

End-Stage Renal Disease Network Program

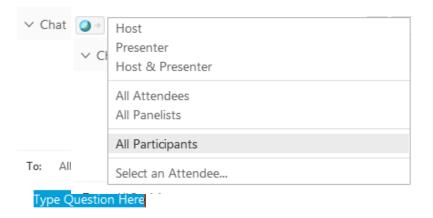
Covid-19 Vaccine Facts Over Fiction

Housekeeping Reminders:



- All lines have been muted upon entry
- Chat and Q&A sections are being monitored

To ask a private question, use the Chat To ask a question for the answer to section in the bottom right corner of your screen sending to All Panelists

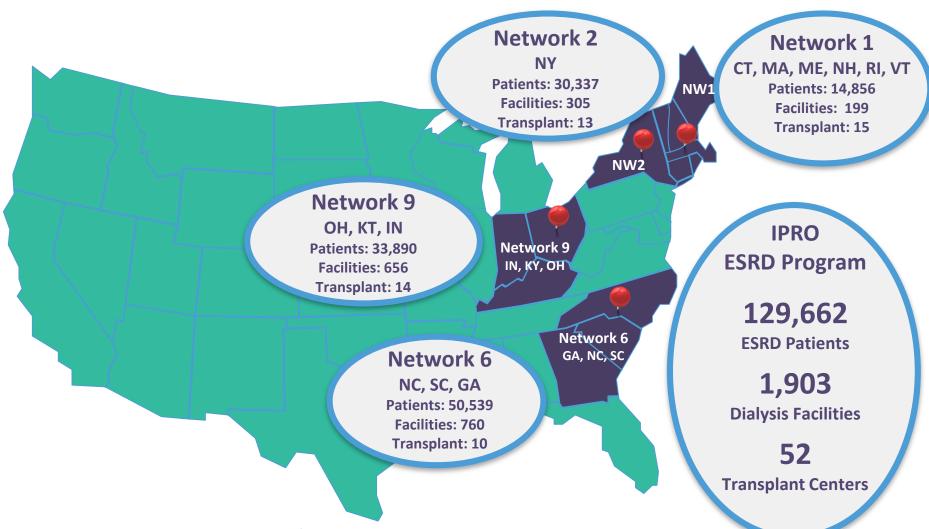


be shared with all Attendees or Privately, use the Q&A section in the bottom right corner of your screen

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Select a question, an	ur answer here,

IPRO ESRD Network Service Areas





Objectives



- List the causes of vaccine hesitancy and how to work to overcome hesitancy
- Discuss the safety and efficacy of the COVID Vaccine
- 3. Describe the facts related to the vaccine and resources you can use to share those facts
- 4. List effective strategies to discuss COVID vaccination with patients.
- 5. Identify best practices to bolster vaccine use and remain safe.
- 6. Q & A

Vaccination Hesitancy



- 40% of Healthcare Workers report hesitancy
 - 29% report will never take any vaccine
- Top three reasons for hesitancy
 - "Real World Proof" Wait 6 mos and see
 - Demographics:
 - Less than college education
 - Rural communities and people of color
 - Systemic Racism
 - Previous poor experience/history of unethical practices
- Adverse reactions
 - 11 anaphylactic reactions recorded out of 1 million doses
 - People with history of allergies and severe reaction
 - All recovered

https://www.vox.com/22214210/covid-vaccine-health-care-workers-safety-fears





- Setting the right tone and example from leadership
- Presenting it as a "Public Act" that benefits others
- Keep it free and easy to receive
- Miss this chance in line, may be trickier to get it later
- Make Access to Valued Settings Conditional on Getting Vaccinated ie schools, restaurants, gyms, cruise lines, air travel and other public places

Safety and Efficacy



Dr. Krishnan, MetroHealth Medical Center, Cleveland OH



- Pulmonary, Critical Care and Sleep Physician at Case Western Reserve University/ MetroHealth Campus
- Major teaching roles include Internal Medicine and fellowship supervision for pulmonary, critical care and sleep medicine
- Chairperson for the American Thoracic Society's Patient and Family Education Committee
- Since the COVID-19 pandemic began, she has worked on the frontline in the MetroHealth Medical Intensive Care Unit, taking on research investigator roles for 2 multicenter/multinational studies related to COVID-19 treatment



Why Is It Important to be Vaccinated

- The greater number of the general population that is vaccinated the better the vaccine will provide immunity
- To protect yourself, your family and your PATIENTS
- Safe way to build protection against the virus
- A promise of future new normal helps stop the Pandemic



Who should be vaccinated?



Triage of persons presenting for mRNA COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	CONDITIONS Immunocompromising conditions Pregnancy Lactation ACTIONS Additional information provided* Is minute observation period	CONDITIONS Moderate/severe acute illness ACTIONS Risk assessment Potential deferral of vaccination 15-minute observation period if vaccinated	CONDITIONS • None ACTIONS • N/A
ALLERGIES	ALLERGIES History of allergies that are unrelated to components of an mRNA COVID-19 vaccine*, other vaccines, injectable therapies, or polysorbate, such as: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies ACTIONS • 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) • 15-minute observation period: All other persons	ALLERGIES History of any immediate allergic reaction ¹ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines ¹ or polysorbate, as these are contraindicated) ACTIONS: Risk assessment Consider deferral of vaccination and/or referral to allergist-immunologist 30-minute observation period if vaccinated	ALLERGIES History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines*: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction* of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)* • Immediate allergic reaction of any severity to polysorbate^* • Consider referral to allergist-immunologist

Who Should Consult Their Physician Prior to Vaccination



People with history of:

- Prior reaction to any vaccine
- Persons with previous history of Polyethylene Glycol Reaction (PEG)
- Persons that routinely carry an Epinephrine injector for allergies
- Cancer patients
- Pregnant or lactating women
- Other complex illnesses



How to Proceed with Vaccine Post COVID infection

- Vaccination should be deferred until recovery from COVID and isolation is discontinued
- No minimal interval between infection and vaccination
- Persons with documented acute COVID infection in the preceding 90 days may defer vaccination until the end of this period,

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html January 7, 2021

Pfizer vs Moderna



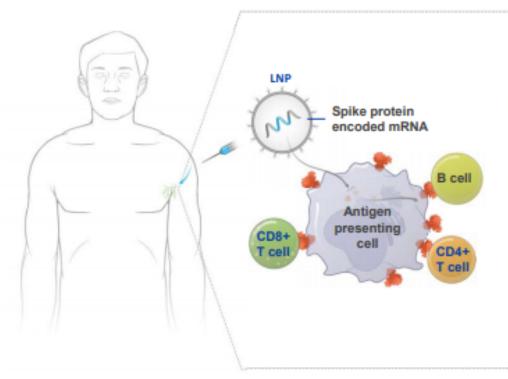
Туре	Efficacy	Authorization	Administration
Pfizer	> 90%	<u>></u> 16 years	 two -dose series second dose 3 weeks(+/- 4 days)
Moderna	> 90%	<u>></u> 18 years	 two -dose series second dose 4 weeks(+/- 4 days)

- Testing sample (18 years and older, all ethnicities and races) and comorbid conditions
 - Comorbid conditions-CKD
 - Test sample did not include ESRD
- mRNA vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines
- Vaccine safety profile within expected range
 - Bell's Palsy occurred at same rate in both control and test groups
 - Local /systemic reaction particularly after the second dose

How the Vaccine Works



Messenger RNA vaccines



- Provides instruction directly to the immune system (Spike protein)
- Efficiently creates specific immune memory
- mRNA can neither interact with nor integrate into DNA

January 7, 2021

Source: https://www.fda.gov/media/144583/download

Facts Over Fiction

Fiction: The Vaccine Can Give Me COVID-19



Fact

- mRNA vaccines do not use the live virus that causes COVID 19
- The vaccine does not affect or enter the recipients DNA in any way
 - mRNA never enters the nucleus of the cell where our DNA or genetic material is kept
 - The cell breaks down and gets rid of the mRNA after it has completed its purpose



Resources



The first two COVID-19 vaccines expected to receive authorization for use in the United States are what is known as messenger RNA vaccines—also called "mRNA" vaccines.



You and your patients may have questions about how mRNA vaccines work and how safe they are.

- Like all vaccines, these COVID-19 mRNA vaccines were tested rigorously for safety before being authorized for use in the United States.
- mRNA technology is new, but not unknown. It has been studied for decades.
- mRNA vaccines do not contain live virus and carry no risk of causing disease in the vaccinated person.
- mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.

A new approach to vaccines

mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response and build immunity to SARS-CoV-2, the virus that causes COVID-19. In contrast, most vaccines use weakened or inactivated versions or components of the disease-causing pathogen to stimulate the body's immune response to create antibodies.

Mechanism for Action

mRNA vaccines have strands of messenger RNA inside a special coating. That coating protects the mRNA from enzymes in the body that would otherwise break it down. The coating also helps the mRNA enter the muscle cells near the vaccination site.

mRNA vaccines tell our cells to make a piece of the 'spike protein' that is found on the surface of the SARS-CoV-2 virus. Since only part of the protein is made, it does not harm the vaccine recipient, but it is antigenic and thus stimulates the immune system to make antibodies. After the piece of the spike protein is made, the cell breaks down the mRNA strand and disposes of it using enzymes in the cell. As stated above, the mRNA strand never enters the cell's nucleus or affects the vaccine recipient's genetic material. Knowing this helps you respond to misinformation about how mRNA vaccines alter or modify someone's genetic makeur.

Once displayed on the cell surface, the protein or antigen causes the immune system to begin producing antibodies. These antibodies are specific to the SARS-CoV-2 virus spike protein, which means the immune system is ready to protect against future infection.

COVID-19 mRNA vaccines will continue to be rigorously evaluated for safety

These COVID-19 mRNA vaccines went through the same rigorous safety assessment as all vaccines do before the Food and Drug Administration authorizes them for use in the United States. This included large clinical trials and data review by a safety monitoring board.

Often, patients are concerned about live vaccines. mRNA vaccines are not live vaccines and do not use an infectious element, so they carry no risk of causing disease in the vaccinated person.

mRNA vaccines are new, but not unknown

Currently, there are no licensed mRNA vaccines in the United States. However, researchers have been studying them for decades.





www.cdc.gov/coronavirus/vaccines

CDC | NCIRD | Healthcare Workers and Employees: Learn About the New mRNA COVID-19 Vaccines

mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV). Recent technological advancements in RNA biology and chemistry, as well as delivery systems, have mitigated the challenges of these vaccines and improved their stability and effectiveness.

Beyond vaccines, numerous preclinical and clinical studies have used mRNA to encode cancer antigens to stimulate immune responses targeted at clearing or reducing malignant tumors.

Benefits of mRNA vaccines

mRNA vaccines have several benefits compared to other types of vaccines, including use of a non-infectious element, shorter manufacturing times, and potential for targeting multiple diseases. mRNA vaccines can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods. In the future, mRNA vaccine technology may allow for one vaccine to target multiple diseases.

Related links

- Talking to Patients about COVID-19 Vaccines
- Patient Information: Understanding mRNA Vaccines
- FDA's Vaccine Development 101
- FDA's Emergency Use Authorization for Vaccines Explained
- FDA Infographic: The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization

Additional resources

- Pardi N, Hogan MJ, Porter FW, Weissman D. mRNA Vaccines—a New Era in Vaccinology. Nature Reviews. Drug Discovery. 2018;17(4):261.
- Maruggi G, Zhang C, Li J, Ulmer JB, Yu D. <u>mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases</u>. *Molecular Therapy*. 2019;27(4):757–72.
- Jackson NAC, Kester KE, Casimiro D, Gurunathan S, DeRosa F. <u>The Promise of mRNA Vaccines: A Biotech and Industrial Perspective</u>. Npj Vaccines. 2020;5(1):1–6.

https://www.cdc.gov/vaccines/covid-19/downloads/healthcare-professionals-mRNA.pdf

Understanding the mRNA vaccine https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html







FACT:



Emergency Use Authorization (EUA)

- Issued by the Food and Drug Administration (FDA)
- Response to a public health emergency
- Review and standards do not change with decreased time frame
- Promote and provide access to
 - access to drugs needed
 - diagnostic testing
 - critical products to fight the public health emergency

Ensuring the Safety of COVID Vaccines in the United States https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

EUA Fact Sheets

THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS https://www.fda.gov/media/144414/download

THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf



Fact: All FDA standards were met when creating and testing the available vaccines

FDA standards for vaccine safety

- Laboratory testing to develop the molecule
- If shows promise, then animal testing
- Clinical trials in human subjects
 - Phase 1: 20-100 healthy volunteers study potential side effects / safety profile
 - Phase 2: Several 100 healthy volunteers continue studying side effects, dosing, and immune effect
 - Phase 3: Thousands of volunteers randomized controlled trials, safety and effectiveness, also studying side effects



https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf

Fiction: This Vaccine Has Severe Side Effects



FACT

- 80-89% of clinical trial participants reported ≤1 local reaction (e.g., pain or swelling at injection site; swollen lymph nodes on same side as vaccinated arm)
- 55-83% of clinical trial participants reported ≤1 systemic reaction (e.g., fever, fatigue, muscle aches, headache, chills)
- Most are mild-moderate in severity, occur within first 3 days of vaccination, and resolve within 1-2 days of onset
- More frequent and severe following the second dose and among younger age groups

Severe Reaction Data YTD



- 21 cases of anaphylaxis reported /
 1.89 million doses administered =
 11.1 cases per million doses
- 17 cases-documented history of allergies or allergic reactions with prior anaphylaxis
- Median interval onset of symptoms 13 minutes
- Follow up 20 persons followed- all recovered



https://www.cdc.gov/coronavirus/2019 -ncov/vaccines/safety/allergic -reaction.html

Talking with Patients

Just the Facts....Talking With Your Patients



- Use credible scientific, fact based sources, CDC, NCC & ASN
- Eliminate personal bias
- Choose the right words
- Refer questions patients may have on any particular health/ comorbid conditions to patients doctor

https://coronavirus.ohio.gov/wps/portal/gov/covid-19/resources/general-resources/frequently-asked-questions+covid-19-vaccine



Making a Strong Recommendation for the COVID-19 Vaccine



- 1. Start from a place of empathy and understanding
- 2. Assume patients will want to be vaccinated and what they should expect
- 3. Let your patients know you plan to recommend COVID-19 vaccination for them.

Example:

"I strongly recommend you get a COVID-19 vaccine once it is widely available"

"This shot is especially important for you because of your a dialysis patient"

"I believe in this vaccine so strongly that I plan to get it as soon as it is available"





Making a Strong Recommendation for the COVID-19 Vaccine cont'd

- 4. Listen to and Respond to Patient Questions
 - Seek to understand your patients' concerns and provide information they need in a way they can understand it. Information and on presentation can be found at this CDC link:
- 5. Wrapping Up the Conversation

Providing Easy to Understand Materials to Review

https://familydoctor.org/covid-19-vaccine-frequently-asked-questions/



Steps to Promote Effective Communication



1. Be Aware of Non-Verbal Communication

 Appropriate body language, posture, and simply adding a smile can go a long way in nurse communication with both patients and colleagues.

2. Use of Active Listening

• Listen to understand; not solely to respond—this is one of the effective principles for active listening.

3. Inspire Trust

- Always keep your word. Never make promises you may not be able to keep.
- Listen to your patients and take all their concerns seriously.

4. Show Compassion

Treat patients with respect and dignity.



Steps to Promote Effective Communication



5. Cultural Awareness

Common practices and gestures are not accepted by all cultures.
 Consider your actions and strive for cultural awareness every time you communicate with a patient.

6. Written Communication

 Provide credible resources created at the level of patient understanding to understand.

7. Presentation Skills

 Plan your message. Create pleasing visual aids that add value to the presentation. Know your audience and understand what they want from your presentation.

8. Be Aware of Who's listening

- Do not discuss personal opinions within earshot of patients
- In the close environment of the dialysis facility this is critical

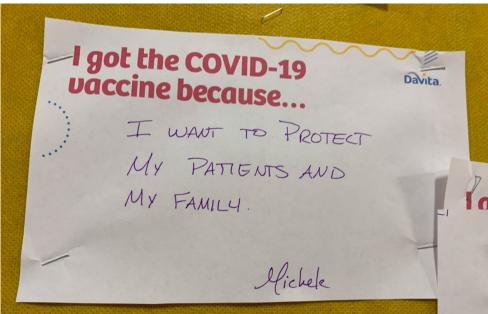
A Patient's Perspective Evan Coaker



Best Practices

Public Announcements Conveying Trust



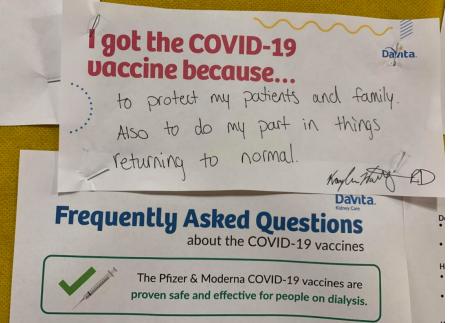


100% of Staff Received COVID Vaccination

Davita Appleseed, Fort Wayne IN.

Lisa Chelf, Group Facility Administrator

Lakeshore Region



Remaining Safe



Continue to follow all CDC COVID precautions until

- > 70% of the population is vaccinated
 - masking
 - social distancing- 6 feet
 - frequent handwashing







Keeping Vigilant- A CDC Refresher



Episode 1:

What's the Goal of Infection Control?

Episode 2:

Sars-Cov-2? Covid-19? What's the Difference?

Episode 3:

What's a Virus?

Episode 4:

What's a Respiratory Droplet? Why Does it Matter?

Episode 5:

How do Viruses Make You Sick?

Episode 6:

How Do Viruses Spread From Surfaces To People?

Episode 7:

How does COVID-19 spread? A Review



Q & A with Dr. Krishnan





Thank You!



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https://esrd.ipro.org/

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