

COVID-19 Vaccine Information for Clinical Staff

This brief manual will provide a summary of the recommended COVID-19 vaccines, and tips on communicating with patients.

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Your Role as a Healthcare Provider

Patients have relied on their providers throughout the pandemic and consider healthcare providers the most trusted source of information when it comes to vaccines.

Having a clear understanding of the science behind COVID-19 vaccines as well as utilizing key strategies and talking points to empathetically and confidently address questions can encourage vaccine acceptance among patients.

Listening carefully and thoughtfully acknowledging concerns in a safe and trusting environment will encourage patients to make informed decisions for what is best for them.



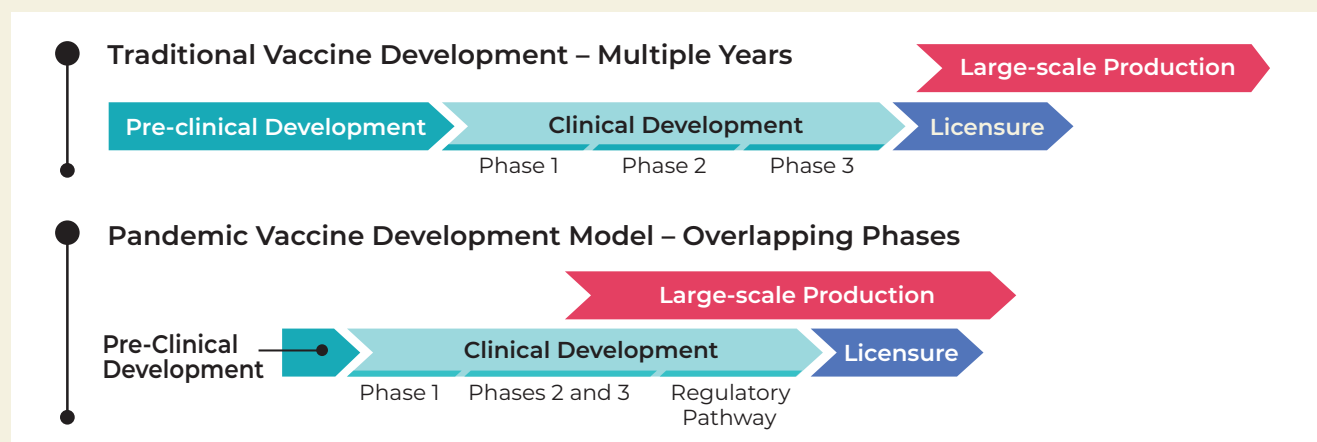
COVID-19 Vaccine Development and FDA Authorization

Even though current authorized COVID-19 vaccines were developed on an accelerated timeline, they still went through the same assessments that occur during traditional vaccine development and were tested in clinical trials involving tens of thousands of people to make sure they are safe and effective in protecting adults of all ages, races, and ethnicities.

Traditional Vaccine Development

Traditional vaccine development, which can take years, includes the following:

- + Basic research and pre-clinical studies
- + Clinical development (trials)
- + Regulatory agency review and approval
- + Manufacturing and quality control



Accelerated COVID-19 Vaccine Development¹

- + Overlapping phases of traditional vaccine development accelerates the timeline. The federal government provided financial support to scale up production while trials were in progress.
- + The mRNA vaccines have been studied for over a decade and are faster to produce than traditional vaccines.
- + The FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines, so manufacturing was started while the clinical trials were still underway.
- + COVID-19 vaccines have gone through the same rigorous safety assessments as other vaccines including large clinical trials and data review.

FDA Emergency Use Authorization vs. Approval

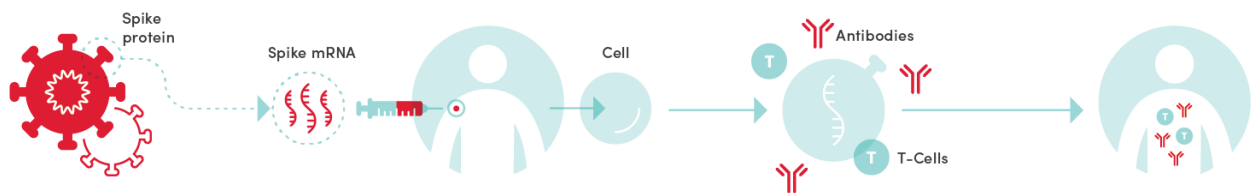
- + Emergency Use Authorization (EUA) allows new medicines or vaccines that treat or prevent serious or life-threatening diseases to be made available to the public during a public health emergency.
- + An EUA is based on the best available evidence from clinical trials and carefully weighs the benefits against potential risks.
- + Vaccine manufacturers are required to have a plan for active follow-up for safety among individuals who receive the vaccine to support continuation of the EUA.
- + Approval means the FDA has thoroughly evaluated extensive data and information from the EUA, such as pre-clinical and clinical data, the manufacturing process, and vaccine testing results to ensure vaccine quality, safety, and effectiveness.

1 www.nejm.org/doi/full/10.1056/NEJMp2020076

COVID-19 Vaccine Biotechnology

mRNA Vaccines

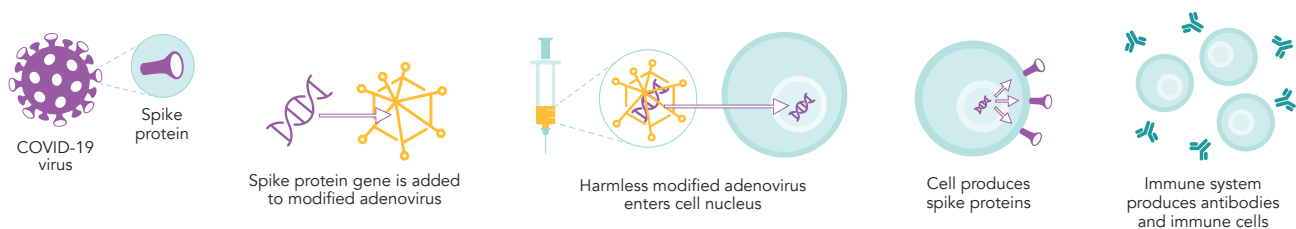
- + The COVID-19 mRNA vaccines instruct cells to make a **harmless** piece of the spike protein found on the surface of the SARS-CoV-2 virus.
- + This protein then triggers the immune system to produce antibodies and memory cells that protect against SARS-CoV-2 infection.
- + After our cells make copies of the protein, they destroy the mRNA from the vaccine.



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Adenovirus Vector Vaccines

- + Adenoviruses are common viruses that typically cause colds or flu-like symptoms.
- + The COVID-19 adenovirus vector vaccine uses a modified adenovirus that contains the gene for the coronavirus spike protein to stimulate an immune response.
- + The **harmless modified** adenovirus enters cells but **can't replicate**. The gene for the spike protein can be read by the cell and copied into messenger RNA, or mRNA.
- + The mRNA leaves the nucleus and spike proteins are then assembled and are recognized by the immune system to mount a response.
- + Viral vector vaccines have been studied for years. Clinical trials are taking place for adenovirus-based vaccines for other diseases. Recently, an adenovirus-based vaccine for Ebola was approved for general use.



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Recommended COVID-19 Vaccines

Pfizer/BioNTech (Comirnaty)		
	Ages 16+	Ages 12 - 15
Biotechnology	mRNA	
Number of Doses	2 doses given 21 days apart	
Dose Administration	0.3mL dose (contains 30mcg of mRNA)	
Status	FDA Approved	Emergency authorization granted
Side Effects	Injection site reaction Fatigue Headache Muscle pain Chills Joint pain Fever <i>More frequent after Dose 2 than after Dose 1</i>	Pain at the injection site Fatigue Headache Chills Muscle pain Fever Joint pain Injection site swelling Injection site redness Lymphadenopathy Nausea <i>More frequent after Dose 2 than after Dose 1</i>
Rare Adverse Events	<p>There is a rare but increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart), particularly for male adolescents and young adults above the age of 16 in the days immediately following the second dose of mRNA COVID-19 vaccines.</p> <p>These conditions are rare, given the hundreds of millions of vaccine doses already administered. Individuals can usually return to their normal daily activities after their symptoms improve.</p> <p>The significant benefits of the COVID-19 vaccine outweigh these risks.</p> <p>Read more here: cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html</p>	
Reference	www.fda.gov/media/144413/download	

Pediatric clinical trials for children younger than 12 are ongoing.

Moderna	
	Ages 18+
Biotechnology	mRNA
Number of Doses	2 doses given 1 month apart
Dose Administration	0.5mL dose (contains 100mcg of mRNA)
Status	Emergency authorization granted
Side Effects	<p>Injection site reaction</p> <p>Fatigue</p> <p>Headache</p> <p>Muscle pain</p> <p>Joint pain</p> <p>Chills</p> <p><i>More frequent after Dose 2 than after Dose 1</i></p>
Rare Adverse Events	<p>There is a rare but increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart), particularly for male adolescents and young adults above the age of 16 in the days immediately following the second dose of mRNA COVID-19 vaccines.</p> <p>These conditions are rare, given the hundreds of millions of vaccine doses already administered. Individuals can usually return to their normal daily activities after their symptoms improve.</p> <p>The significant benefits of the COVID-19 vaccine outweigh these risks.</p> <p>Read more here: cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html</p>
Reference	www.fda.gov/media/144637/download

Pediatric clinical trials for those younger than 18 are ongoing.

Janssen (Johnson & Johnson)	
	Ages 18+
Biotechnology	Adenovirus vector
Number of Doses	1 dose
Dose Administration	0.5mL single dose
Status	Emergency authorization granted
Side Effects	Injection site reaction Fatigue Myalgia Headache Nausea
Rare Adverse Events	<p>Guillain-Barré syndrome (GBS) is a rare disorder with symptoms that include muscle weakness and sometimes paralysis which may occur during the 42 days following vaccination. Most people fully recover.</p> <p>Thrombosis with thrombocytopenia syndrome (TTS) is a rare condition which involves blood clots with low platelets. Women, especially those younger than 50 years old, should be aware of the rare but increased risk of TTS.</p> <p>The benefits of vaccination, such as prevention of COVID-19 disease and hospitalizations, outweigh the risks associated with these adverse events.</p> <p>Read more here: www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html</p>
Reference	fda.gov/media/146304/download

Pediatric clinical trials for those younger than 18 are ongoing.

COVID-19 Variants

- Viruses constantly change through mutation and new variants of a virus are expected to occur over time.
- All variants are monitored but some may be classified as variants of interest, concern, or high consequence based on how easily they spread, how severe their symptoms are, and how they are treated.

Variants of concern have increased transmissibility, increased disease severity, and decreased response to treatments.

- Current COVID-19 vaccines offer protection against these variants, including prevention from severe illness. Vaccination is essential to prevent continued community spread and the introduction of new variants.**

Circulating Variants of Concern

Name	First Identified	Transmission	Disease Severity	Treatment
Alpha <i>B.1.1.7</i>	United Kingdom	<ul style="list-style-type: none"> Spreads much faster than other variants 	<ul style="list-style-type: none"> Hospitalizations and case fatality data show increased severity, and may cause more people to get sicker and to die. 	<ul style="list-style-type: none"> Treatments are effective against this variant.
Beta <i>B.1.351</i>	South Africa	<ul style="list-style-type: none"> May spread faster than other variants. 	<ul style="list-style-type: none"> Current data do not indicate more severe illness or death than other variants. 	<ul style="list-style-type: none"> Certain monoclonal antibody treatments are less effective against this variant
Gamma <i>P.1</i>	Japan/ Brazil	<ul style="list-style-type: none"> Spreads faster than some other variants 	<ul style="list-style-type: none"> Current data do not indicate more severe illness or death than other variants. 	<ul style="list-style-type: none"> Certain monoclonal antibody treatments are less effective against this variant.
Delta <i>B.1.617.2</i>	India	<ul style="list-style-type: none"> Highly contagious and spreads much faster than other variants. Fully vaccinated people who do become infected can spread the virus to others. 	<ul style="list-style-type: none"> May cause more severe cases than the other variants. 	<ul style="list-style-type: none"> Certain monoclonal antibody treatments are less effective against this variant.

Read more here:

cdc.gov/coronavirus/2019-ncov/variants/variant.html

cdc.gov/coronavirus/2019-ncov/variants/variant-info.html

Facts on Adolescents and COVID-19 Vaccination

- + Adolescents are at risk for COVID-19 infection, severe illness, hospitalization, and death, and represent an increasing proportion of recent COVID-19 cases.
- + Adolescents who get infected with COVID-19 may also indirectly impact others' health, including older vulnerable populations, and contribute to transmission in households and communities.
- + The two dose Pfizer BioNTech COVID-19 Vaccine (Comirnaty) series for adolescents, aged 12-15, is safe and has gone through the same stringent and rigorous process for authorization.
- + Vaccinated adolescents generate a robust antibody response and side effects are well tolerated from the vaccine.

Facts on Pregnancy and COVID-19 Vaccination

- + Pregnancy causes changes in the body that could increase the risk for developing severe COVID-19 illness, hospitalization, and poor pregnancy outcomes.
- + COVID-19 vaccination during pregnancy reduces the risk of infection and hospitalization. Antibodies made after a pregnant person is vaccinated may also help protect newborns against COVID-19.
- + There is currently no evidence that the COVID-19 vaccines cause fertility problems.
- + The American College of Obstetricians and Gynecologists, the Society for Maternal Fetal Medicine and the CDC recommend vaccination for people who are pregnant, breastfeeding, or might become pregnant in the future.



Read more here:

cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html#anchor_1614967211600

Additional Vaccine Dose

There are two distinct potential uses for an additional vaccine dose:

- + **Additional dose after an initial primary vaccine series when the initial immune response is likely to be insufficient.**

Some immunocompromised people don't always build the same level of immunity after vaccination as others do. Fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized breakthrough cases and are more at risk for serious, prolonged illness.

People with moderately to severely compromised immune systems should receive an additional dose of mRNA COVID-19 vaccine after the initial 2 doses. This includes people who have:

- Been receiving cancer treatment (such as chemotherapy)
- Been receiving an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Have another cause of moderate or severe immunodeficiency (genetic syndromes)
- Advanced or untreated HIV infection
- Active treatment drugs that may suppress the immune response

- + **A booster dose when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.**

Booster doses for all individuals may be available in the near future.

Read more here: [cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups.html)



Section 2

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Strategies for Discussing COVID-19 Vaccination with Patients

1. Start from a Place of Empathy and Understanding

- ✚ Acknowledge the disruption COVID-19 has caused in all our lives. Recognize that many patients have concerns about getting the vaccine given long-standing mistrust in and maltreatment by the medical system. Some of the concerns include mistrust of the health care system, side effects, and vaccine effectiveness.

2. Give Your Strong Recommendation

- ✚ **Share** your personal experience with patients to help them feel more comfortable about getting vaccinated.
 - Approach the conversation by saying “Here’s why I got vaccinated” rather than “Here’s why you should get vaccinated.”
 - A strong recommendation from a trusted source is a powerful tool for increasing confidence in the COVID-19 vaccine.

3. Provide Tailored Information

- ✚ Not all patients will have the same concerns or will value the same reasons for getting vaccinated.
 - **Identify** specific concerns so that you can respond with appropriate evidence and information.
 - **Address** individual patients’ specific concerns by using evidence and language that resonates with them (see detailed information on the following pages).

4. Be an Active Listener

- ✚ **Listen** and ask questions to understand patients’ concerns.

5. Keep the Conversation Going

- ✚ **Inform patients of their options** to continue the conversation by scheduling another appointment or providing additional information about the COVID-19 vaccine.
- ✚ The **comfort level** around a new vaccine will vary. Continue to remind them about the importance of getting a COVID-19 vaccine during future routine visits.
- ✚ Provide fact sheets and other handouts.

6. Emphasize Benefits of Getting Vaccinated

- ✚ Less likely to experience severe illness or be hospitalized
- ✚ Spending time with friends and loved ones indoors
- ✚ Ability to engage in more activities
- ✚ Have peace of mind
- ✚ Sharing the new benefits can help patients feel why getting vaccinated is important

Specific Talking Points

Emphasize the Importance of Vaccination for Eligible Patients

Emphasizing WHY it is important to get vaccinated may encourage patients to make informed decisions.

- + Data indicates that getting a COVID-19 vaccine will help keep you from getting seriously ill even if you do get infected with the virus that causes COVID-19.
- + Getting vaccinated will also protect people around you, particularly people at increased risk for severe illness from COVID-19.
- + COVID-19 vaccination is a safe way to help the immune system build protection against COVID-19, and an important tool to help stop the pandemic.
- + Vaccination helps with community immunity, or herd immunity, which can help keep the community healthy and reduce the spread of disease.
- + Millions of people have been vaccinated in the United States.

Explain to Patients How COVID-19 Vaccines Work

Explaining HOW vaccines trigger an immune response to help protect the body may help alleviate fear or concerns.

Consider discussing the following key points:

- + Different types of vaccines work in different ways to offer protection, but with all types of vaccines, the body is left with a supply of “memory” immune cells that will remember how to fight the virus in the future.
- + The process of building immunity after vaccination can cause side effects, such as fever, which is a normal sign.
- + Multiple doses of the vaccine may be required for maximum protection, and depends on the type of vaccine you receive.

Efficient Communication

Educate yourself so that you can be a suitable vaccination advocate.

- + Remind colleagues and employees about their influence on patients and leading by example
- + Keep yourself informed with reliable information, such as from the CDC and FDA.

Understand your target audience.

- + Understand cultural competency.
- + Be aware of different cultural practices and world views and tailor your communication strategies to help reassure patients about vaccine safety and effectiveness.

Word choice matters.

The utilization of certain verbiage can oftentimes be viewed as a trigger word for discomfort, fear, anxiety, and lack of safety, because of the negative connotation. Avoid the following:

- + The use of the word “shot”
- + Any subjective or judgmental statement
- + Anything resembling a patronizing, condescending or authoritative tone

Nonverbal communication is just as important (i.e.: vaccination wrist bands, stickers, buttons, etc.).



LANGUAGE THAT WORKS TO IMPROVE VACCINE ACCEPTANCE

Communications Cheat Sheet

TIPS



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



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



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



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



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

Use These Words MORE:

Use These Words LESS:

The benefits of taking it

Getting the vaccine will keep you safe

A return to normal

Your family

Medical experts

Research

Medical researchers

Damage from lockdowns

A transparent, rigorous process

Safety

Pharmaceutical companies

Advanced/groundbreaking

Vaccination

America's leading experts

Skeptical/concerned about the vaccine

The consequences of not taking it

Getting the vaccine is the right thing to do

Predictability/certainty

Your community

Scientists/health experts

Discover/create/invent

Drug companies

Inability to travel easily and safely

The dollars spent; number of participants

Security

Drug companies

Historic

Injection/inoculation

The world's leading experts

Misled/confused about the vaccine

Address Questions about Vaccine Safety and Efficacy



Safety

Explain that the FDA carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits

outweigh potential risks, and continues to monitor safety with the CDC.

The COVID-19 vaccines were tested in clinical trials, involving tens of thousands of people

to make sure they are safe and effective in protecting adults of all ages, races, and ethnicities. Every study was carefully reviewed and approved by a safety board at the FDA.

Real world results from multiple studies show significant protection against severe illness, hospitalization, and death for fully vaccinated individuals.

cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html



Efficacy

Remind patients that current COVID-19 vaccines are highly effective. Even with variants of concern circulating, the COVID-19

vaccines still offer substantial protection and help prevent severe disease.



Current Vaccines

Explain that the biotechnology used for the different vaccines have been studied for years.

The vaccines do not contain the SARS-CoV-2 virus, do not carry a

risk of causing diseases in the vaccinated person, and will not affect or alter a person's DNA.

Speed of Vaccine Development

Explain the reasons the COVID-19 vaccines were able to be developed so quickly:



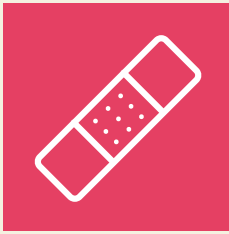
Given the unprecedented public health emergency of the COVID-19 pandemic, there were groundbreaking collaborations between medical experts and researchers across the world.



Researchers have been studying coronaviruses for decades, so they were able to get to work quickly on developing the COVID-19 vaccine once the genetic code of the virus that causes COVID-19 was understood.

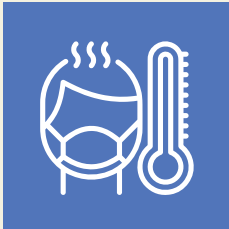


Because of the urgency of COVID-19 pandemic, both the FDA and CDC made the review and authorization of COVID-19 vaccines their highest priority.



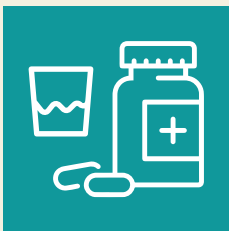
Describe What to Expect after Getting Vaccinated

- + Side effects after vaccination are normal and mean that the body is building protection.
- + Side effects may feel like the flu, but should go away in a few days.
- + Let the patient know to contact you or the contact center if:
 - o The redness or tenderness at the vaccination site increases after 24 hours
 - o Side effects do not go away after a few days
- + If there's a concern for a severe reaction, explain to the patient **a small number of people have had a severe allergic reaction ("anaphylaxis") shortly after vaccination, but this is extremely rare** and if it does happen, vaccination providers have medicines available to effectively and immediately treat the reaction.
- + Explain to the patient they will be asked to **stay for 15-30 minutes after they get their vaccine** so they can be observed and provided treatment in the rare case it is needed.



Common Side Effects

- + Pain or swelling on the arm at the vaccination site
- + Fever
- + Chills
- + Tiredness
- + Headache



Helpful Tips

- + Encourage patients to speak with a doctor about taking over-the-counter medications, such as ibuprofen or acetaminophen, if they are experiencing pain or discomfort.
- + To reduce pain and discomfort:
 - o On the vaccination site:
 - Apply a clean, cool, wet washcloth over the area
 - Use or exercise your arm
 - o From fever:
 - Drink plenty of fluids
 - Dress lightly

Discuss Expanded Safety Monitoring Systems

After a COVID-19 vaccine is authorized or approved for use, many different vaccine safety monitoring systems watch for adverse events (possible side effects). This continued monitoring can pick up on adverse events that may not have been seen in clinical trials.

Below are a select few you can highlight to patients that add an additional layer of safety monitoring, which gives CDC and FDA the ability to evaluate COVID-19 vaccine safety in real time.

Monitoring System	Description	CDC	FDA
V-Safe	A health checker that uses text messaging and web surveys from CDC to check in with recipients following COVID-19 vaccination and provides second vaccine dose reminders and telephone follow up to anyone who reports medically significant adverse events.	✓	
Vaccine Adverse Event Reporting System (VAERS)	A national vaccine safety surveillance system that collects, monitors, and tracks reports from healthcare professionals, vaccine manufacturers, and the public on adverse events that happen after vaccination.	✓	✓
Vaccine Safety Datalink (VSD)	A network which conducts active surveillance and research to help monitor safety of vaccines and conduct studies about rare and serious adverse events following vaccination.	✓	
National Healthcare Safety Network (NHSN)	A monitoring system for acute and long term care facilities which can report to VAERS on COVID-19 vaccine adverse event reporting rates.	✓	

Remember to Share FACTS

FACT: Eggs are **NOT** used to make any of the authorized COVID-19 vaccines.

FACT: There is **NO DATA** that supports the claim that COVID-19 vaccines cause infertility. Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy suggest that the benefits of vaccination outweigh any known or potential risks of vaccination during pregnancy.

FACT: Serious side effects that would cause a long-term health problem are extremely unlikely after vaccination. If serious side effects do occur, they generally happen between two to six weeks after receiving a vaccine dose. Current safety data show no significant safety signals for the mRNA vaccines.

FACT: Given the circulation of variants, fully vaccinated individuals should still continue to take precautions when in certain settings or during certain activities that could be at high risk for transmission.

Read more here:
cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

FACT: The vaccines do **NOT** contain the virus that causes COVID-19. Symptoms that you may develop after the vaccine are likely signs that your immune system is building protection against the virus.

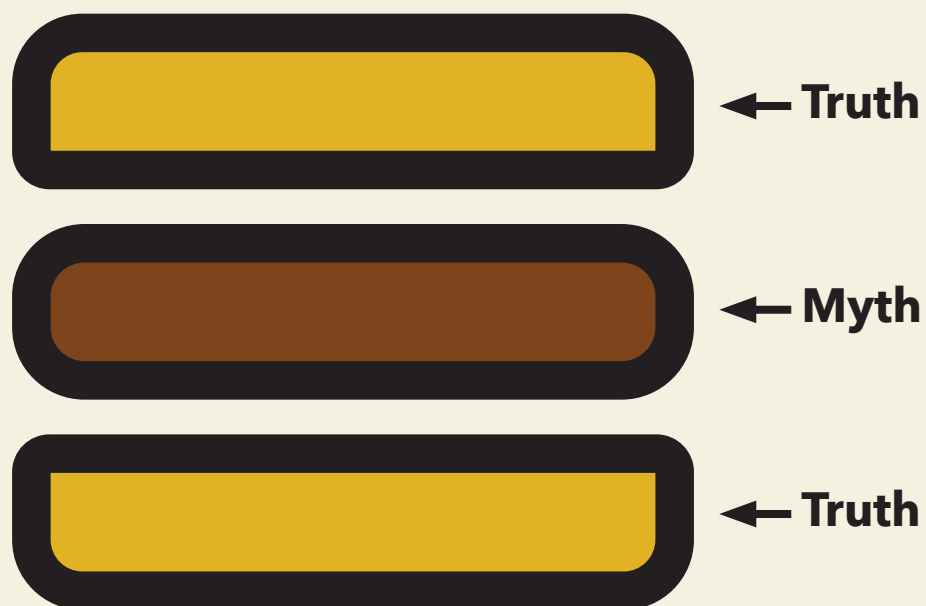
FACT: The COVID-19 vaccine **CAN** be administered with other vaccines without regard for timing, whether simultaneously or within 14 days.

Read more here:
cdc.gov/vaccines/covid-19/hcp/faq.html

FACT: The vaccines will **NOT** affect or alter your DNA.

**Remember to Use the Truth Sandwich to
Debunk Myths and Address Misinformation**

The Truth Sandwich



Start with the truth. The first frame gets the advantage.

Address the myth or misinformation. Avoid amplifying the specific language, if possible.

Return to the truth. Always repeat the truths so that the falsehood is neither the first impression nor the takeaway.

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