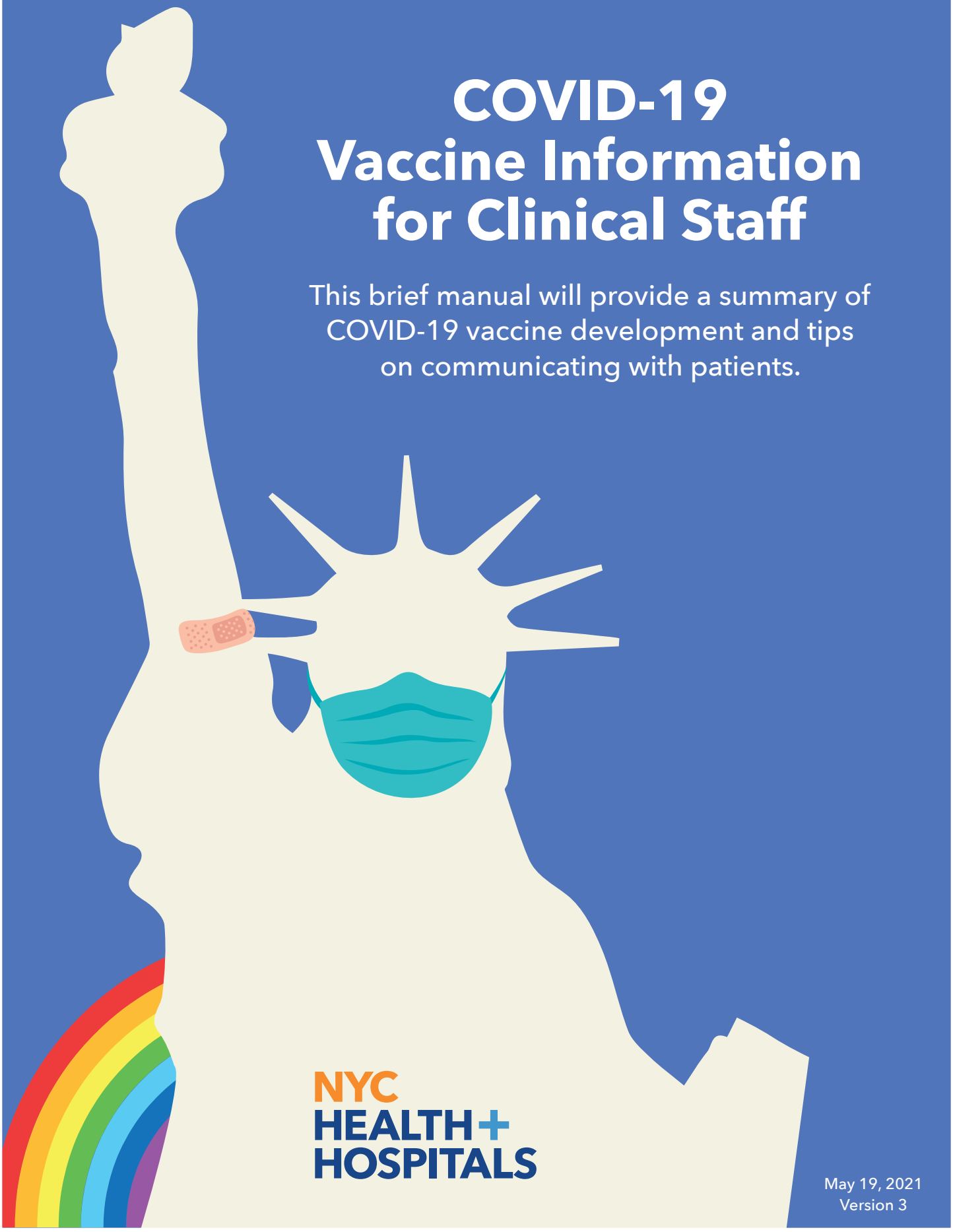
COVID-19 Vaccine Information for Clinical Staff

This brief manual will provide a summary of COVID-19 vaccine development and tips on communicating with patients.



NYC HEALTH+ HOSPITALS

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Version 3

Section 1

What You Need To Know

Your Role

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.

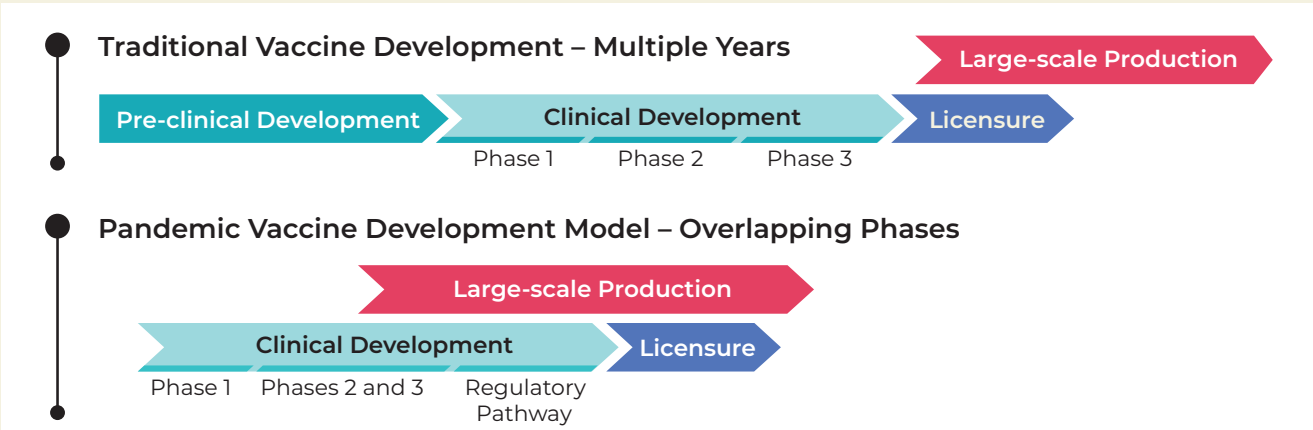
COVID-19 Vaccine Development and FDA Authorization

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 Development[1]

- 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 and FDA Authorization 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.
- An EUA remains effective until the public health emergency declaration ends and can be revised or revoked based on new data.

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

Current Authorized COVID-19 Vaccines

Pfizer/BioNTech

	Ages 16+	Ages 12 - 15
Biotechnology	mRNA	mRNA
Clinical Trial Efficacy	95%	100%
Trial Participants	36,621 trial participants	2,260 trial participants
Number of Doses	2 doses given 21 days apart	2 doses given 21 days apart
Dose Administration	0.3mL dose (contains 30mcg of mRNA)	0.3mL dose (contains 30mcg of mRNA)
Dilution	Must be diluted with 0.9% sodium chloride	Must be diluted with 0.9% sodium chloride
Storage	Ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F)	Ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F)
Status	Emergency authorization granted	Emergency authorization granted
Side Effects	Injection site reaction Fatigue Headache Muscle pain Chills Joint pain Fever *More frequent after Dose 2 than after Dose 1*	Pain at the injection site Fatigue Headache Chills Muscle pain Fever Joint pain Injection site swelling Injection site redness Lymphadenopathy Nausea *More frequent after Dose 2 than after Dose 1*
Reference	https://www.fda.gov/media/144413/download	

Pediatric clinical trials for children younger than 12 are ongoing.

Current Authorized COVID-19 Vaccines

Moderna	
	Ages 18+
Biotechnology	mRNA
Clinical Trial Efficacy	94.1%
Trial Participants	30,350 trial participants
Number of Doses	2 doses given 1 month apart
Dose Administration	0.5mL dose (contains 100mcg of mRNA)
Dilution	No dilution required
Storage	Frozen between -25° to -15°C (-13° to 5°F)
Status	Emergency authorization granted
Side Effects	Injection site reaction Fatigue Headache Muscle pain Joint pain Chills *More frequent after Dose 2 than after Dose 1*
Reference	http://fda.gov/media/144434/download

Pediatric clinical trials for those younger than 18 are ongoing.

Current Authorized COVID-19 Vaccines

Janssen (Johnson & Johnson)

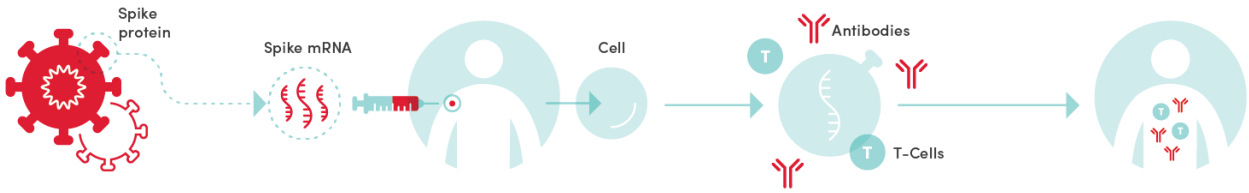
	Ages 18+
Biotechnology	Adenovirus vector
Clinical Trial Efficacy	72% (USA)
Trial Participants	43,783 trial participants
Number of Doses	1 dose
Dose Administration	0.5mL single dose
Dilution	No dilution required
Storage	2°C to 8°C (36°F to 46°F)
Status	Emergency authorization granted
Side Effects	Injection site reaction Fatigue Myalgia Headache Nausea Thrombosis with thrombocytopenia syndrome (TTS) is a rare adverse event. People, specifically women younger than 50 years old, should be aware of this rare but increased risk of TTS.
Reference	http://fda.gov/media/146304/download

Pediatric clinical trials for those younger than 18 are ongoing.

mRNA and Adenovirus Vector Vaccines

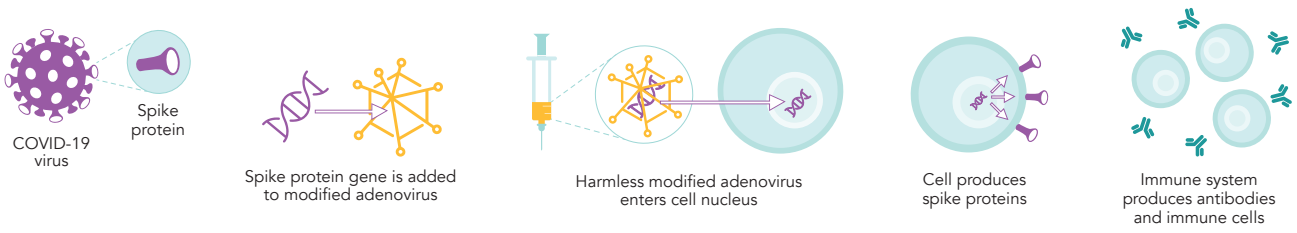
mRNA Vaccines

- 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.



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 or cause illness**. 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, including HIV and Zika virus. Recently, an adenovirus-based vaccine for Ebola was approved for general use.



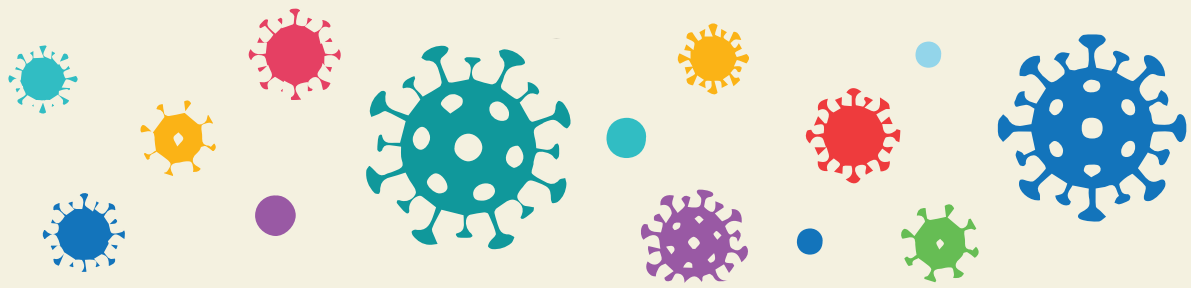
Additional COVID-19 Vaccines Planned for Use in the US

Company	Biotechnology	Description
AstraZaneca	Recombinant Adenovirus Vector (Vector Vaccine)	• Currently in Phase 3 of Clinical Trials • 30,000 Participants • This vaccine uses a modified adenovirus which contains genetic material for the SARS-CoV-2 virus and has been made unable to replicate. • The adenovirus enters human cells which then produce the coronavirus spike protein, but not the coronavirus itself. • The immune system will then mount a response to the spike protein, thereby allowing it to recognize and fight off a future infection by the virus.
Novavax	Recombinant Protein Nanoparticle Technology (Protein subunit vaccine)	• Currently in Phase 3 of Clinical Trials • 30,000 Participants • This vaccine is made from a stabilized form of the coronavirus spike protein using recombinant protein nanoparticle technology. • The gene for the spike protein is inserted into a baculovirus—an insect virus—and inserted into cells where the spike protein is then produced. The proteins are harvested from the cells and assembled with nanoparticles to mimic the structure of the virus. The spike protein nanoparticles in the vaccine cannot replicate and cannot cause COVID-19. • After vaccination, the immune system will mount a response to the spike protein nanoparticles, thereby allowing it to recognize and fight off a future infection by the virus.

To learn about other potential COVID-19 vaccines currently in earlier phases in clinical trials visit **clinicaltrials.gov**

COVID-19 Variants of Concern

- Viruses constantly change through mutation and new variants of a virus are expected to occur over time.
- Multiple variants of the virus that causes COVID-19 are are currently circulating.
    - The United Kingdom (UK) identified a variant called B.1.1.7 in the fall of 2020. This variant has many mutations, and spreads more easily and quickly than other variants.
    - In South Africa, another variant called B.1.351 emerged independently of B.1.1.7. Originally detected in early October 2020, B.1.351 shares some mutations with B.1.1.7.
    - In Brazil, a variant called P.1 emerged. This variant contains a set of additional mutations that may affect its ability to be recognized by antibodies.
    - Additional emerging variants include a New York City variant, called B.1.526 and California variant, called B.1.427/B.1.429.
    - **For up to date information on variants of concern, visit cdc.gov/coronavirus/2019-ncov/transmission/variant.html**
- **Current COVID-19 vaccines still offer substantial protection against these variants, including the prevention of severe disease. It is important that patients receive these vaccines while others are in development in order to prevent continued community spread and the introduction of new variants.**
- Currently authorized vaccines may need a booster dose for improved efficacy and protection against these and other new variants.



Section 2

Tips for Communicating Effectively with Patients about COVID-19 Vaccines

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 are:
  - Significant or somewhat significant concerns that the health care system is not looking out for their interests **(36% of Whites, 50% of Hispanic, 58% of Blacks)***
  - Having the necessary information to make a decision about getting vaccinated **(81% of Whites, 70% of Hispanics, 62% of Blacks, 61% of Asians)***
  - Get the vaccine right away **(78% of Whites, 54% of Hispanics, 39% of Blacks)**
  - Significant or somewhat significant concerns about the vaccine's effectiveness **(45% of Whites, 68% of Hispanics, 80% of Blacks)***
  - Significant or somewhat significant concerns about the vaccine's side effects **(47% of Whites, 67% of Asians, 72% of Hispanics, 77% of Blacks)***

*Survey results from ABNY COVID Vaccine Survey 01/2021

2. Give Your Strong Recommendation

- **Share** your personal experience with patients to help them feel more comfortable about getting vaccinated.
  - "Here's why I got vaccinated" vs. "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.
- rovide fact sheets and other handouts.

6. Emphasize Benefits of Getting Vaccinated

- 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 from clinical trials indicate that getting a COVID-19 vaccine can help keep you from getting seriously ill even if you do get COVID-19.
- Getting vaccinated may 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.
- Over 26 million people – and counting – have been vaccinated in 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.
- Either one or two doses of vaccine are required for maximum protection, and depends on the type of vaccine you receive.

Efficient Communication: Word Choice Matters

Educate yourself so that you can be a suitable vaccination advocate

- Remind colleagues and employees about their influence on patients and leading by example
- Review reliable data

Identify and understand your target audience

- Cultural competency encompasses being aware of one's own world view, developing positive attitudes towards cultural differences, gaining knowledge of different cultural practices and world views, and developing skills for communication and interaction across cultures.

Avoid the following:

- The use of the word "shot"
- Any subjective or judgmental statement
- Anything resembling a patronizing, condescending or authoritative tone:
- 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.

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

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LANGUAGE THAT WORKS TO IMPROVE VACCINE ACCEPTANCE

Communications Cheat Sheet

TIPS

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

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

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

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

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

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

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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 a study that followed over 3,000 people after vaccination for 13 weeks showed that following the second dose of vaccine, the risk of infection was reduced by 90% and after a single dose of either vaccine, the risk of infection was reduced by 80%.

cdc.gov/media/releases/2021/p0329-COVID-19-Vaccines.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 authorized vaccines has been studied for years, does not contain a live virus, does not carry a risk of causing disease in the vaccinated person, and will not affect or alter a person's DNA.

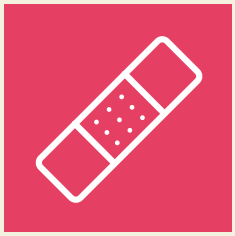
Speed of Vaccine Development

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.

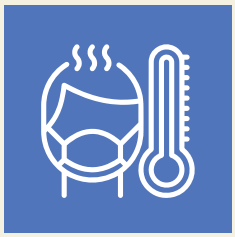
Researchers have been studying coronaviruses for decades, so they were able to get to work quickly on developing the COVID-19 vaccine once the genetic code of the virus that causes COVID-19 was understood.

Because of the urgency of COVID-19 pandemic, both the FDA and CDC made the review and approval 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:
  - The redness or tenderness at the vaccination site increases after 24 hours
  - 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.
- **Thrombosis with thrombocytopenia syndrome** (TTS) following the use of the Janssen vaccine has been reported following one to weeks after vaccination. People, especially women younger than 50 years old, should be aware of the rare but increased risk. Symptoms of TTS may include:
  - 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.



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:
  - On the vaccination site:
    - Apply a clean, cool, wet washcloth over the area
    - Use or exercise your arm
  - 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: 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: Studies show that protection from COVID-19 lasts at least 6 months after being fully vaccinated. Strength of immunity generated by the vaccine may decrease over time, but long-term immunological memory (e.g. memory T and B cells) might retain information about the coronavirus for years or even decades.

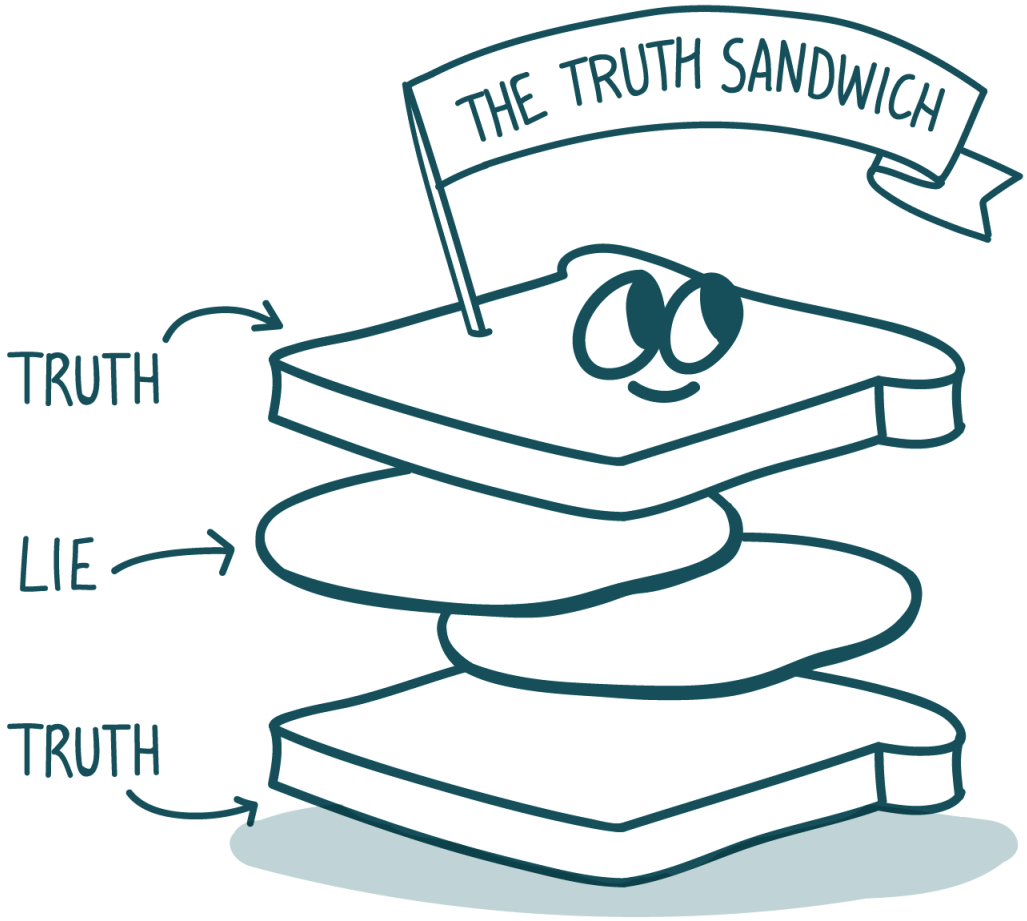
FACT: There is **NO DATA** that supports the claim that COVID-19 vaccines cause infertility. The myth started when a claim was made that antibodies to COVID-19 can bind to the placenta. Individuals with COVID-19 who develop who develop antibodies have not been found to have higher rates of miscarriage.

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

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.

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



https://bit.ly/3kHbhDo

First state what is true.

Then introduce the truthless or misleading statement.

Then repeat what is true, so that the falsehood is neither the first impression nor the takeaway.

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