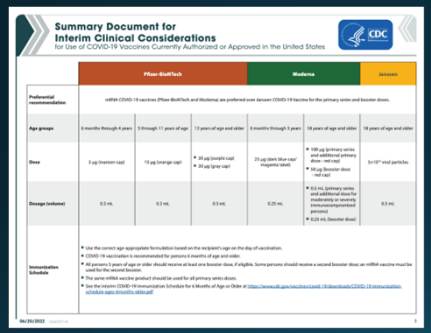
CDC: Pfizer



CDC:Moderna

6/24/22 40

40



CDC: *Interim Clinical Considerations* (For the most up to date guidance on use of COVID-19 vaccines in the US

SOURCE:CDC

6/24/22 41

41

COVID-19 vaccines 6 months -17 years old

6/24/22 42

42

COVID-19 Vaccines for 6 months - 4 years (Pfizer) or 6 months - 5 years (Moderna

- Pfizer-BioNTech COVID-19 vaccine
  - Children ages **6 months – 4 years**
  - 3 doses
- Moderna COVID-19 vaccine
  - Children ages **6 months – 5 years**
  - **2 doses**
- **There is NO COVID-19 vaccine currently authorized or approved for children younger than 6 months.**

6/24/22 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised 43

43

Pfizer-BioNTech COVID-19 vaccine schedule: ages 6 months through 17 years for most children

- Children ages 6 months–4 years: Should receive a 3-dose primary series. The first and second doses are separated by 3–8 weeks and the second and third doses are separated by at least 8 weeks. Currently, a booster dose is not authorized for this age group.
- Children ages 5–11 years: Should receive a 2-dose primary series separated by 3–8 weeks and 1 booster dose at least 5 months after completion of the primary series.
- Adolescents ages 12–17 years: Should receive a 2-dose primary series separated by 3–8 weeks and 1 booster dose at least 5 months after completion of the primary series.

6/24/22 44

44

Pfizer-BioNTech COVID-19 vaccine schedule: ages 6 months through 17 years for people who are moderately or severely immunocompromised

- Children ages 6 months–4 years: Should receive a 3-dose primary series. The first and second doses are separated by 3 weeks and the second and third doses are separated by at least 8 weeks. Currently, a booster dose is not authorized for this age group.
- Children ages 5–11 years: Should receive a 3-dose primary series and 1 booster dose. For the primary series, the first and second doses are separated by 3 weeks and the second and third doses are separated by at least 4 weeks. The booster dose is administered at least 3 months after completion of the primary series.
- Adolescents ages 12–17 years: Should receive a 3-dose primary series and 2 booster doses. For the primary series, the first and second doses are separated by 3 weeks and the second and third doses are separated by at least 4 weeks. The first booster dose is administered at least 3 months after completion of the primary series and the second booster dose at least 4 months after the first booster dose.

6/24/22 45

45

Summary of GRADE

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

Outcome	Importance	Design (# studies)	Findings	Evidence type
Benefits				
1a. Symptomatic lab-confirmed COVID-19 (efficacy)	Critical	RCT (1)	Pfizer-BioNTech COVID-19 vaccine is effective in preventing symptomatic COVID-19; certainty in the estimate was very low	4
1b. Symptomatic lab-confirmed COVID-19 (immunobridging)	Critical	RCT (1)	Pfizer-BioNTech COVID-19 vaccine is effective in preventing symptomatic COVID-19	2
2. Hospitalization due to COVID-19	Important	No studies	Data not available from any studies	ND
3. Multisystem inflammatory syndrome in children (MIS-C)	Important	No studies	Data not available from any studies	ND
4. Asymptomatic SARS-CoV-2 infection	Important	No studies	Data not available from any studies	ND
Harms				
5. Serious adverse events	Critical	RCT (1)	1.0% of participants with SAEs among vaccinated and 1.5% among unvaccinated; certainty in the estimate was very low. 2 SAEs in 1 participant in the vaccine arm were judged to be related to vaccination.	4
6. Reactogenicity	Important	RCT (1)	Severe reactions were slightly more common in vaccinated; any grade ≥3 reaction was reported by 4.3% of vaccinated vs. 3.6% of placebo group	2

Evidence type: 1=high; 2=moderate; 3=low; 4=very low; ND, no data

55

6/24/22 46

46

Pfizer-BioNTech

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series Dose	Primary series Injection volume	Booster doses† Dose	Booster doses† Injection volume
6 months–4 years‡	Maroon	Maroon	Yes	3 µg	0.2 mL	NA	NA
5–11 years	Orange	Orange	Yes	10 µg	0.2 mL	10 µg	0.2 mL
12 years and older	Purple	Purple	Yes	30 µg	0.3 mL	30 µg	0.3 mL
12 years and older	Gray	Gray	No	30 µg	0.3 mL	30 µg	0.3 mL

Pfizer-BioNTech Dosing and formulations

6/24/22 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised 47

47

Moderna COVID-19 vaccine schedule: ages 6 months through 17 years for most children and adolescents

- Children ages **6 months–11 years:**
  - Children ages 6 months–5 years: Should receive a 2-dose primary series separated by 4–8 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.
  - Children ages 6–11 years: Should receive a 2-dose primary series separated by 4–8 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.
  - Adolescents ages 12–17 years: Should receive a 2-dose primary series separated by 4–8 weeks. Currently, a booster dose is not authorized for adolescents in this age group who receive a Moderna primary series.

6/24/22 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised 48

48

Moderna COVID-19 vaccine schedule: ages 6 months through 17 years for people who are moderately or severely immunocompromised

- Children ages 6 months–5 years: Should receive a 3-dose primary series. The first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.
- Children ages 6–11 years: Should receive a 3-dose primary series. The first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.
- Adolescents ages 12–17 years: Should receive a 3-dose primary series. The first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks. Currently, a booster dose is not authorized for adolescents in this age group who receive a Moderna primary series

6/24/22 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised 49

49

Summary of GRADE

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

Outcome	Importance	Design (# studies)	Findings	Evidence type
Benefits				
1. Symptomatic lab-confirmed COVID-19	Critical	RCT (1)	Moderna COVID-19 vaccine is effective in preventing symptomatic COVID-19	1
1b. Symptomatic lab-confirmed COVID-19 (immunobridging)	Critical	RCT (1)	Moderna COVID-19 vaccine is effective in preventing symptomatic COVID-19	2
2. Hospitalization due to COVID-19	Important	No studies	Data not available from any studies	ND
3. Multisystem inflammatory syndrome in children (MIS-C)	Important	No studies	Data not available from any studies	ND
4. Asymptomatic SARS-CoV-2 infection	Important	RCT (1)	The vaccine did not demonstrate efficacy in prevention of asymptomatic SARS-CoV-2 infection	3
Harms				
5. Serious adverse events	Critical	RCT (1)	0.5% of participants with SAEs among vaccinated and 0.2% among unvaccinated; certainty in the estimate was very low. Two SAEs which occurred in one participant were judged by the investigator to be related to vaccination.	4
6. Reactogenicity	Important	RCT (1)	Severe reactions were more common in vaccinated; any grade ≥3 reaction was reported by 7.7% of vaccinated vs. 4.1% of placebo group	1

Evidence type: 1=high; 2=moderate; 3=low; 4=very low; ND, no data

50

Moderna

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series Dose	Primary series Injection volume	Booster doses† Dose	Booster doses† Injection volume
6 months–5 years	Dark blue	Magenta	No	25 µg	0.25 mL	NA	NA
6–11 years§	Dark blue	Purple	No	50 µg	0.5 mL	NA	NA
12–17 years	Red	Light blue	No	100 µg	0.5 mL	NA	NA
18 years and older	Red	Light blue	No	100 µg	0.5 mL	50 µg	0.25 mL
18 years and older	Dark blue	Purple	No	NA	NA	50 µg	0.5 mL

Moderna Dosing and Formulations

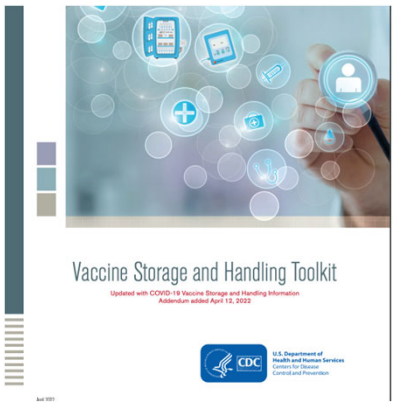
6/24/22 51

51

Storage and Handling Guidelines

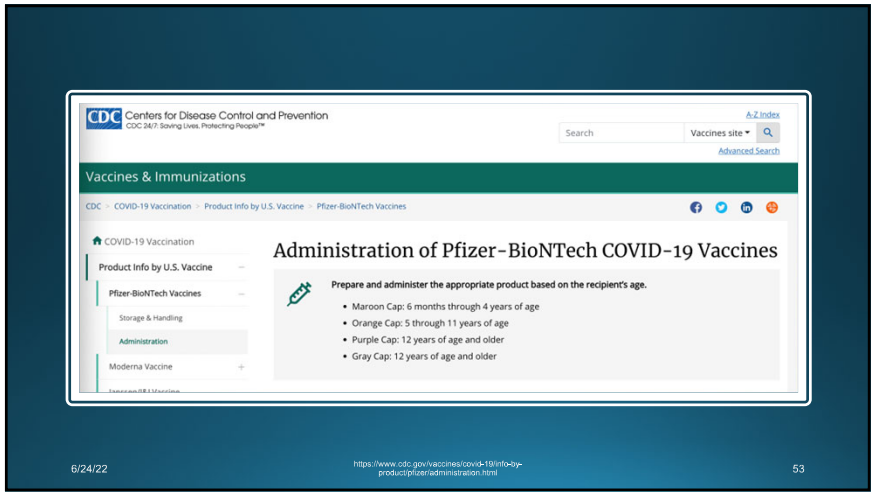
- **Follow Georgia Department of Health, CDC's and manufacturer's guidance for vaccine storage.** Some vaccine storage conditions are associated with beyond-use dates and times. Providers should track these time frames.
- Vaccine should **NOT** be used after the expiration date or beyond-use date/time.

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

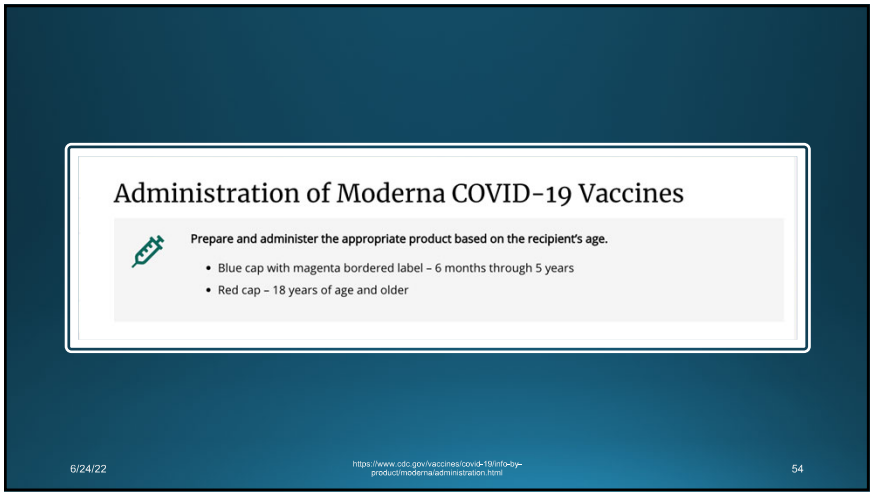


6/24/22 52

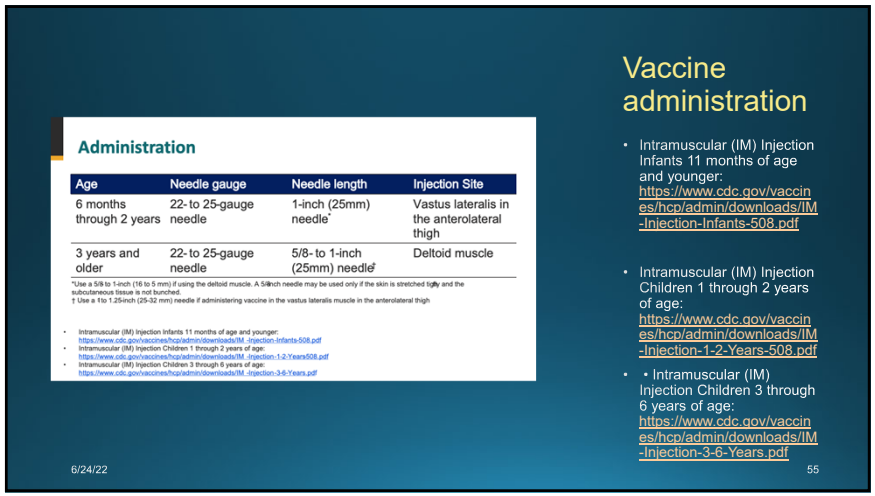
52



53



54

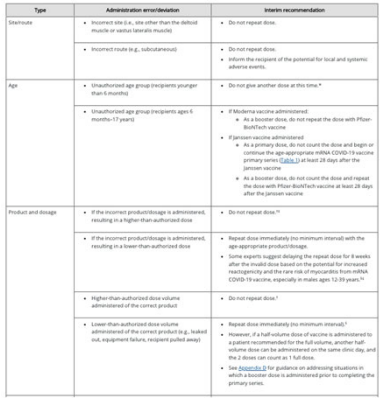


55

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

COVID-19 Vaccine Administration errors



56

Children 5-17 years

6/24/22 57

57

COVID-19 vaccine for 5-17 year olds

- As of 6/24/22 both Moderna and Pfizer BioNTech COVID-19 vaccines are both available for use in 5 to 17-year-olds.
- Children and adolescents ages 5 – 17 years are at risk of severe illness from COVID-19 – Over 10.3 million cases have occurred in the United States to date – With over 600 deaths since the beginning of the pandemic
- Children and adolescents who have received COVID-19 vaccines have better outcomes than children who are unvaccinated, particularly against severe illness
- As of 6/1/2022, 65% of U.S. children ages 5 – 11 years and 30% of U.S. adolescents ages 12 – 17 years have not yet received COVID-19 vaccination

6/24/22 58

58

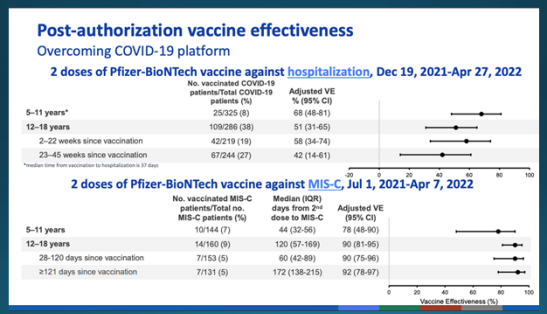
Pfizer COVID-19 Vaccine Full Approval for ages 12 years and older

- July 8, 2022 the FDA granted full approval for COMIRNATY (Pfizer, COVID-19 vaccine) for persons 12 years and older.
- Vaccines under EUA (Emergency Use Authorization):
  - Pfizer COVID-19 Vaccine 6 months through 11 years old
  - Moderna COVID-19 vaccine 6 months through 17 years old

6/24/22 59

59

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



6/24/22 60

60

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

61

Can you interchange mRNA COVID-19 vaccine products?

- In general, the same mRNA vaccine product should be used for all doses in the primary series.
- In rare situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, any age-appropriate mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series.
- **Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine should be administered at least 8 weeks after the second dose to complete the 3-dose primary series.**

62

Co-administration with other childhood vaccines

- Is allowed
- When deciding whether to co-administer another vaccine(s) with COVID-19 vaccine, providers and parents/guardians may consider:
  - whether a child is behind or at risk of becoming behind on recommended vaccines and the likelihood of the child returning for another vaccination;
  - the child's risk of becoming infected with a vaccine-preventable disease and their risk for severe disease if infected;
  - and the reactogenicity profile of the vaccines.

63

Best practices for multiple injections

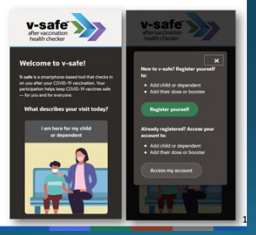
- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable.
- Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccine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

64

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/



6/24/22 65

65

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

6/24/22 66

66

COVID-19 Vaccination schedule

6/24/22 67

67

Table 2. COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised

6 months through 11 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose†	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	6 months–4 years	3	3	NA	3–8 weeks	At least 8 weeks	NA
Pfizer-BioNTech	5–11 years	3	2	1	3–8 weeks	At least 5 months	NA
Moderna	6 months–5 years	2	2	NA	4–8 weeks	NA	NA
Moderna	6–11 years	2	2	NA	4–8 weeks	NA	NA

12 through 17 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose†	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	12–17 years	3	2	1	3–8 weeks	At least 5 months	NA
Moderna	12–17 years	2	2	NA	4–8 weeks	NA	NA

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised

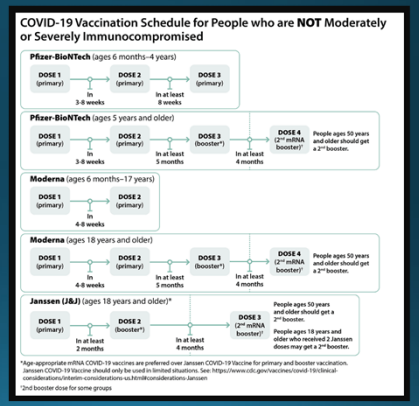
6/24/22 68

COVID-19 vaccination schedule for most children

68

COVID-19 vaccination schedule for most people

- COVID-19 vaccination schedule for most people



69

Table 3. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised

Ages 6 months through 11 years

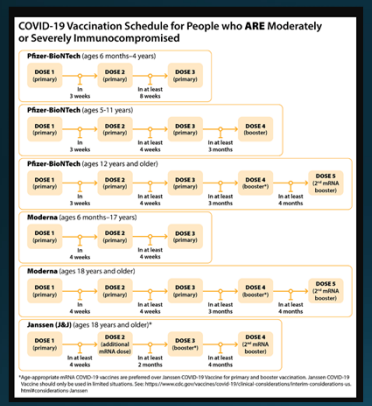
Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose	Interval between 4th and 5th dose
Pfizer-BioNTech	6 months–4 years	3	3	NA	3 weeks	At least 8 weeks	NA	NA
Pfizer-BioNTech	5–11 years	4	3	1	3 weeks	At least 4 weeks	At least 3 months	NA
Moderna	6 months–5 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA
Moderna	6–11 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA

12 through 17 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose	Interval between 4th and 5th dose
Pfizer-BioNTech	12–17 years	5	3	2	3 weeks	At least 4 weeks	At least 3 months	At least 4 months
Moderna	12–17 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA

COVID-19 schedule for children who are moderately or severely immunocompromised

70



COVID-19 vaccination schedule for people who are moderately or severely immunocompromised

71

Boosters and Additional Doses

72

Additional vaccine dose versus a booster dose

Additional dose after an initial primary vaccine series: A subsequent dose of vaccine administered to people who were 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 should receive an additional dose.

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

73

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

- A **3-dose primary series** is recommended for people ages 5 years and older who are moderately or severely immunocompromised **at the time of vaccination.** The same mRNA vaccine product should be used for all doses of the primary series.
- People who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for their primary series should receive an additional dose.

74

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 or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- 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.

75

Safety considerations in Children and adolescents

76

Safety considerations for mRNA COVID-19 vaccines in children

- Among children ages 6 months–4 years (Pfizer-BioNTech) or 6 months–5 years (Moderna), pain/tenderness at the injection site was the most frequent local reaction.
- The most common systemic symptom in older children was fatigue; 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.

77

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.

78

Myocarditis and pericarditis

- A rare risk for myocarditis and/or pericarditis has been observed following receipt of mRNA COVID-19 vaccines. These rare cases of myocarditis or pericarditis have occurred most frequently in adolescent and young adult males within the first week after receiving the second dose of an mRNA COVID-19 vaccine. The reporting rates for myocarditis after mRNA COVID-19 vaccination exceed the background rates in several age groups in males and females. Some, but not all, observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males ages 18–39 years following the second dose of Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines.
- To date, data suggest the risk for myocarditis and/or pericarditis after mRNA COVID-19 booster doses in adolescents and young adults is generally lower than the risk after the second mRNA COVID-19 vaccination.

79

Myocarditis and pericarditis (2)

- Most patients with myocarditis after mRNA COVID-19 vaccination have been hospitalized for short periods. CDC is assessing long-term outcomes in people with myocarditis after mRNA COVID-19 vaccination. Preliminary data from surveys conducted with healthcare providers caring for persons ages 5–29 years at least 90 days after the myocarditis diagnosis showed most patients were fully recovered from their myocarditis.
- After reviewing available data on the risks and benefits, ACIP and CDC determined that the benefits (e.g., prevention of COVID-19 cases and its severe outcomes) outweigh the risks of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines for children, adolescents, and young adults.
- People receiving mRNA COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 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. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.

80

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

- **An 8-week interval between the first and second doses of an mRNA COVID-19 vaccine primary series may be optimal for some people as it may reduce the small risk of myocarditis and/or pericarditis associated with mRNA COVID-19 vaccines.**
- mRNA COVID-19 vaccines are FDA-approved or authorized for a **3-week** (Pfizer-BioNTech vaccine) or **4-week** (Moderna vaccine) interval between the first and second dose.
- A 3- or 4-week interval continues to be the recommended interval for people who are moderately to severely immunocompromised, adults ages 65 years and older, and others who need rapid protection due to increased concern about community transmission or risk of severe disease.
- mRNA COVID-19 vaccines are safe and effective at the FDA-approved or FDA-authorized intervals, but a longer interval may be considered for some populations.
- While absolute risk remains small, the relative risk for myocarditis is higher for males ages 12-39 years, and this risk might be reduced by extending the interval between the first and second dose.
- Some studies in adolescents (ages 12-17 years) and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks.

81

Myocarditis and pericarditis after vaccination in young children

- 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.
- In postmarketing 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. However, it is not yet known if this represents an increased risk of myocarditis. Safety monitoring is ongoing to assess for possible risk of myocarditis and pericarditis after mRNA COVID-19 vaccination in all age groups.

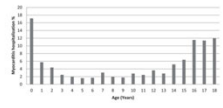
82

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



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

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

59

83

Special considerations

84

Special considerations

- 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 (see Table 2).
- 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).

85

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

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

86

COVID-19 Vaccines when Transitioning from a younger to older age group(2)

Children who will turn from age 4 years to 5 years: FDA authorization of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 4 years to 5 years between any dose in the primary series to receive

- A 2-dose primary series using the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years

OR

- A 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years. Each of doses 2 and 3 may be with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years, **or** the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years.

87

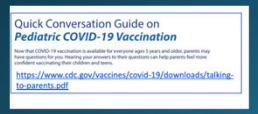
COVID-19 Vaccines when Transitioning from a younger to older age group (3)

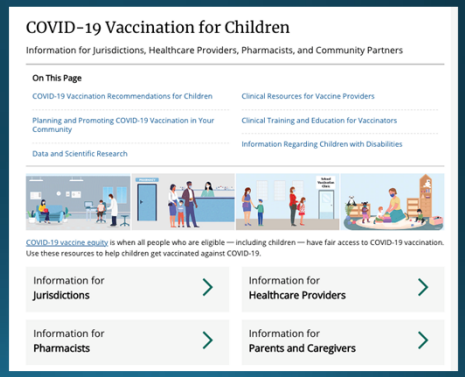
Children who will turn from age 11 years to 12 years: FDA authorization of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 11 years to 12 years between their first and second dose in the primary series to receive, for either dose: (1) the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years or (2) the Pfizer-BioNTech COVID-19 Vaccine product authorized for people ages 12 years and older.

88

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





6/24/22 89

89

Other guidelines related to COVID-19 Vaccination

6/24/22 90

90

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

In addition, 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 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.

- COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma. (90 day waiting period no longer needed).

91

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
3. The patient resides in an area where the COVID-19 community level is high or is otherwise at increased risk for exposure to SARS-CoV-2 (e.g., through occupation, travel, large gatherings)

SOURCE: CDC

6/24/22 92

92

COVID-19 Vaccine Interim Clinical Considerations
Preference for mRNA vaccines

- An mRNA COVID-19 vaccine series is preferred over Janssen COVID-19 Vaccine for primary and booster vaccination.
- A person is considered fully vaccinated with vaccines against SARS-CoV-2 infection ≥2 weeks after receipt of the second dose in a 2-dose series (Pfizer-BioNTech and Moderna) or ≥2 weeks after receipt of a single dose of the Janssen COVID-19 Vaccine.
- CDC recommends that people remain up to date with their vaccines, which includes additional doses for individuals who are immunocompromised or booster doses at regular time points.

SOURCE: CDC

6/24/22 93

93

Up to Date for COVID-19 vaccines

- People ages 6 months and older are up to date with their COVID-19 vaccines when they have received all doses in the primary series and all booster doses recommended for them, when eligible.

6/24/22 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised 94

94

COVID-19 Vaccination of Pregnant People or Lactating Women

- 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.
- COVID-19 vaccination is recommended for all people aged 5 years and older, including people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future.
- mRNA vaccines are recommended for all vaccine-eligible populations, including for people who are pregnant or lactating. Those who are considering receipt of the Janssen COVID-19 Vaccine should be counseled about the rare risk of TTS which can occur (typically within 2 weeks) after receipt of the Janssen COVID-19 Vaccine, and need for a booster dose 2 months or more after the initial dose.
- There is no evidence that any of the COVID-19 vaccines affect current or future fertility.

SOURCE:CDC
SOURCE: ACOG

6/24/22 95

95

COVID-19 Vaccine Interim Clinical Considerations
Recommendations for those vaccinated outside the US

- People who initiated vaccination outside of the United States are considered to be up to date with their COVID-19 vaccines using the following table, Appendix A at:
  - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-a
- Age-appropriate Pfizer-BioNTech and Moderna COVID-19 Vaccine products can be used in people ages 6 months and older to initiate or complete vaccination.

6/24/22 SOURCE: CDC 96

96

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

97

Vaccination of people with certain underlying medical conditions with COVID-19 Vaccine

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

SOURCE:CDC

98

Table 4. Contraindications and precautions to COVID-19 vaccination

Medical condition or history	Contraindication, not recommended, or precaution	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 (i.e., mRNA or Janssen COVID-19 Vaccine).
History of a known diagnosed allergy to a component of the COVID-19 vaccine	Contraindication	See Appendix E for actions and additional information.
For **the Janssen COVID-19 Vaccine**, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)	Contraindication	Do not vaccinate with Janssen COVID-19 Vaccine. See Safety considerations for Janssen COVID-19 Vaccine for additional information on vaccinating this group with an mRNA COVID-19 vaccine.
For **the Janssen COVID-19 Vaccine**, history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic heparin-induced thrombocytopenia (HIT)	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.
For the **Janssen COVID-19 Vaccine**, Guillain-Barré syndrome (GBS) within 6 weeks after receipt of Janssen COVID-19 Vaccine	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.

Contraindications and Precautions (1)

- SOURCE: CDC

99

Contraindications and Precautions (2)

Precaution	Recommended Action(s)
History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])	The benefit of vaccination outweighs the risks for most people. See Appendix C for actions and additional information.
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 (i.e., mRNA or Janssen) have a precaution to the **same type of COVID-19 vaccine**	
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to **the other type** of COVID-19 vaccine (e.g., people with a contraindication to an mRNA COVID-19 vaccine have a precaution to Janssen COVID-19 vaccine and vice versa).	
Moderate or severe illness, with or without fever	Defer vaccination until the illness has improved.
For mRNA COVID-19 vaccines, history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine	A subsequent dose of any COVID-19 vaccine should generally be avoided. See Considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna for additional considerations.
For Janssen COVID-19 Vaccine, a history of GBS[†]	See Considerations for Janssen COVID-19 Vaccine and Special populations for additional information.

SOURCE: CDC

100

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

6/24/22 SOURCE: CDC 101

101

- **Observation after COVID-19 vaccination**

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

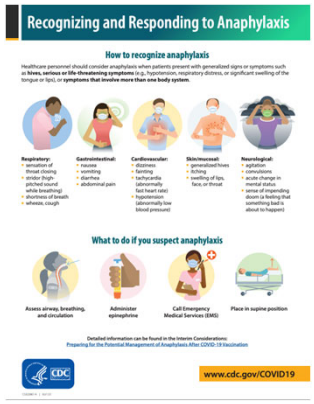
-History of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.

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

-History of anaphylaxis due to any cause.

15 minutes:
All other people

6/24/22



102

102

Immunity after COVID-19 vaccination

- We are still learning about COVID-19 vaccines. CDC continues to review evidence and update guidance as more information is learned.
- 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

6/24/22 CDC: boosters SOURCE:CDC SOURCE: NFID 103

103

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.

6/24/22 104

104

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.

CDC 6/24/22 105

105

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

6/24/22 106

106

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.

6/24/22 107

107

Adverse events after COVID-19 vaccines

6/24/22 108

108

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	SYSTEMIC REACTIONS
• Pain • Redness • Swelling	• Fatigue • Headache • Chills • Fever • Muscle pain • Nausea

SOURCE: CDC

6/24/22 109

109

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

6/24/22 110

110

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

6/24/22 111

111

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

6/24/22 112

112

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.

6/24/22

SOURCE: CDC

113

113

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

6/24/22

SOURCE: CDC

114

114

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.

6/24/22

SOURCE: FDA SOURCE: CDC

115

115

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

6/24/22

116

116

Myocarditis and Pericarditis after mRNA vaccination

- Myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines.
- These rare cases of myocarditis or pericarditis have occurred most frequently in adolescent and young adult males within the first week after receiving the second dose of an mRNA COVID-19 vaccine
- Most patients have been hospitalized for short periods, with most achieving resolution of acute symptoms.
- Accumulating evidence from multiple sources suggests there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of the Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines.

6/24/22 SOURCE: CDC 117

117

Myocarditis and Pericarditis after mRNA vaccination (2)

- The risk of myocarditis or pericarditis associated with SARS-CoV-2 infection is greater than the risk of myocarditis or pericarditis occurring after receipt of an mRNA COVID-19 vaccine in adolescents and adults.
- After reviewing available data on the risks and benefits, ACIP determined that the benefits (e.g., prevention of COVID-19 cases) outweigh the risks of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines for children, adolescents, and young adults.
- People receiving mRNA COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae.

6/24/22 SOURCE: CDC 118

118

Myocarditis and Pericarditis after mRNA vaccination - recommendations for Clinicians

- Report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS.
- Consider myocarditis and pericarditis in adolescents or young adults with **acute chest pain, shortness of breath, or palpitations after vaccination**. In this younger population, coronary events are less likely to be a source of these symptoms.
- Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.
- **Ask about prior COVID-19 vaccination** if you identify these symptoms, as well as relevant other medical, travel, and social history.
- Until additional safety data are available, experts recommend that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine.

Current CDC guidance for clinicians SOURCE: CDC

6/24/22 119

119

For vaccinated persons

- Uses voluntary smartphone-based text messaging and web surveys to provide personalized health check-ins after receiving a COVID-19 vaccination
- Information sheet provided at time of vaccination to every person
- Simple to register, only takes 1-2 minutes to answer each text message request
- Need help?
  - Call 800-CDC-INFO
  - Open 24 hours, 7 days a week

6/24/22 SOURCE:v-safe 120

120

COVID-19 Disease: testing and quarantine

121

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

122

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

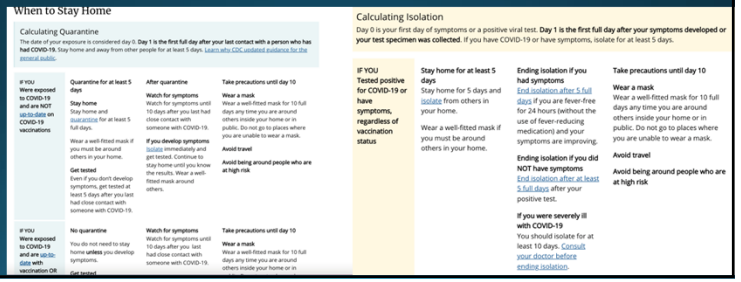
SOURCE: CHOP and SOURCE: CDC

123

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.



CDC: HCP's

Source: CDC

124

Critical Elements for Immunization Services

- Health care provider resources: training, toolkits, job aids
- Ordering vaccines
- Billing and Coding
- Vaccine Administration
- Vaccine Communication

125

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

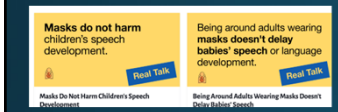
126

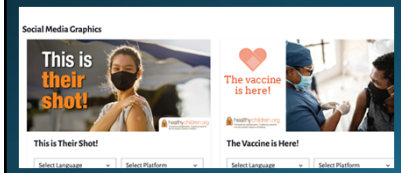
Health Care Provider Training

- 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

127

AAP Resources for Providers and Parents (Vaccine Campaign Toolkit)





SOURCE:AAP

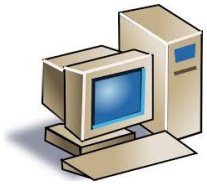
128

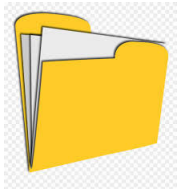
Patient and Health Care Provider Resources

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/





6/24/22 129

129

Preparing for COVID-19 vaccination in Pediatric practices

6/24/22 130

130

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

6/24/22 131

131

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?

6/24/22 132

132

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

6/24/22 133

133

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

GA DPH

134

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
-

6/24/22 135

135

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.

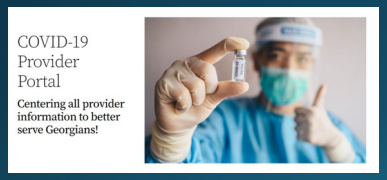
GA DPH

19

136

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

20

137

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

21

138

Coding for COVID-19 Services- ? Update

- 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
  - If you have submitted claims with these codes and received a claim denial, DCH will automatically reprocess any claims with DOS 1/1/2021 through 3/3/2021. Reprocessing to be completed by 3/31/21.

6/24/22 SOURCE: GA AAP 139

139

Billing for COVID-19 Services - ? Update

Billing:

- You may bill for vaccine administration (Commercial, Medicaid, Medicare, HRSA uninsured fund)
- Differentiate Pediatric from Adult (12 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.

6/24/22 SOURCE: GA AAP 140

140

CPT Codes - ? Update

Vaccine Product Information	Vaccine Manufacturer	CPT Codes: Product	1st Dose Admin	2nd Dose Admin	3rd Dose Admin	Booster Admin	Patient Age
SARS-CoV-2 (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, PF, **30 mcg/ 0.3mL** dosage, diluent reconstituted, for IM use	Pfizer, Inc	91300	0001A	0002A	0003A	0004A	≥12 years
SARS-CoV-2 (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, PF, 30 mcg/0.3 mL dosage, **tris-sucrose** formulation, for IM use	Pfizer, Inc	91305 ✓	0051A	0052A	0053A	0054A	
SARS-CoV-2 (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, PF, **10 mcg/0.2 mL dosage**, diluent reconstituted, tris-sucrose formulation, for IM use	Pfizer, Inc	91307 ✓	0071A	0072A	N/A	N/A	5-11 years
SARS-CoV-2 (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, PF, **100 mcg/0.5mL** dosage, for IM use	Moderna, Inc	91301	0011A	0012A	0013A	N/A	≥18 years
SARS-CoV-2 (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, PF, $5x10^{10}$ viral particles/0.5mL dosage, for IM use	AstraZeneca, Plc	91302 ✓	0021A	0022A	N/A	N/A	
SARS-CoV-2 (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, PF, 5x1010viral particles/ 0.5mL dosage, for IM use	Janssen	91303	0031A	N/A	N/A	N/A	≥18 years
SARS-CoV-2 (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, PF, 5 mcg/0.5 mL dosage, for IM use	Novavax, Inc	91304 ✓	0041A	0042A	N/A	N/A	

✓ Indicates pending FDA approval.
Links to ACIP recommendations are embedded in the vaccine manufacturer when available.
Abbreviations: Admin, administration; IM, intramuscular; PF, preservative free, SARS-CoV-2; Severe acute respiratory syndrome coronavirus 2

141

Billing for Pfizer Vaccine (Needs update for Pfizer and Moderna)

- Pfizer Vaccine ADULT – 91300 – zero charge PEDIATRIC 91307- zero charge
- Pfizer Dose 1 admin 0001A – Medicare rate $40.00 PEDIATRIC DOSE 1 ADMIN 0071A
- Pfizer Dose 2 admin 0002A – Medicare rate $40.00 PEDIATRIC DOSE 2 ADMIN 0072A
- Link to Z.23
- When adding to well visit use the 25 modifier

142

Reimbursement for COVID-19 vaccines

COVID-19 Vaccine Administration Free Increase - Effective April 1, the Georgia Department of Community Health the COVID-19 vaccine administration fee is now $40.00 per dose for category of services: outpatient hospital, physician, physician assistant, midwife nurse, FQHCs, hospital-based rural health center, freestanding rural health center, advanced nurse practitioner, and diagnostic screening & preventative services.

Vaccine Name	Code	Description	DCH FFS Reimbursement
Pfizer-BioNTech COVID-19 Vaccine	*0001A (1st dose)* *0002A (2nd dose)*	***91300** - Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus diseases [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use*	1st [illegible] $40 2nd [illegible] $40
Moderna COVID-19 Vaccine	*0011A (1st dose)* *0012A (2nd dose)*	***91301** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus diseases [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use*	1st [illegible] $40 2nd [illegible] $40
Janssen Covid-19 Vaccine	*0031A (single dose)*	***91303** - Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus diseases [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use*	Single dose $40

143

3rd dose of COVID-19 vaccine

- ***Medicaid Opens Administration Codes for 3rd Dose:*** **As of** Aug 12, the Ga. Dept. of Community Health will permit a third dose of the Pfizer and Moderna COVID-19 vaccines for individuals who have undergone solid organ transplantation, or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
- Vaccine administration of these vaccines is $40.00

144

3rd dose of COVID-19 vaccine (2)

- **Pfizer CPT Code 91300 –** vaccine in individuals 12 years age or older per the following administration codes:
  - 0001A – 1st dose; 0002A - 2nd dose; and 0003A – 3rd dose.
- **Moderna CPT Code 91301-** vaccine for in individuals 18 years of age or older per the following administration codes:
  - 0011A – 1st dose;0012A – 2nd dose;0013A – 3rd dose

145

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/0.3 mL 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*	59267-3525-1 59267-3525-01
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*	59267-1078-1 59267-0078-01 59267-1078-4 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 Booster*	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*	80777-279-05 80777-0279-05
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/coronavirus/2019-ncov/vaccines/covid-19-vaccines-us.html#Authorized-vaccines

146

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.georgia.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

147

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.

148

Codes, CMO Procurement & Downcoding

- **ICD 10 Z codes** – "... *the reporting of secondary ICD-10-CM codes to explain the increased complexity caused by the SDOH will be important so payers know the whole story*."
- Social Determinants of Health Assessments – Hunger Vital Sign™; IHELP; or Pediatric ACEs and Related Life-events Screener (PEARLS)
- **Screening Brief Intervention & Referral to Treatment (SBIRT)** – Reporting time to address a positive finding in a screening: CPT code 99408 for 15 – 30 mins. and 99409 for > 30 mins.; Medicaid pays $33.41 and $65.51 for these codes.
- **Procurement Update** – The Ga Dept. Community of Health announced its procurement process to identify Medicaid Care Management Organizations (CMOs); this Suppliers' Library note key focus areas for comments on this new contract.
- **Downcoding/Leveling of Care**– The Chapter is having ongoing discussions about this issue with Peach State Health Plan and Amerigroup; appealing a claim would appear to be cost prohibitive. Additionally, this practice of changing the reported code, indirectly changes the medical record of the visit.

6/24/22 149

149

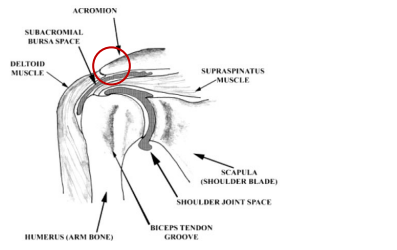
Vaccine Administration

6/24/22 150

150

SIRVA

Shoulder anatomy



HRSA Healthcare Systems

4

SIRVA = Shoulder Injury Related to Vaccine Administration

TIPS TO AVOID THIS INJURY

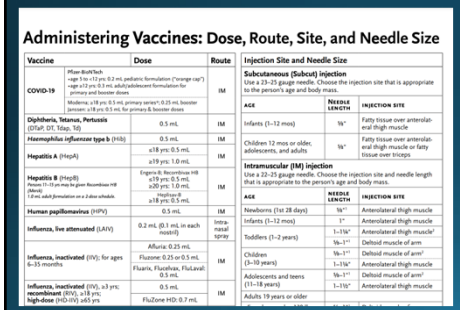
- **Landmark the site---don't "eyeball" it**
- **If possible, be seated to vaccinate a seated pt.**
- **Expose the shoulder completely**
- **Roll the sleeve up---don't pull the shirt over the neck**
- **REMEMBER!**
  2-3 FINGERS DOWN FROM THE ACROMION

SOURCE: HHS

6/24/22 151

151

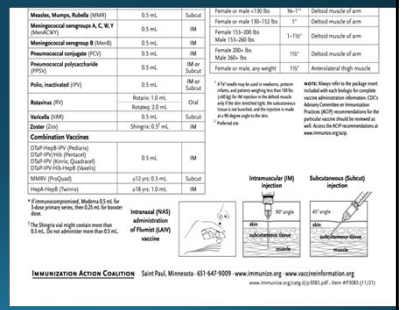
Vaccine Administration Best practices – Route, Dose, Site, Needle Size



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 (persons ≥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 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, FluLaval, 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

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)	⅝"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	⅝"	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)	⅝"†	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 years)	1–1¼" ⅝–1"†	Anterolateral thigh muscle‡ Deltoid muscle of arm
Children (3–10 years)	⅝–1"† 1–1¼"	Deltoid muscle of arm‡ Anterolateral thigh muscle
Adolescents and teens (11–18 years)	⅝–1"† 1–1½"	Deltoid muscle of arm‡ Anterolateral thigh muscle
Adults 19 years or older		



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

Female or male <130 lbs	⅝–1"†
Female or male 130–152 lbs	1"
Female 153–200 lbs Male 153–260 lbs	1–1½"
Female 200+ lbs Male 260+ lbs	1½"
Female or male, any weight	1½"

* 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.

‡ A ⅝" 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 height, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

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.

Intramuscular (IM) injection

Subcutaneous (Subcut) injection

Intranasal (NAS) administration of Flumist (LAIV) vaccine

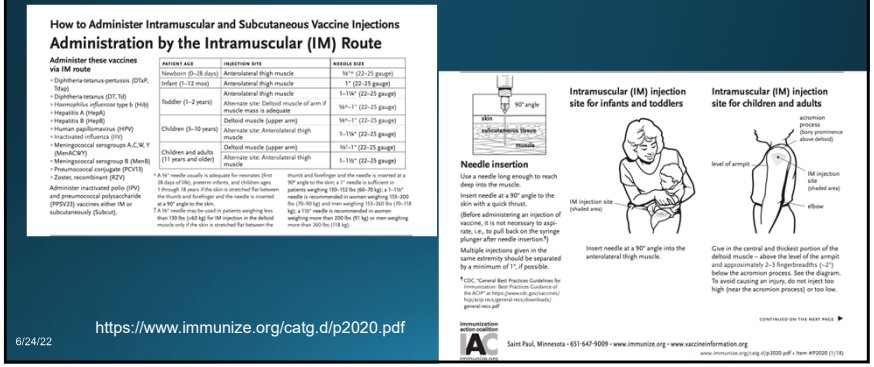
IMMUNIZATION ACTION COALITION Saint Paul, Minnesota · 651-647-9009 · www.immunize.org · www.vaccineinformation.org

www.immunize.org/catg.d/p3085.pdf · Item #P3085 (11/21)

6/24/22 https://www.immunize.org/catg.d/p3085.pdf 152

152

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	⅝"* (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	⅝*–1" (22–25 gauge)
Children (3–10 years)	Deltoid muscle (upper arm)	⅝*–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)	⅝*–1" (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1½" (22–25 gauge)

* A ⅝" 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 ⅝" 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 ▶

immunization action coalition

Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

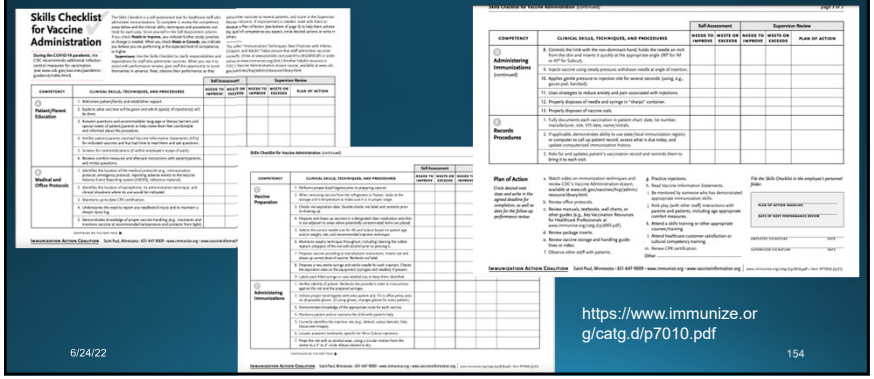
www.immunize.org/catg.d/p2020.pdf • Item #P2020 (1/18)

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

6/24/22

153

Training Tools: Skills Checklist for Vaccine Administration



Skills Checklist for Vaccine Administration

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

6/24/22

154

154

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.

6/24/22

155

155

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

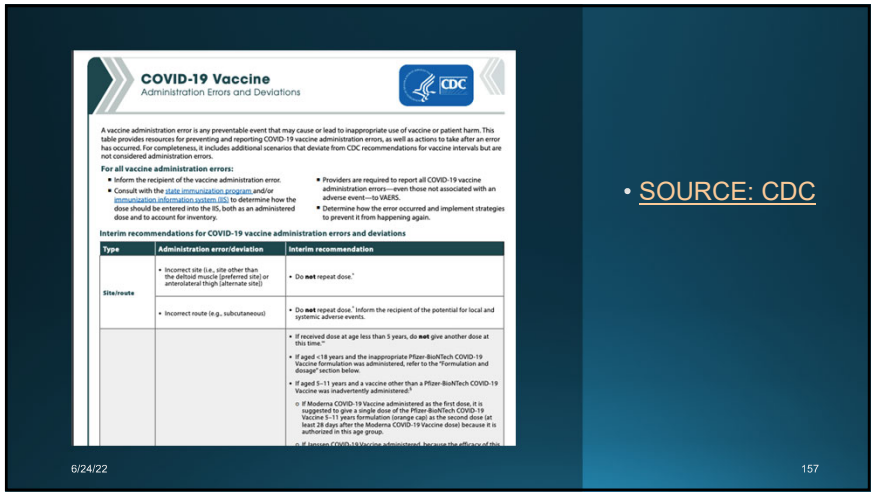
Waste of Vaccine Doses

- 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

156



• SOURCE: CDC

157

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

158

Reporting of vaccine adverse events

- 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
- Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

SOURCE: CDC

159

For vaccinated persons
- Uses voluntary smartphone-based text messaging and web surveys to provide personalized health check-ins after receiving a COVID-19 vaccination
- Information sheet provided at time of vaccination to every person
- Simple to register, only takes 1-2 minutes to answer each text message request
- Need help?
  - Call 800-CDC-INFO
  - Open 24 hours, 7 days a week

SOURCE:v-safe

160

Vaccine Communication

6/24/22 161

161

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

6/24/22 162

162

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

6/24/22 163

163

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

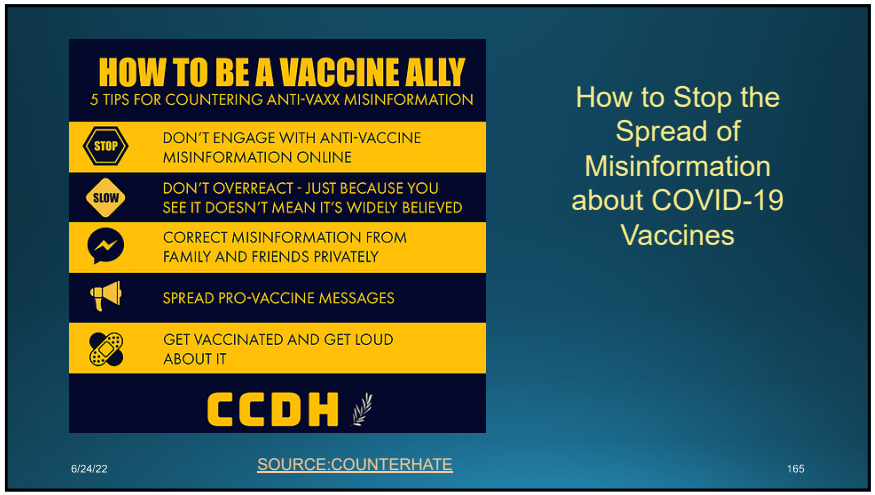
Think Twice Global Vaccine Institute

NATIONAL VACCINE INFORMATION CENTER

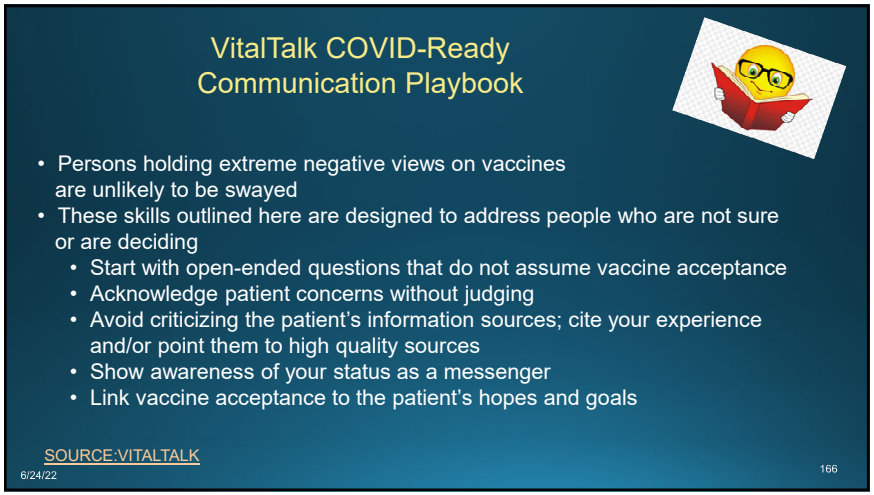
People Advocating PAVE Vaccine Education

164

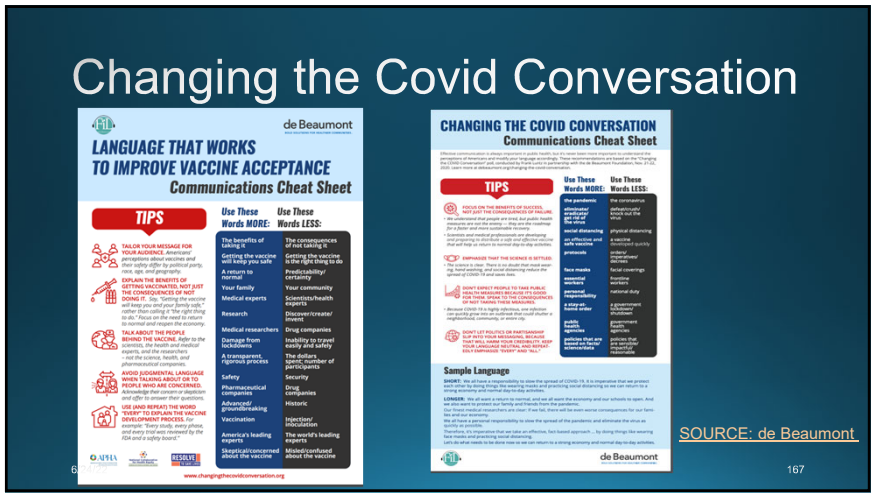
164



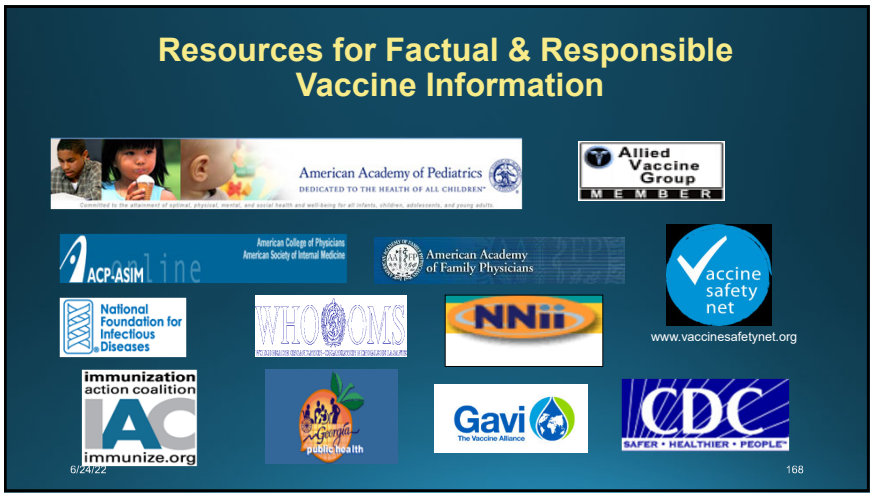
165



166



167



168

Additional Resources

- CDC COCA Slides - What Clinicians Need to Know About Adolescent Pfizer Vaccine Administration
- Pfizer EUA Fact Sheet for caregivers- last revised 10/20/21 may be updated again. No VIS for EUA vaccine.
- Pfizer fact sheet CDC website
- HRSA Uninsured Claims
- Pfizer-BioNTech COVID-19 Beyond Use Date/Time (BUD) Tracking Label (cdc.gov)

6/24/22 169

169

Test Your Knowledge and FAQs EPIC 2022

6/24/22 170

170

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

6/24/22 171

171

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.**

6/24/22 172

172

Which children are eligible to receive an additional dose of COVID-19 vaccine? (Choose the correct answer)

- All children and adolescents 5 years and older. Administer the additional dose 5 months after completion of the Pfizer vaccine series.
- Children and adolescents 5 years and older who are moderately or severely immunocompromised. Administer the dose 5 months after completing the Pfizer vaccine series.
- All children and adolescents 5 years and older. Administer the additional dose 1 month after completion of the Pfizer vaccine series.
- Children and adolescents 5 years and older who are moderately or severely immunocompromised. Administer the dose 1 month after completing the Pfizer vaccine series.

6/24/22 173

173

Which children are eligible to receive an additional dose of COVID-19 vaccine? (Choose the correct answer)

- All children and adolescents 5 years and older. Administer the additional dose 5 months after completion of the Pfizer vaccine series.
- Children and adolescents 5 years and older who are moderately or severely immunocompromised. Administer the dose 5 months after completing the Pfizer vaccine series.
- All children and adolescents 5 years and older. Administer the additional dose 1 month after completion of the Pfizer vaccine series.
- CORRECT: Children and adolescents 5 years and older who are moderately or severely immunocompromised. Administer the dose 1 month after completing the Pfizer vaccine series.

6/24/22 174

174

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

- 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

6/24/22 175

175

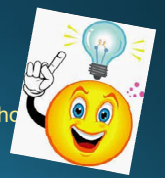
FAQS

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 scho
Some employers may require this.



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

6/24/22 176

176

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.

6/24/22

SOURCE: NFID and SOURCE: CDC

177

177

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

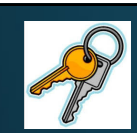
Immunization Action Coalition
E-mail admin@immunize.org
Phone 651.647.9009
Website www.immunize.org

6/24/22

178

178

KEYS TO PREVENTION






6/24/22

179

179