EPIC Immunization 2021 Update

SARS-CoV-2 (COVID-19)

May 2021

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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

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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

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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 the storage, handling, and administration of COVID-19 vaccines
- Name 3 of 5 keys to prevention of COVID-19 disease

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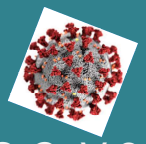

SARS-CoV-2 virus (COVID-19 disease)*

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

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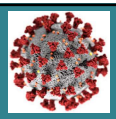

SARS-CoV-2 virus (COVID-19 disease) in children and adolescents

National data

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.

(4/29/21) Over 3.78 million children have tested positive for COVID-19 since the onset of the pandemic.

Children represent 13.8% of total cumulated cases. There have been 296 deaths due to COVID-19 in children.

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)

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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

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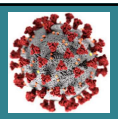

MIS-C in children and adolescents (5/14/21)

CDC: MIS-C

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.

3,742 MIS-C cases have been reported in the U.S. as of May 3, 2021. Most cases of MIS-C were in children and adolescents between the ages of 1 and 14 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. 21% of cases occurred in adolescents 12-17 years.

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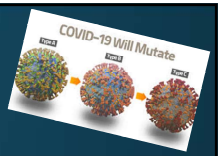
COVID-19 VARIANTS



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

Multiple COVID-19 variants are circulating globally.

CDC is studying these variants 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

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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

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COVID-19 VACCINE OVERVIEW

(4/25/21) Subject to change as other vaccines are authorized

	Pfizer-BioNTech	Moderna	Janssen
Vaccine Type	mRNA	mRNA	Non-replicating Human adenovirus 26 vector
EUA granted	Yes	Yes	Yes
# of doses	2	2	1
Storage	Ultracold Freezer/Refrigerator	Freezer/Refrigerator	Refrigerator

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

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mRNA vaccines

Pfizer-BioNTech and Moderna are the two mRNA COVID-19 vaccines authorized for use in the U.S. under an EUA (as of 4/25/21)

The vaccines work by:

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

Myths and facts about mRNA vaccines:

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

SOURCE: CDC

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COVID-19 mRNA Vaccines

	Pfizer-BioNTech	Moderna
Vaccine Type	mRNA (messenger RNA) Efficacy ≈ 95% in preventing symptomatic disease	mRNA (messenger RNA) Efficacy ≈ 94.1% effective in preventing symptomatic disease
Age Indication	≥ 12 years of age** (age subject to change based on FDA review)	≥ 18 years of age** (age subject to change based on FDA review)
Recipient EUA (Emergency Use Authorization) factsheet	https://www.fda.gov/media/144414/download	https://www.fda.gov/media/144638/download
Vaccine Presentation	• Multi-dose vial, 5 doses per vial	• Multi-dose vial,10 doses per vial
Packaging	195 vials/tray (975 doses)	10 vials/carton (100 doses)
Dose	0.3 mL (IM)	0.5 mL (IM)
Dosing Regimen	2 doses, separated by 21 days	2 doses, separated by 28 days

SOURCE: CDC and SOURCE: Immunization Action Coalition

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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 (as of 4/25/21)

The vaccines work by:

- Using a modified version of a different virus to deliver instructions via a gene to a cell. Our cells are taught how to make the spike protein of the SARS- CoV2 virus. This triggers an immune response inside our bodies through the formation of antibodies to prevent infection and to develop 'memory cells' to help protect us against infection with the actual SARS-CoV2 virus in the future.

Myths and facts about non-replicating viral vector vaccines:

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

SOURCE: CDC

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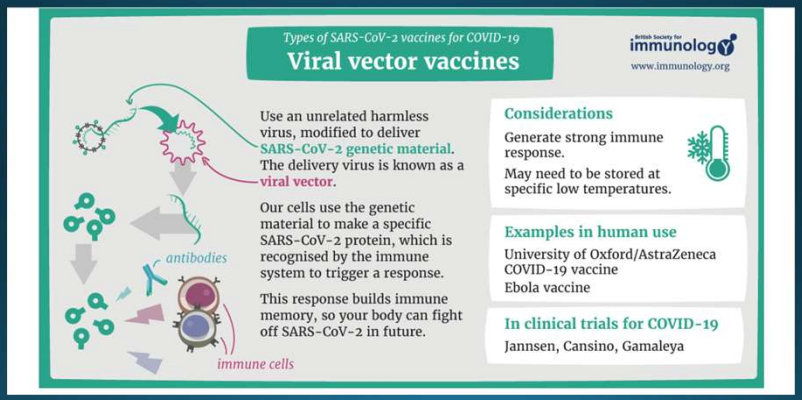

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COVID-19 non-replicating viral vector vaccines

	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
Recipient EUA (Emergency Use Authorization) factsheet	FDA Fact sheet for Recipients
Vaccine Presentation	• Multi-dose vial, 5 doses per vial
Packaging	Each carton contains 10 multi-dose vials (50 doses)
Dose	0.5 mL (IM)
Dosing Regimen	1 dose

SOURCE: CDC

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COVID-19 Vaccine ingredients (3/30/21)

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
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	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	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	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(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
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

SOURCE: CDC

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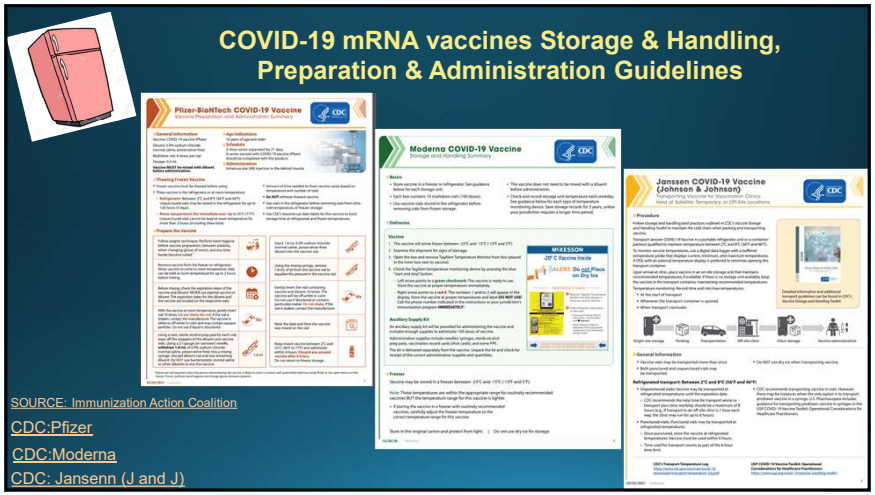

SOURCE: Immunization Action Coalition

CDC:Pfizer

CDC:Moderna

CDC: Jansenn (J and J)

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Pause and then resumption of use of J and J vaccine 4/13/2021-4/23/2021

- CDC and the U.S. Food and Drug Administration (FDA) recommend use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine resumed in the United States, after a temporary pause.
- Reports of adverse events following the use of J&J/Janssen vaccine suggest an increased risk of a rare adverse event called thrombosis with thrombocytopenia syndrome (TTS). Nearly all reports of this serious condition, which involves blood clots with low platelets, have been in adult women younger than 50 years old. There have also been cases in a few men.
- A review of all available data at this time shows that the J&J/Janssen COVID-19 Vaccine's known and potential benefits outweigh its known and potential risks.
- However, women younger than 50 years old should be aware of the rare but increased risk of this adverse event and that there are other COVID-19 vaccine options available for which this risk has not been seen.
- CDC and FDA will continue to monitor the safety of all COVID-19 vaccines

SOURCE: CDC

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

- **severe headache,**
- **backache,**
- **new neurologic symptoms,**
- **severe abdominal pain,**
- **shortness of breath,**
- **leg swelling,**
- **tiny red spots on the skin (petechiae), or**
- **new or easy bruising**

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

SOURCE: CDC

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What should providers do?

- Review the revised LINK: EUA Fact Sheet for Vaccination Providers
- Keep up to date and read the official CDC health alert, LINK: Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine, which includes details about how to assess and care for a patient that presents with thrombosis or thrombocytopenia.
- Share available information with your patients about signs and symptoms to watch for after receiving the J and J vaccine
- Report adverse events to the Vaccine Adverse Event Reporting System.

SOURCE: HEMATOLOGY SOURCE: CDC 21

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Vaccination of children and adolescents (5/14/21)

- Persons 12 years and older are now eligible to receive the Pfizer-BioNTech COVID-19 vaccine. (age subject to change based on FDA review of pending trials)
- Children and adolescents younger than 18 years of age are not authorized to receive the Moderna or Janssen COVID-19 vaccines at this time.
- Clinical trials are underway for children and adolescents younger than 12 years of age with Pfizer vaccine and younger than 18 years of age with Moderna and Janssen vaccines (5/14/21).

SOURCE: CDC 22

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AAP Policy Statement COVID-19 vaccination children and adolescents (5/12/21)

- The AAP recommends COVID-19 vaccination for all children and adolescents 12 years 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 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.
- Given the importance of routine vaccination and the need for rapid uptake of COVID-19 vaccines, the 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

SOURCE: AAP 23

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UPDATES CLINICAL TRIALS Vaccination of children and adolescents (5/14/21)

- Update as information received
- Pfizer vaccine trials (ages 6 months to 12 years old) enrolling, ongoing
- Moderna vaccine trials (ages 6 months to 18 years old) enrolling, ongoing
- Janssen vaccine trials (under 18 years of age) enrolling

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COVID-19 Vaccine Interim Clinical Considerations (Updated 5/14/2021) 1

- The (ACIP) interim recommends the use of Pfizer-BioNTech COVID-19 vaccine in adolescents ages 12–15 years May 10, 2021
- Estimated efficacy 100% in preventing symptomatic, lab confirmed COVID-19 disease. 2260 participants ages 12-15 years old enrolled
- Immune response similar to that observed in adolescents and young adults ages 16–25 years
- Reactogenicity symptoms (within 7 days post vaccination): 90.9% of vaccine recipients reported any local reaction and 90.7% reported any systemic reaction, mostly mild to moderate
- Pain at the injection site was the most common local reaction. Systemic adverse reactions (e.g., fever, fatigue, headache, muscle pain) were more commonly reported after the second dose than after the first dose. The local and systemic reactions were similar to those reported in persons aged ≥16 years. No specific safety concerns were identified among adolescent vaccine recipients

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (Updated 5/14/2021) 2

- COVID-19 vaccines and other vaccines may now be administered without regard to timing.
- It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.
- 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.

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (Updated 5/14/2021) 3

- Adolescents ages 12–17 years are eligible to receive the Pfizer-BioNTech COVID-19 vaccine and may be vaccinated with appropriate assent.
- Follow current state/jurisdictional policies and practices in place for other routine immunizations in this age group.

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (Updated 5/14/2021) 4

History of MIS-C or MIS-A

- Children with MIS-C have high antibody titers to SARS-CoV-2. It is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.
- People with a history of MIS-C or MIS-A may choose to be vaccinated.
- Consider delaying vaccination until recovery from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A
- For people who develop MIS-C or MIS-A that is associated with a confirmed SARS-CoV-2 infection but occurs after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered.

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (Updated 5/14/2021) 5

- ACIP does not state a product preference (provided it meets age requirements.
- Vaccines are NOT interchangeable
- The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]).
- Second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid.
- Second dose may be administered up to 6 weeks (42 days) after the first dose. Currently, only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond this window.
- No booster (additional) doses of COVID-19 vaccines (after the initial dosing series) are recommended at this time.

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (5/14/21) 6

- People who were vaccinated outside the United States with an FDA-authorized COVID-19 vaccine and have received all the recommended doses **do not need** any additional doses.
- In some circumstances people who received a COVID-19 vaccine not currently authorized in the United States may be offered revaccination with an FDA-authorized vaccine. Refer to Clinical considerations for further details.

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (5/14/21) 7

- COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection.
- Defer vaccination until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation.

SOURCE: CDC

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COVID-19 Vaccine Interim Clinical Considerations (5/14/21) 8

- Before vaccination, counsel patients about expected local and systemic reactions and the availability of the v-safe program
- No CDC VIS is yet available
- Give appropriate EUA to vaccine recipients

SOURCE: CDC

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

Any currently authorized COVID-19 vaccine can be administered to people with underlying medical conditions who have no contraindications to vaccination. ACIP does not state a product preference.

- Persons with autoimmune conditions
- Persons with past history of Guillain-Barre` Syndrome or Bells' Palsy
- Persons who are immunocompromised (they may have a reduced immune response to the vaccine)

SOURCE:CDC

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COVID-19 Vaccination of Pregnant or Lactating Women

- Pregnancy is a factor that leads to increased risk for severe COVID-19 disease and adverse pregnancy outcomes.
- ACOG recommends COVID-19 vaccine should not be withheld from pregnant or lactating women.
- Prior conversation with a clinician may be helpful but should not be required .
- A pregnancy registry is looking at safety data and is ongoing.
- Pregnancy testing should not be required prior to receiving an approved COVID-19 vaccine.
- COVID-19 vaccines do not alter your DNA.
- ACOG recommends vaccination of persons who are actively trying to become pregnant. There is no evidence that any of the COVID-19 vaccines affect future fertility.

SOURCE:CDC
SOURCE: ACOG

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COVID-19 Vaccination Other considerations

- Vaccination should be deferred for at least 90 days in persons who previously received passive antibody therapy for COVID-19 infection
- COVID-19 vaccine breakthrough case: a person who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after they complete all recommended doses of an FDA-authorized COVID-19 vaccine. CDC encourages local health departments, healthcare providers, and clinical laboratories to
  - Request the respiratory specimen be held for further testing
  - Report the case to the state health department where the individual resides
  - COVID-19 vaccine breakthrough cases that result in hospitalization or death should be reported to VAERS
- COVID-19 vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis to prevent SARS-CoV-2 infection in a person with a known exposure

SOURCE:CDC
SOURCE: ACOG

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VACCINE CONTRAINDICATIONS AND PRECAUTIONS

Contraindications

- Persons with a severe allergic reaction (anaphylaxis) after a previous dose or to any component of COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a vaccine component (including PEG for either mRNA vaccine and polysorbate 80 for Janssen vaccine)
- People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector)

Precautions

- Persons with a history of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- People with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction

SOURCE: CDC

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VACCINE CONTRAINDICATIONS AND PRECAUTIONS (2)

Neither Contraindications nor precautions to COVID-19 vaccination

- Allergic reactions (including severe allergic reactions) not related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications.
- The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy.
- COVID-19 vaccines do not contain eggs or gelatin, people with allergies to these substances do not have a contraindication or precaution to vaccination.

SOURCE: CDC

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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
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation [CPR] mask)

SOURCE: CDC

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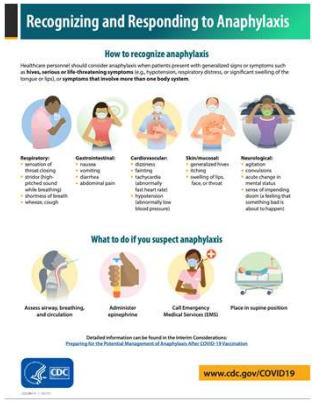
Observation after COVID-19 vaccination

30 minutes:
- History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
- People with a contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis due to any cause

15 minutes:
All other people



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Vaccine Adverse Events (1)

- 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

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VACCINE ADVERSE EVENTS (2)

- 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

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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

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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

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Immunity after COVID-19 vaccination or COVID-19 disease

- After having COVID-19 disease, getting the virus again (reinfection) is uncommon in the 90 days after the first infection with the virus that causes COVID-19. It is unknown how long this type of protection lasts.
- After receiving a COVID-19 vaccine, it is not yet known how long the protection from those doses will last. These are new vaccines for a disease that emerged only recently, which means there are not yet long-term data.
- For continued protection, follow CDC guidelines re: wearing masks, social distancing, avoiding large crowds, and hand washing after receiving your vaccine

SOURCE:CDC
SOURCE: NFID

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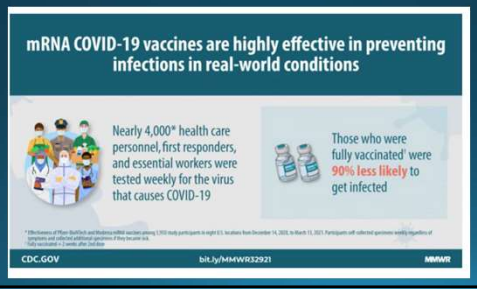
Vaccine effectiveness in real-world studies

- Update as information is received
- CDC: SOURCE: MMWR



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COVID-19 Vaccine Interim Clinical Considerations (5/14/21) 11

TB skin tests and COVID-19 vaccines

- COVID-19 vaccines should not be delayed because of testing for TB infection.
- Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before or during the same encounter as COVID-19 vaccination.
- When testing with TST or IGRA cannot be done at the same time as COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of COVID-19 vaccination but generally should not be cancelled.

SOURCE: CDC

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Recommendations for Fully Vaccinated People (5/16/21)

- Definition of fully vaccinated people: those who received all dose(s) of a specific vaccine, and it has been at least 2 weeks since their final dose.

- You can resume activities that you did prior to the pandemic.
- Fully vaccinated people can resume activities without wearing a mask or physically distancing, except where required by federal, state, local, tribal, or territorial laws, rules, and regulations.
- You will still need to follow guidance at your workplace and local businesses.

- You will still be required to wear a mask on public transportation traveling into, within, or out of the United States, airports and stations.
- If you have symptoms of COVID-19, you should get tested and stay away from others.
- Those with weakened immune systems should consult with their healthcare provider about activities.

SOURCE: CDC

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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

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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.
- 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

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QUARANTINE RECOMMENDATIONS (COVID-19 DISEASE)

- For the most up-to-date guidance please review CDC guidance*
- Quarantine recommendations after known or possible exposure
  - Stay home for 14 days after last contact with COVID-19 patient
  - Watch for fever of 100° F. or higher
  - Be alert to problems with shortness of breath or other COVID-19 symptoms
  - If possible, stay away from others, especially people who are at higher risk for getting very sick from COVID-19
- Persons who have been in close contact with a COVID-19 patient are not required to quarantine if:
  - they have been fully vaccinated within the last 3 months and have no symptoms
  - they have tested positive for COVID-19 within the past 3 months and recovered

Source: CDC

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QUARANTINE RECOMMENDATIONS (COVID-19 DISEASE) (2)

- Options to reduce quarantine based on recommendations of local health departments
  - After day 10 without testing
  - After day 7 after receiving a negative test on day 5 or later

After stopping quarantine

Watch for symptoms until after 14 days of exposure

If symptoms develop, immediately self-isolate and contact your physician

Practice ALL prevention measures, i.e. masks, social distancing, hand washing, avoiding crowds

Source: CDC

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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.

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

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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 during that period of time, the person could become infected.

Should someone who has had COVID-19 disease get the vaccine?
Yes, the CDC recommends this. Vaccine should be deferred until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation. If a person received monoclonal antibodies or convalescent plasma as treatment for COVID-19 disease it is recommend to wait 90 days prior to vaccination.

Will persons be required to show proof of vaccination at work or school?
Some employers may require this.

SOURCE: NFID and SOURCE: CDC

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Critical Elements for Immunization Services

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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

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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

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Patient and Health Care Provider Resources

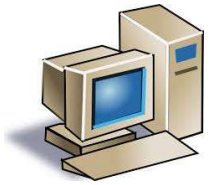
Vaccine Package Inserts

- 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)

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/



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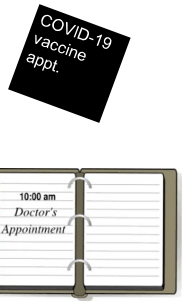
Where to Find Vaccination Location Sites

- GA Department of Public Health at: www.dph.Georgia.gov/covid-vaccine
  - Participating vaccine sites
  - Link to the Vaccine Dashboard for interactive search
  - FAQs re: safety of COVID-19 vaccines
  - Other covid-19 related information for Georgia residents

www.vaccinefinder.org

www.Planyourvaccine.org



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Preparing for COVID-19 vaccination in Pediatric practices

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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

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Becoming a COVID-19 vaccination provider/site

- In order to receive shipments of COVID vaccine when it becomes available, you will need to complete an online enrollment application. **GRITS** has added new functionality to allow COVID-19 Providers to submit their Enrollment forms electronically versus paper forms. Please visit (https://www.grits.state.ga.us) to be taken to the GRITS homepage.
- Links for mandatory trainings are included on the enrollment application
- Electronic signature and license number of Medical Director and Chief Medical Director required

SOURCE: DPH GA

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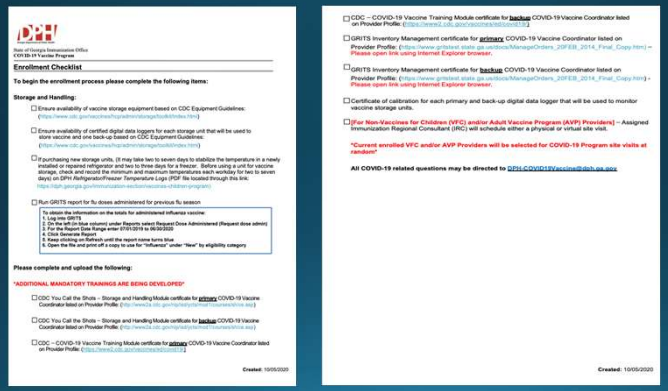
DPH, COVID-19 Vaccine Program, Enrollment Checklist



Enrollment Checklist

To begin the enrollment process please complete the following items:

Storage and Handling:

- ☐ Ensure availability of vaccine storage equipment based on CDC Equipment Guidelines: (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
- ☐ Ensure availability of certified digital data loggers for each storage unit that will be used to store vaccine and one back-up based on CDC Equipment Guidelines: (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
- ☐ If purchasing new storage units, (it may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator and two to three days for a freezer. Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday for two to seven days) on DPH Refrigerator/Freezer Temperature Logs (PDF file located through this link: https://dph.georgia.gov/immunization-section/vaccines-children-program)
- ☐ Run GRITS report for flu doses administered for previous flu season

To obtain the information on the totals for administered influenza vaccine:
1. Log into GRITS
2. On the left (in blue column) under Reports select Request Dose Administered (Request dose admin)
3. For the Report Date Range enter 07/01/2019 to 06/30/2020
4. Click Generate Report
5. Keep clicking on Refresh until the report name turns blue
6. Open the file and print off a copy to use for "Influenza" under "New" by eligibility category

Please complete and upload the following:

ADDITIONAL MANDATORY TRAININGS ARE BEING DEVELOPED

- ☐ CDC You Call the Shots – Storage and Handling Module certificate for primary COVID-19 Vaccine Coordinator listed on Provider Profile (http://www2a.cdc.gov/nip/isd/ycts/resources/shrss.asp)
- ☐ CDC You Call the Shots – Storage and Handling Module certificate for backup COVID-19 Vaccine Coordinator listed on Provider Profile (http://www2a.cdc.gov/nip/isd/ycts/resources/shrss.asp)
- ☐ CDC – COVID-19 Vaccine Training Module certificate for primary COVID-19 Vaccine Coordinator listed on Provider Profile (https://www2.cdc.gov/vaccines/ed/covid19/)

Created: 10/05/2020

- ☐ CDC – COVID-19 Vaccine Training Module certificate for backup COVID-19 Vaccine Coordinator listed on Provider Profile (https://www2.cdc.gov/vaccines/ed/covid19/)
- ☐ GRITS Inventory Management certificate for primary COVID-19 Vaccine Coordinator listed on Provider Profile (https://www.gritstest.state.ga.us/docs/ManageOrders_20FEB_2014_Final_Copy.htm) – Please open link using Internet Explorer browser.
- ☐ GRITS Inventory Management certificate for backup COVID-19 Vaccine Coordinator listed on Provider Profile (https://www.gritstest.state.ga.us/docs/ManageOrders_20FEB_2014_Final_Copy.htm) – Please open link using Internet Explorer browser.
- ☐ Certificate of calibration for each primary and back-up digital data logger that will be used to monitor vaccine storage units.
- ☐ [For Non-Vaccines for Children (VFC) and/or Adult Vaccine Program (AVP) Providers] – Assigned Immunization Regional Consultant (IRC) will schedule either a physical or virtual site visit.

Current enrolled VFC and/or AVP Providers will be selected for COVID-19 Program site visits at random

All COVID-19 related questions may be directed to DPH.COVID19Vaccine@dph.ga.gov

Created: 10/05/2020

SOURCE: DPH GA

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Coding for COVID-19 Services

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

SOURCE: GA AAP

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Reimbursement for COVID-19 vaccines

COVID-19 Vaccine Administration Free Increase - Effective April 1, the Georgia Department of Community Health will increase COVID-19 vaccine administration fee from $10.00 per dose to $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 disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use	1st dose: $10 2nd dose: $10
Moderna COVID-19 Vaccine	0011A (1st dose) 0012A (2nd dose)	**91301** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use	1st dose: $10 2nd dose: $10
Janssen Covid-19 Vaccine	0051A (single dose)	**91303** - Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use	Single dose $10

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COVID-19 vaccine distribution and reporting (5/17/21)

- Ancillary supplies (needles, syringes, alcohol swans, vaccine card, diluent, limited masks and face shields) will be included with Pfizer vaccine, COVID-19 vaccination records must be submitted within 24 hours of administration
- Speak with your GRITS representative about entering doses into GRITS
  - All doses are entered and stored as public doses in GRITS
  - Receipt of shipments must be manually entered into GRITS inventory
- For additional guidance visit: https://dph.georgia.gov/covid-vaccine-information-providers

Provider Technical Support

- **GRITS Hotline** (Technical/IT questions): 866-483-2958 or email at dph-gaimmreg@dph.ga.gov
- **Provider Support** (Provider enrollment questions, Pin #s): 888-920-0165 or email DPH-COVID19vaccine@dph.ga.gov

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Pfizer-BioNTech COVID-19 Vaccine Recommended Training

- Pfizer-BioNTech COVID-19 Vaccine
  - https://www.cvdvaccine.com/
- Preparation and Administration Video
  - https://www.cvdvaccine-us.com/dosing-and-administration

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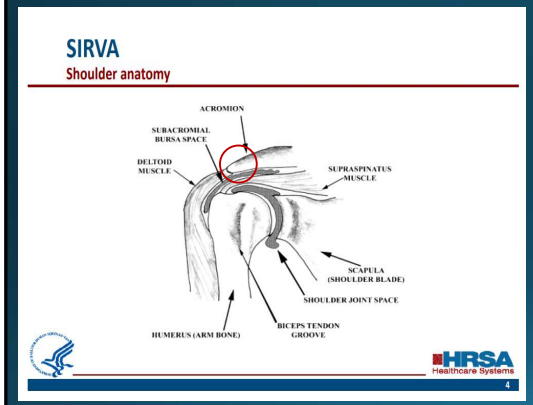

SIRVA = Shoulder Injury Related to Vaccine Administration

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

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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.

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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

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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

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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

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v-safe after vaccination health checker

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

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Vaccine Communication

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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

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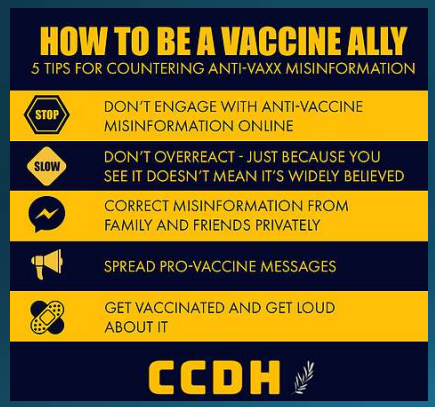

How to Stop the Spread of Misinformation about COVID-19 Vaccines

SOURCE:COUNTERHATE

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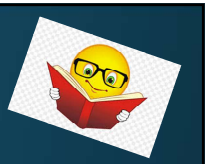
VitalTalk COVID-Ready Communication Playbook



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

SOURCE:VITALTALK

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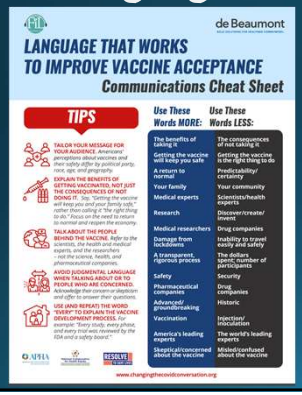
Changing the Covid Conversation



SOURCE: de Beaumont

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Resources for Factual & Responsible Vaccine Information

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

Allied Vaccine Group MEMBER

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

American Academy of Family Physicians

National Foundation for Infectious Diseases

WHO OMS

NNii

vaccine safety net
www.vaccinesafetynet.org

immunization action coalition
IAC
immunize.org

Georgia public health

Gavi The Vaccine Alliance

CDC
SAFER • HEALTHIER • PEOPLE™

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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

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Test Your Knowledge!
EPIC 2021

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Interchangeability of COVID-19 Vaccines

The same vaccine product does not have to be used for both doses. Another COVID-19 vaccine product can be used to complete the series.(TRUE or FALSE)

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Interchangeability of COVID-19 Vaccines

- Answer: (FALSE, however, okay in rare situations)
  - FALSE: A series started with a particular COVID-19 vaccine should be completed with the same product. There have been no trials testing the efficacy of a mixed-product series – that is, a series that includes 2 different COVID-19 vaccine products.
  - But, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.
  - The safety and efficacy of Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established. However, in limited, exceptional situations where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. See Contraindications and Precautions section for additional information on use of Janssen COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series.

SOURCE:CDC

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