End-Stage Renal Disease
Network Program

Welcome to the IPRO ESRD Network Program

Patient Webinar: Understanding the COVID-19 Vaccine and Cultural Implications which Impact Vaccination

The webinar will begin promptly at 5:00PM.
Thank you for your participation!

IPRO

Better healthcare, realized.

Understanding the COVID-19 Vaccine and the Cultural Implications that Impact Vaccination

Opening Remarks

Laura Rodriguez-Carbone

Patient and Family Engagement ESRD Network Program Team

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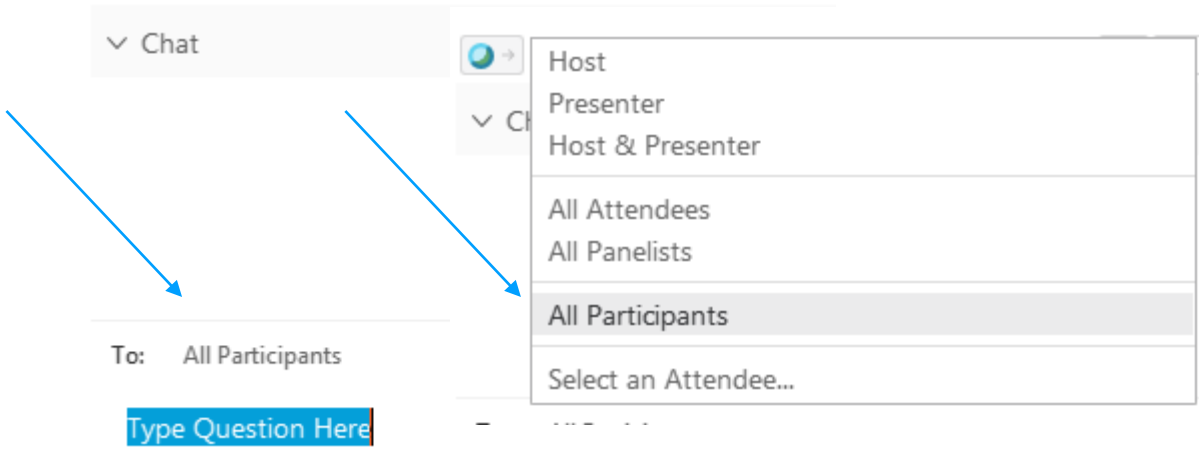
Meeting Reminders

- All phone lines are muted upon entry to eliminate background noise/distractions
- If you get disconnected, please don't place the call on hold, instead disconnect your line and rejoin the call when able
- Be present and engaged in our topic presentations
- We will be monitoring our WebEx Q & A throughout the webinar for questions or comments
- All slides will be shared within a week of completion of the meeting

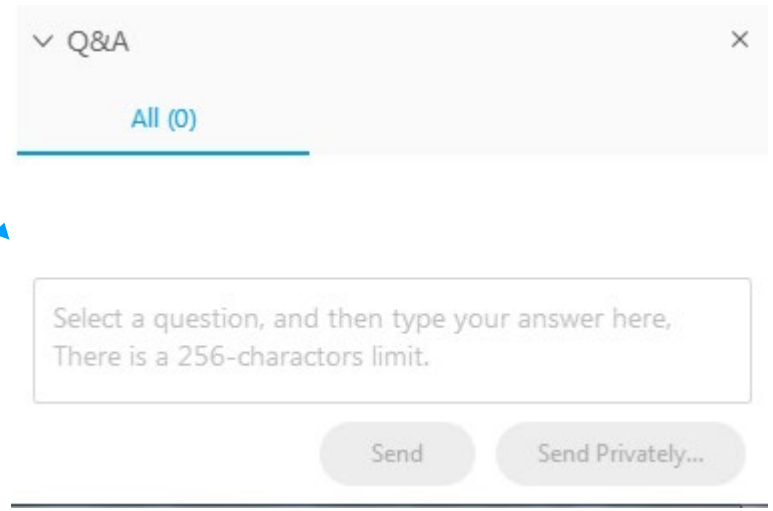
Housekeeping Reminders

- This WebEx will be recorded and slides will be made available on the Network's Website.
- All lines have been muted to eliminate background noise.

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



To ask a question for the answer to be shared with all Attendees or Privately, use the Q&A section in the bottom right corner of your screen



Learning Objectives

- Understand the influence of cultural beliefs and values that can impact healthcare decisions and vaccination choices
- Recognize the historical racism, bias and discrimination that can impact vaccine hesitancy in the Black, Indigenous and People of Color (BIPOC) Communities
- Learn about health inequities that exist today in the ESRD community, how they impact patients' care decisions, and how to overcome these challenges
- Discover the science related to the development and trials of the COVID-19 Vaccine, understand the safety and benefits of obtaining vaccination
- List credible resources for patients to become educated to make informed decisions about the COVID vaccinations
- Hear the Patient Experience with receiving the COVID Vaccine

Guest Speakers

Dr. Krishnan, Nephrologist
MetroHealth Medical Center

Renita Peck,
Patient Subject Matter Expert

Cultural Implications Impacting Vaccination

Laura Rodriguez-Carbone

What are cultural values?
How do they impact healthcare decisions?

- **Culture**: traditions, habits, or customs that are shared and can be observed, as well as ideas, beliefs, customs, knowledge, and values that are handed down from one generation to the next in a society.

- **Values**: core beliefs and practices. Each culture possesses its own particular values, traditions, and ideals. Cultural groups may endorse shared values (either in favor of or against).
  - Cultural values are formed through environmental adaptations, historical factors, social and economic evolution, and contact with other groups.

How do we honor cultural values and beliefs in healthcare decisions?

- **Cultural beliefs** can affect how a patient will seek care and from whom, how they will manage self-care, and make health choices. Cultural issues play a key role in adherence (a person's willingness to adhere to the doctor's recommendations).

- **Shared decision making** is a key component of patient-centered health care. It is a process where clinicians and patients work together to make decisions like selecting tests, treatments and care plans based on clinical evidence that balances risks, benefits, and expected outcomes with patient preferences and values.

Differences in Culture Inform Viewpoints about Medicine and Medical Care

- **All cultures have systems of health beliefs** to explain what causes illness, how it can be cured or treated, and who should be involved in the process.

- Cultural viewpoints on medical care, **coupled with historical experiences, and societal bias can also affect how patients view the COVID-19 vaccine and its safety.**

- **Cultural, social, and family influences shape attitudes, beliefs, perceptions and definitions of health and illness,** and can impact health literacy (the ability to understand) and health outcomes.

Poll Question: Do you think your cultural values have influenced your healthcare decisions?

Recognizing the Influence of Historical Events

Danielle Andrews

Cultural Challenges and Healthcare Misconceptions

- BIPOC is an acronym for Black, Indigenous and People of Color
- BIPOC communities have ongoing experiences of societal discrimination, racism and prejudice within the American Healthcare System.
- Past experiences of racialized medical trauma has influenced recent hesitancy in the BIPOC population regarding the COVID-19 vaccine.
- Common Misconceptions:
  - Black patients exaggerate their pain and have a higher tolerance for pain
  - People of color have thicker skin or less sensitive nerve endings
  - Black patients have higher tolerance to heat and stronger immunity to illnesses (built for labor)
  - Biases that have associated people of color with drug seeking behaviors

What can we do as a community to overcome medical mistrust?

Protective Factors:

- African-Americans place a strong emphasis/value on collectivism, kinship, the importance of extended families, the centrality of spirituality, and holistic thinking. Family relations can be a motivating factor in behavior change.

- Hispanic populations also tend to respect and consult older family members when it comes to health decisions.

- We all need to be sensitive and AWARE of the cultural implications – which includes values of family/community, religion, gender roles, health beliefs, perspectives on death, illness, and medications

Influence of Historical Events on Medical Racism

- **History of Medical Experimentation:** A highly publicized example of overt racial discrimination in health related practices was the **Tuskegee Syphilis Study (1932-1972)** in which African Americans were subjected to unethical medical treatment over a 40 year span. The lack of transparency and disregard for well-being contributed to a legacy of mistrust that continues to manifest as health inequities among the African American population.

- **The Havasupai Tribe of the Havasupai Reservation v. Arizona Board of Regents and Therese Ann Markow case in 2009:** described researchers' misuse of DNA from members of the Havasupai Tribe in research studies for which the member did not provide informed consent.

- **Eugenics:** people were lied to about the intent of medical procedures to promote forced sterilization. Widespread concerns are known to exist in communities of color regarding the safety and equitable participation of diverse populations during pre-production and testing vaccines.

What Has Been Done to Protect Patients from Medical Harm

The **Belmont Report** was created in 1974 to identify the **basic ethical principles** that should be **taken into consideration when biomedical and behavioral research involving human beings** are conducted.

1. **Respect for Person:** Individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection
2. **Beneficence:** People are treated in an ethical manner not only by respecting their decision and protecting them from harm but also by making efforts to secure their wellbeing: Do Not Harm, Maximize Possible Benefits, and Minimize Possible Harms
3. **Justice:** Who receives the benefits of research and who bears the burden?

Civil Rights Enforcement

The Office of Civil Rights (OCR) has enforcement authority with respect to:

- Health programs and activities that receive Federal financial assistance from the U.S. Department of Health and Human Services (HHS) or its agencies; or are administered by HHS; or any entity established under Title I of the Affordable Care Act or its amendments.
- You can learn more about filing a complaint with OCR here: https://www.hhs.gov/ocr/complaints/index.html
- **Contact ESRD Network for support!** As a dialysis patient, if you are not satisfied with the care you receive, you have several options for filing a grievance.
- https://esrd.ipro.org/patients-family/grievances-concerns/

Title VI, Civil Rights Act of 1964

- Protects beneficiaries from discrimination based on race, color and national origin
- No person in the United States shall, on the grounds of **race**, **color** or **national origin**, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal Financial Assistance ("FFA").

IPRO ESRD Network

Your Network can work with you and your facility to help resolve your concerns or grievances regarding care received by your facility.

- Before filing a grievance with the Network, discuss your concern directly with a staff member at your facility. Ask to speak with someone with whom you feel comfortable sharing your concerns.
- If you do not wish to identify yourself, ask about how an anonymous grievance can be filed.
- If you do not feel comfortable filing a grievance with your facility or you feel dissatisfied with the response of facility staff to your concerns, you have the right to file a grievance with your Network and with your state agency.

Learn more about the grievance process on our website:
https://esrd.ipro.org/providers/patient-services/grievances/

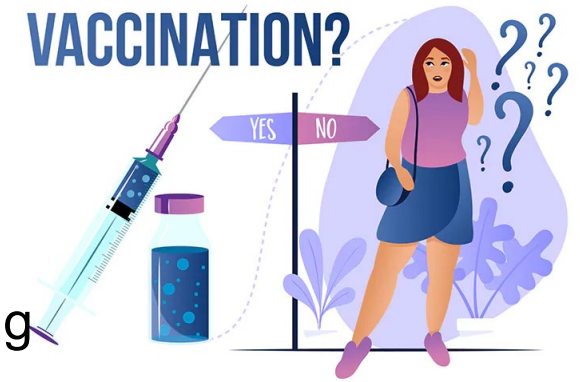
Building Vaccine Confidence in Communities of Color

- Vaccination hesitancy is defined as a delay in acceptance or refusal of vaccines despite availability.

- Questions and hesitancy about the COVID-19 vaccine are part of a larger historical framework of mistrust of the American Healthcare system by communities of color due to long-entrenched bias, discrimination, and systemic racism.

- The COVID-19 pandemic has magnified historically embedded racial, ethnic, and socioeconomic inequities for patients in communities of color.

- Widespread concerns are known to exist in communities of color regarding the safety and equitable participation of diverse populations during pre-production and testing vaccines.



Promoting Vaccine Confidence Through Community Engagement

Strategies to Overcome:

- Create a safe space through the establishment of common ground and validation the real, history- and experience-based reasons why people may be hesitant. (Empathy)
- Include staff members that are representative of the BIPOC population
- Dispel myths and misconceptions about the vaccine and how it was developed and how the trials were conducted to help patients become informed.
- Building trust within the interdisciplinary team and providing information about vaccine importance can mitigate gaps in vaccination uptake.
- Creating mechanisms for vaccine distribution that incorporate cultural norms and address barriers, such as vaccination sites that address off-work hours and transportation access
- Identifying barriers to vaccination acceptance and other appropriate health interventions is necessary to deploy a safe and trusted vaccination program successfully.

Chat Check-in: What is influencing your decisions regarding the vaccine? Where do you get information about the vaccine?

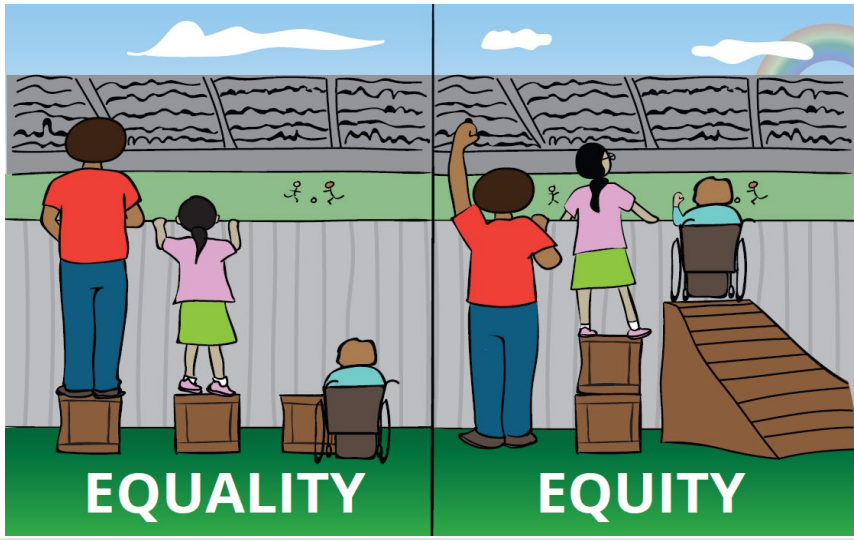
Overcoming Health Inequities

Danielle Andrews

What are Health Inequities?

According the World Health Organization (WHO) health inequalities are systematic differences in healthcare outcomes.

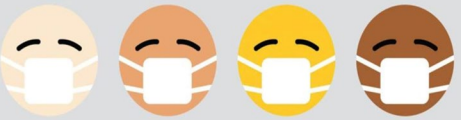
- **Social Determinants of Health:** conditions in places where individuals live, learn, work, and play that affect a wide range of health and quality of life, risks and outcomes.
- **Health Inequities:** are differences in health status or in the distribution of health resources between different population groups, arising from the social conditions in which people are born, grow, live, work and age.
  - Neighborhood and Physical Environments
  - Health and Healthcare
  - Income and Wealth Distribution
  - Education



Viewpoints About Vaccination that Can Exist in BIPOC Communities

COVID-19 has magnified historical racism, disparities and inequity in Communities of Color, which can result in vaccine hesitancy...

- Anticipation of negative experiences when interacting with health officials due to negative interactions in their past
- Expectation of the existence of oppression or harm
- Negative, marginalizing, and demeaning experiences with health systems can fracture patients trust
- Aversion toward blood and needles (common among cultures with strong holistically based medical beliefs
- Multigenerational mistrust of authority or formalized systems



How to Combat Health Inequities?

Combating health inequities relies on governmental resource allocation, improved access to resources, and a standardized educational system within the community and healthcare team.

Here are some things your healthcare team can do to help increase health equity:

1. **Create a safe space free of shame or judgement o**f a patient's healthcare knowledge
2. Engage in **open communication using active listening** techniques
3. Clearly describing a patient's illness and treatment **without the use of medical jargon**
   - Having the patient repeat back their interpretation of their illness and ongoing treatment, with the medical staff filling-in the gaps to provide further clarity
4. **Creating responsive healthcare plans** that attests to a patient's specific healthcare barriers while providing them with a complete picture of possible treatment options, with a list of treatment providers, pharmacies, and supplies needed

Importance of Vaccinations

Jeanine Pilgrim

Poll Question: Did you receive a flu shot this season?

What is a Vaccine?

- An injected vaccine is designed to stimulate your immune system to produce antibodies that attack and kill the virus invading your body.
- Vaccines teach your immune system how to create antibodies that protect you from diseases.
- Our immune systems help defend us from invading organisms. When a new virus attacks the body, cells of the immune system are stimulated to make specialized proteins called antibodies, that recognize the invading virus particles, attach to the virus particles and destroy them.
- Vaccines are given to “jump-start” the immune system to produce these antibodies before the first virus infection, so that they go to work immediately if you catch the virus.

Why Vaccinations are Important?

- Vaccines are one of the best defenses against serious diseases
- Many diseases have been eliminated in the United States because of vigorous vaccination programs i.e. Polio, Smallpox, Measles
- Vaccination is safe and effective. All vaccines undergo long and careful review by scientists, doctors, and the federal government to make sure they are safe
- Vaccines won't give you the disease they are designed to prevent
- Vaccines work better when more people are vaccinated
- Vaccination protects others you care about, including family members, friends, and community members

Chat Check-in: Questions or Comments?

COVID-19 Vaccination Facts Over Fiction

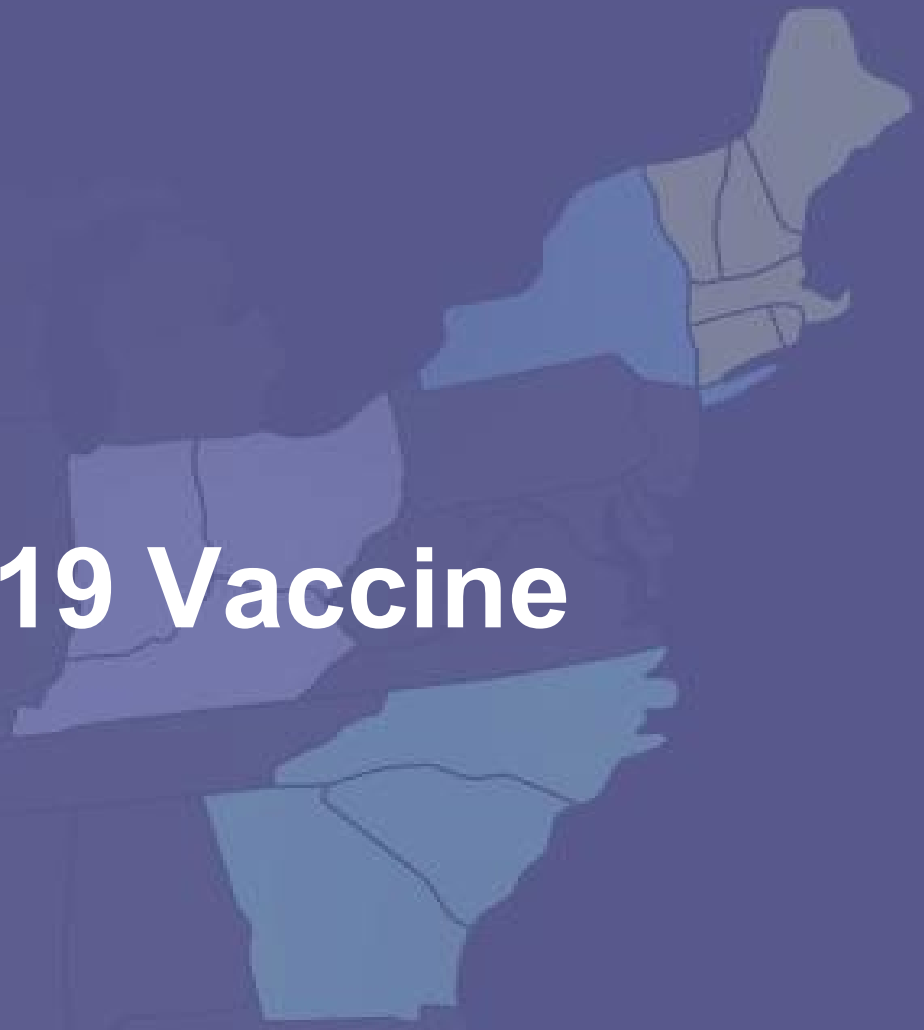
Guest Speaker Presentations

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

Poll Question: Do you feel the COVID-19 vaccine is safe for ESRD patients?

Understanding the COVID-19 Vaccine



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

Appendix A: 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* • 15 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‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† 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^# **ACTIONS** • Do not vaccinate# • Consider referral to allergist-immunologist

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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

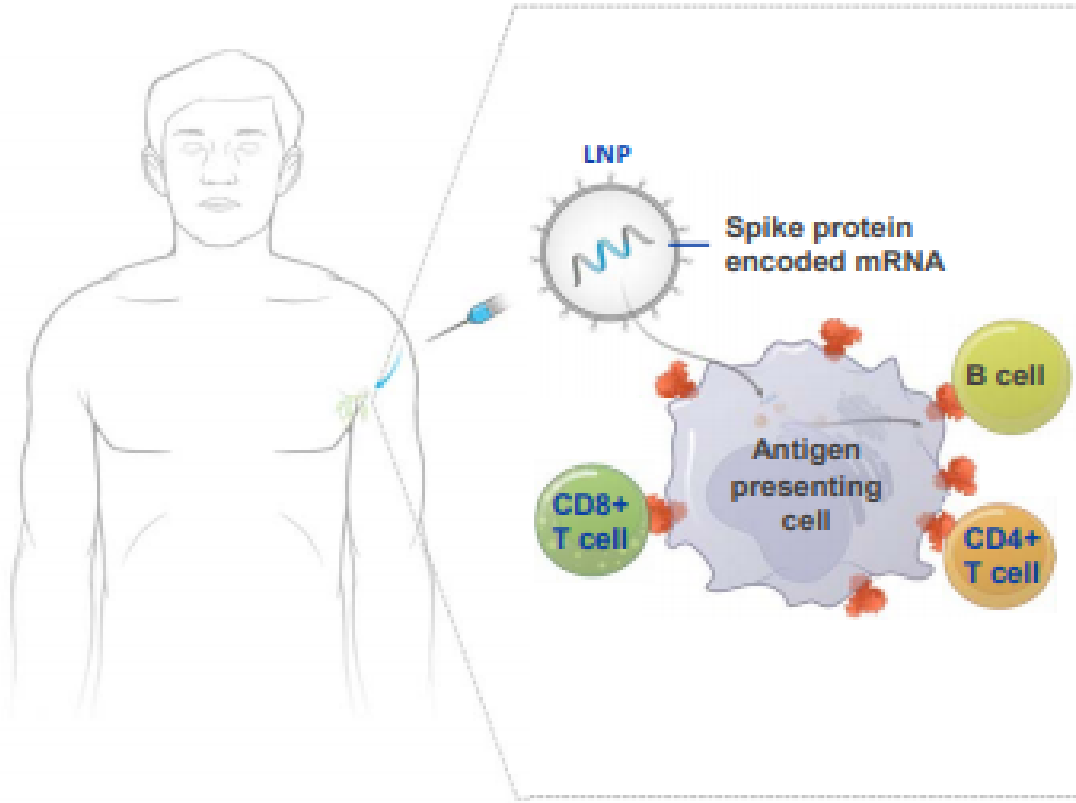
Pfizer vs Moderna

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

- Testing sample (18 years and older, all ethnicities and races) and co-morbid 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

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

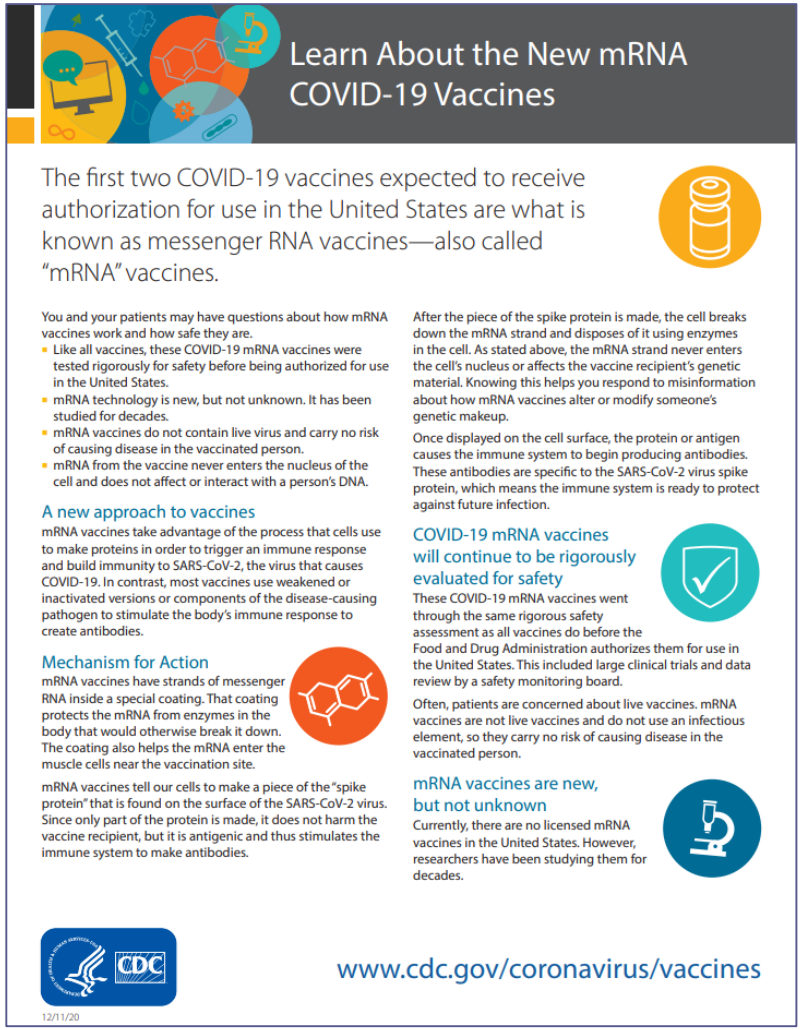
January 7, 2021

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



Learn About the New mRNA COVID-19 Vaccines

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 makeup.

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

12/11/20

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. mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases. *Molecular Therapy*. 2019;27(4):757–72.
- Jackson NAC, Kester KE, Casimiro D, Gurunathan S, DeRosa F. The Promise of mRNA Vaccines: A Biotech and Industrial Perspective. *Npj Vaccines*. 2020;5(1):1–6.

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

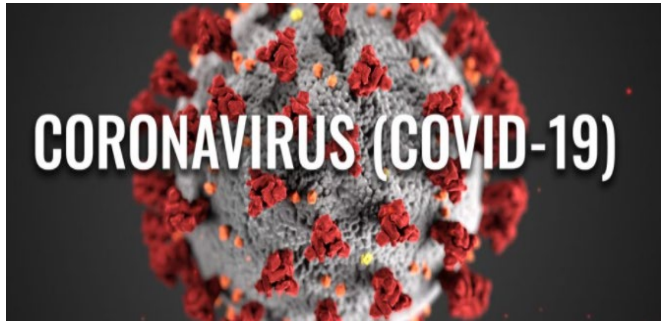
Understanding the mRNA vaccine https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html

Fiction: There Was a Rush to Get The Vaccine Approved

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



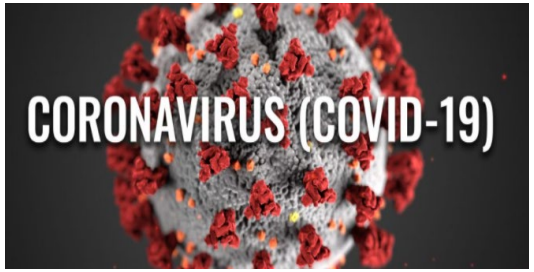
Ensuring the Safety of COVID Vaccines in the United States
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

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

Diversity in COVID-19 Vaccine Trials for Pfizer and Moderna

Table 1: Race/Ethnicity of Participants in Pfizer-BioNTech and Moderna COVID-19 Vaccine Clinical Trials			
	Total US Population Age 16+	**Pfizer-BioNTech***	**Moderna**
Total	**258 million**	**40,277**	**27,817**
Race			
White	73.6%	81.9%	79.4%
Black	12.3%	9.8%	9.7%
Asian	5.9%	4.4%	4.7%
American Indian/Alaska Native	0.8%	0.6%	0.8%
Native Hawaiian or Other Pacific Islander	0.2%	0.2%	0.2%
Ethnicity			
Hispanic	17.6%	26.2%	20.0%
Non-Hispanic	82.4%	73.2%	79.1%

NOTES: *Pfizer-BioNTech data are for all participants globally; of which 76.7% are in the United States. Pfizer results provided for Phase 2/3 trial, Moderna results for Phase 3 trial. The Pfizer trial included those ages 16 and older. The Moderna trial included those ages 18 and older.
SOURCES: Racial/ethnic distribution of total population age 16 or older based on KFF analysis of 2019 American Community Survey data; FDA, Briefing Document: Pfizer-BioNTech COVID-19 Vaccine, December 10, 2020; FDA, Briefing Document: Moderna COVID-19 Vaccine, December 17, 2020

The data show, that, overall, people of color are underrepresented in these trials relative to their share of the total U.S. population (Table 1), with the largest disparity among the Black population, but that the rates are comparable proportionally. While the trials have not included the overrepresentation of people of color that some had suggested, as noted above, these trials have achieved greater diversity than many previous trials for other drugs. In both COVID-19 trials, the demographics of the placebo and vaccine groups are similar, as are the characteristics between all participants and the safety populations (the group of individuals receiving the vaccine and followed for safety). In addition, similar vaccine efficacy results were observed across racial and ethnic groups in both the Pfizer and Moderna trials."

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

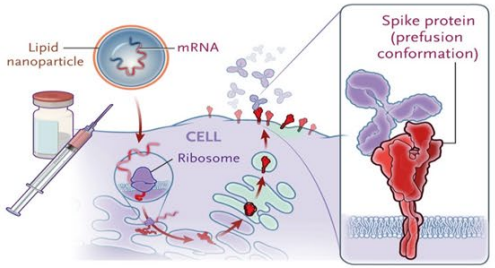
Efficacy:
The vaccine showed protection 7 days after the second dose; 95% efficacy was observed.

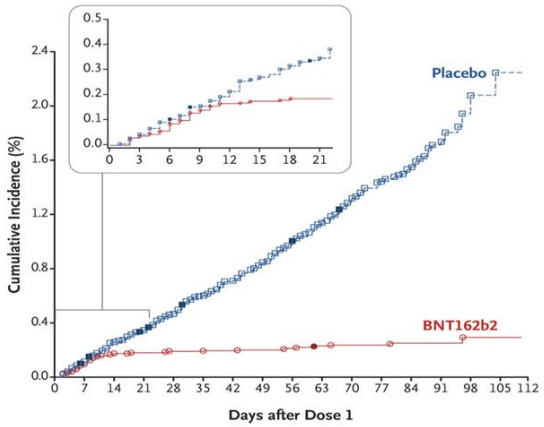
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

Links: Full article | Quick Take | Editorial





Vaccine efficacy of 95% (95% credible interval, 90.3 –97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

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In December 2020, the New England Journal of Medicine published safety and efficacy results for the Pfizer vaccine.

According to the study, “vaccine efficacy similar to that observed in the overall population was generally consistent among subgroups defined by age, gender, race, ethnicity, obesity, or presence of a comorbidity.”

The results of this study show a high effective rate for the vaccine and that it is well tolerated. Read More Here

Information about the Moderna COVID-19 Vaccine

Updated Jan. 25, 2021 Languages Print

General information

Name: mRNA-1273

Manufacturer: ModernaTX, Inc.

Type of vaccine: mRNA

Learn more about how COVID-19 vaccines work and get a better understanding of COVID-19 mRNA vaccines.

Number of shots: 2 shots, one month (28 days) apart

How given: Shot in the muscle of the upper arm

Does not contain:

More Information for Healthcare Professionals

Administration Overview

Information on the safety and efficacy of the Moderna COVID-19 Vaccine can be found here: The CDC has data on the outcome of trials, trial demographics, as well as possible side effects are provided. The vaccine has been found to have been safer in patients than those that were given a placebo vaccine.

Poll Question: Once I am eligible to receive a COVID-19 vaccine, I plan to be vaccinated.

Patient Perspective on the COVID-19 Vaccine

Renita Peck

Patient Subject Matter Expert (PSME)
Member of IPRO ESRD Network Patient Advisory Committee (PAC) and Medical Review Board

Conversation with Renita Peck

- What prompted you to get the vaccine?
- How you do think race has affected your outlook on the vaccine?
- How has systematic racism and discrimination shaped your perspective on the healthcare system in general.
- Have you had conversations with other patients that have concerns about the vaccine?
- What helped alleviate your concerns about the vaccine?

Q&A with Guest Speakers: Renita and Dr. Krishnan

Approaches to Patient Education and Empowerment

Laura Rodriguez-Carbone

What Can We Do to Support BIPOC ESRD Patients?

- **Continue to create a safe space (like PAC Meetings or Support Group Meetings)** where community members can honestly and freely discuss concerns or mistrust toward public health systems, ask questions, and receive feedback and resources to ensure equitable access to information about their dialysis care.

- **Include ESRD Patients across the BIPOC ESRD Community** in efforts to suggest and advocate for strategies for improving understanding of culturally competent dialysis care practices at facilities

- **Positionality when speaking with patients** (cultural awareness and competency)

What can ESRD Patients do to Help Increase Cultural Competency in their Health Care?

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Ask Your Provider These Questions

- Are you familiar with my community's beliefs, values and attitudes toward healthcare? If not, are you willing to learn about my cultural background and respect my perspective?
- Do you have experience treating people from my cultural background?
- Are you or members of your staff bilingual?
- How would you include aspects of my cultural identity, such as age, faith, gender identity or sexual orientation, in my care?

What can ESRD Patients do to Help Alleviate the Unknowns About the COVID-19 Vaccine?

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Arm Yourself with the Facts! Knowledge is Power!

- Get as much information as you can about the COVID-19 vaccine from research from credible websites.
- Contact providers and credible agencies that work with people from your same cultural background or look for providers and agencies that have worked with people who have a similar cultural background to ask questions and express concerns.
- Research this online or ask for referrals from cultural organizations in your community.
- If you have health insurance, ask the health plan for providers that match your cultural background.

Important Takeaways for Patients

- **Given the known risk of COVID-19 infection to dialysis patients, and the data so far available about the vaccines, this is a safe treatment to consider.**
- **Tackle Misconceptions with the SAFE acronym …**
  - **Safe** - the risks and side effects are small compared with the benefits.
  - **Available** - based on risk group.
  - **Free** - although some providers may charge an administration cost.
  - **Effective** - both the Moderna and Pfizer vaccines are approximately 95% effective in preventing COVID-19 disease when administered as directed (which requires two doses).

Important Takeaways for Patients and Providers

- Encourage all dialysis patients to speak with their nephrologist and healthcare team to consider getting COVID-19 vaccination as soon as it is available.

- If you contract COVID-19 before you get vaccinated, speak with your nephrologist and consider getting an infusion of monoclonal antibodies.

- If you reside in states not currently distributing vaccine to dialysis patients, contact your state health departments and legislators to advocate for prompt distribution of vaccine to dialysis patients.

Available Educational Resources

Danielle Andrews

COVID? ...FLU? ...COLD? ...ALLERGY?
"How can I tell the difference?"

GUIDELINES FOR DETERMINING SYMPTOMS

Symptoms	COVID-19	Flu	Common Cold	Allergies
Fever greater than 102°	X	X		
Moderate temperature			X	
Cough	X	X	X	SOMETIMES
Shortness of breath	X			
Head and body aches	X	X	X	
Loss of taste or smell	X			
Sore throat	X	X	X	SOMETIMES
Nasal Congestion/Stuffy Nose	X	X	SOMETIMES	SOMETIMES
Nausea and/or vomiting	X	X		
Fatigue	X	X	SOMETIMES	
Runny nose		X	X	X
Post-nasal drip			X	SOMETIMES
Sneezing			X	X
Plugged-up ears				X
Tickle in back of throat				X
Seasonal symptoms				X

If you have questions about your facility or to file a grievance, please contact your local ESRD Network:

IPRO End-Stage Renal Disease Network of New England (CT, MA, ME, NH, RI, VT)
1952 Whitney Avenue, 2nd Floor, Hamden, CT 06517
Patient Toll-Free: (866) 286-3773
Main: (203) 387-9332 • Fax: (203) 389-9902
E-mail: esrdnetwork1@ipro.us
Web: network1.esrd.ipro.org

IPRO End-Stage Renal Disease Network of New York (NY)
1979 Marcus Avenue, Lake Success, NY 11042-1072
Patient Toll-Free: (800) 238-3773
Main: (516) 209-5578 • Fax: (516) 326-8929
E-mail: esrdnetwork2@ipro.us
Web: network2.esrd.ipro.org

IPRO End-Stage Renal Disease Network of the South Atlantic (GA, NC, SC)
909 Aviation Parkway, Suite 300, Morrisville, NC 27560
Patient Toll-Free: (800) 524-7139
Main: (919) 463-4500 • Fax: (919) 388-9637
E-mail: esrdnetwork6@ipro.us
Web: network6.esrd.ipro.org

IPRO End-Stage Renal Disease Network of the Ohio River Valley (IN, KY, OH)
3201 Enterprise Pkwy., Suite 210, Beachwood, OH 44122
Patient Toll-free: (844) 819-3010
Main: (216) 593-0001 • Fax: (216) 593-0101
E-mail: esrdnetwork9@ipro.us
Web: network9.esrd.ipro.org

v.4 1/5/2021

End-Stage Renal Disease Network Program

The IPRO End-Stage Renal Disease Network Program, ESRD contractor for Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont (NW1), New York (NW2); Georgia, North Carolina, South Carolina (NW6) and Ohio, Indiana and Kentucky (NW9) developed this material under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. CMS Contract Numbers: NW1: HHSM-500-2016-00019C; NW2: HHSM-500-2016-00020C; NW6: HHSM-500-2016-00006C; and NW9: HHSM-500-2016-00009C

IMPORTANT NOTICE:
A High-Risk Person Lives Here!

Are you experiencing any of these symptoms?

- Fever
- Cough
- Difficulty breathing
- Fatigue
- Recent loss of taste and smell
- Body aches
- Nasal or chest congestion
- Vomiting or Diarrhea

Have you recently traveled to a "Hot Zone" or out of the country?

STOP

If the answer to any of these questions is "Yes," please don't come in.

Otherwise, please make sure your hands are clean, wear a mask or face covering, and try to maintain six feet of social distancing.

Thank you for your cooperation!

End-Stage Renal Disease Network Program

esrd.ipro.org

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The COVID-19 Vaccine: What ESRD & Transplant Patients Need to Know

IT IS SAFE: The available COVID-19 vaccines are approved and recommended by the FDA and the CDC's Advisory Committee on Immunization Practices following standard testing and approval processes. Though Messenger RNA (or mRNA) vaccines, like the COVID-19 vaccine, are new, the MRNA technology used in COVID-19 vaccines have been studied for decades. **mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person. mRNA from the COVID-19 vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.**

IT IS FREE: The COVID-19 vaccine is being administered free of charge to all individuals by the federal government. Insurance information may be asked for by those administering the vaccine in order to bill-back to insurance. However, you will not be charged. If you do not have insurance, you are still eligible to receive the vaccine free of charge.

YOU NEED TWO DOSES TO BE FULLY VACCINATED: Until you are fully vaccinated, you can still contract and spread COVID-19. *Not everyone will be vaccinated when you are. And while we know it dramatically reduces severe cases and symptoms, we are still learning about the protection that COVID-19 vaccines provide under real-life conditions. Continue to wear a mask, wash your hands, keep distance and avoid groups between doses and even after your second dose.*

When You Should Get Your Second Shot:

Pfizer vaccine: 21 days following first dose
Moderna vaccine: 28 days following first dose

Before leaving your first dose appointment, schedule or confirm how to set up your next appointment.

Possible Side Effects After Receiving the COVID-19 Vaccine

After receiving the vaccine, you may have mild flu-like symptoms like

- **Fever,**
- **Body Aches, and**
- **Pain at the Injection Site**

These symptoms mean your body is building protection to fight the virus and should not be an immediate cause for concern. If symptoms persist for more than a few days, call your doctor. You may be asked to register and use V-safe, a smartphone based tool that uses text messages and web surveys, to monitor your symptoms after vaccination. Learn more about V-safe here: www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

IT WILL TAKE A FEW WEEKS TO BUILD UP IMMUNITY TO THE COVID-19 VIRUS: Protection may vary for pre-and post-transplant and ESRD patients. *Now is not the time to let up on the safety precautions you have been observing. It is important that you continue to wear your mask, practice frequent hand hygiene, physical distance from others and avoid unnecessary outings.* ***Do not stop these safety measures until you're told to.***

YOU SHOULD GET THE COVID-19 VACCINE EVEN IF YOU ALREADY HAD COVID-19 AND RECOVERED: Due to the severe health risks associated with COVID-19 and the fact that re-infection is possible, the vaccine should be offered to you regardless of whether you already had the COVID-19 infection.

- *At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19.*
- *The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.*

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about. ***It's better to be safe than sorry: the benefits outweigh the risks of getting the COVID-19 vaccine for ESRD and transplant patients.***

ESRD AND TRANSPLANT PATIENTS SHOULD GET THE VACCINE: The vaccine is safe, is not a live virus, nor does it contain weakened or killed virus. The vaccine relies on a completely different technology to attack the virus that causes COVID-19. You will not be exposed to the COVID-19 virus from the vaccine in any way. *As a transplant or ESRD patient, you are more likely to suffer more severe outcomes from COVID-19 than people who are not organ recipients or on dialysis. COVID-19 is a dangerous disease. If you get the disease, it could be fatal.*

SEEK OUT CREDIBLE SOURCES OF INFORMATION: Make sure you are getting your information from credible sources. *Learn more about the COVID-19 vaccine, how it was developed, what you can expect, and browse frequently asked questions from the Centers for Disease Control (CDC) at* **https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.** *Additional resources for kidney and transplant patients are available from your IPRO ESRD Network at* **https://esrd.ipro.org/home/covid-19-patient-resources/**

LEARN MORE IF YOU ARE STILL UNSURE OR HAVE QUESTIONS ABOUT THE VACCINE: Talk to your primary care doctor, dialysis medical team, transplant team or infection prevention expert to ask questions and learn more.

COVID-19 and the Black Community: A Tyler Perry Special

https://youtu.be/M56q6TIJ890

Join us on Friday, March 5 at 1pm for a Facebook Live Screening of this special in our Patient Facebook group https://www.facebook.com/groups/IPROESRDPAC

Celebrate Black History Month

Understanding Kidney Disease and the Black Community:

- Americans of African descent have the highest risk of acquiring kidney failure when compared to any other race.
- About 1 in 3 kidney failure patients living in the United States are Black or African descent.
- Black Americans make up about 13 percent of the population, but they account for 35 percent of the people with kidney failure in the United States.
- Diabetes and high blood pressure are the leading causes of kidney failure among African Americans.

Credible Websites for Research, Information, and Resources on COVID-19 Vaccine

- **Centers for Disease Control (CDC):** https://www.cdc.gov/vaccines/covid-19/index.html
- **World Health Organization (WHO):** https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines
- **Medical Library Association:** Medspeak translates Medical jargon and lists credible resources on the vaccine for patients. Featuring health department directories, podcasts, and print resources for parents, kids, and older adults, the focus is on evidence-based information you can easily understand. https://www.mlanet.org/p/cm/ld/fid=1717

- https://www.kidney.org/coronavirus/vaccines-kidney-disease
- https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html
- https://www.dpcedcenter.org/news-events/news/dialysis-patients-and-covid-19-vaccine-and-antibody-treatment/?bblinkid=248429772&bbemailid=28877262&bbejrid=1858602109
- https://www.dpcedcenter.org/news-events/news/five-important-questions-about-pfizers-covid-19-vaccine/
- https://www.webmd.com/coronavirus-in-context/video/sharon-allison-ottey

Closing Remarks
Next Steps

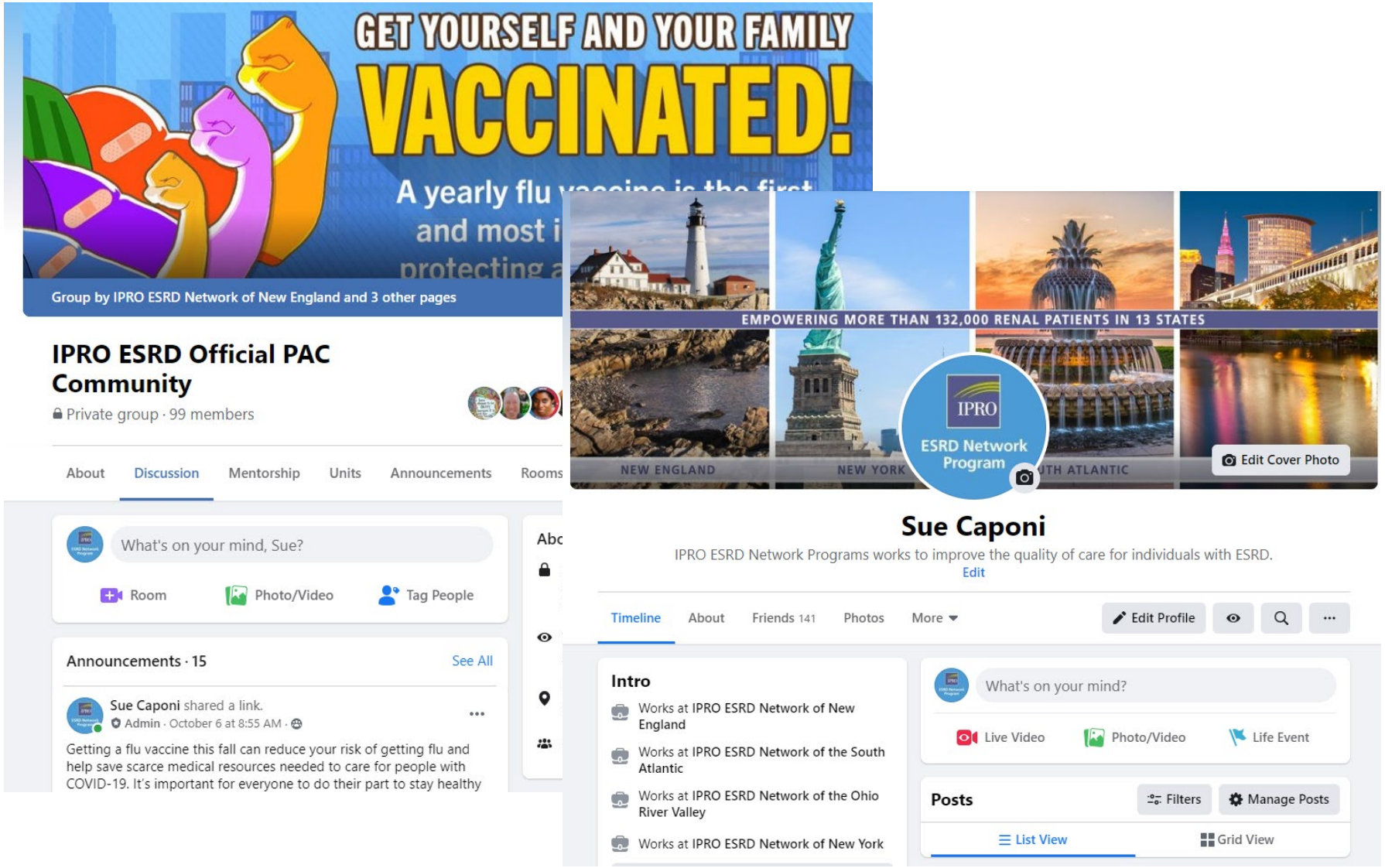
Laura Rodriguez-Carbone

Next Steps

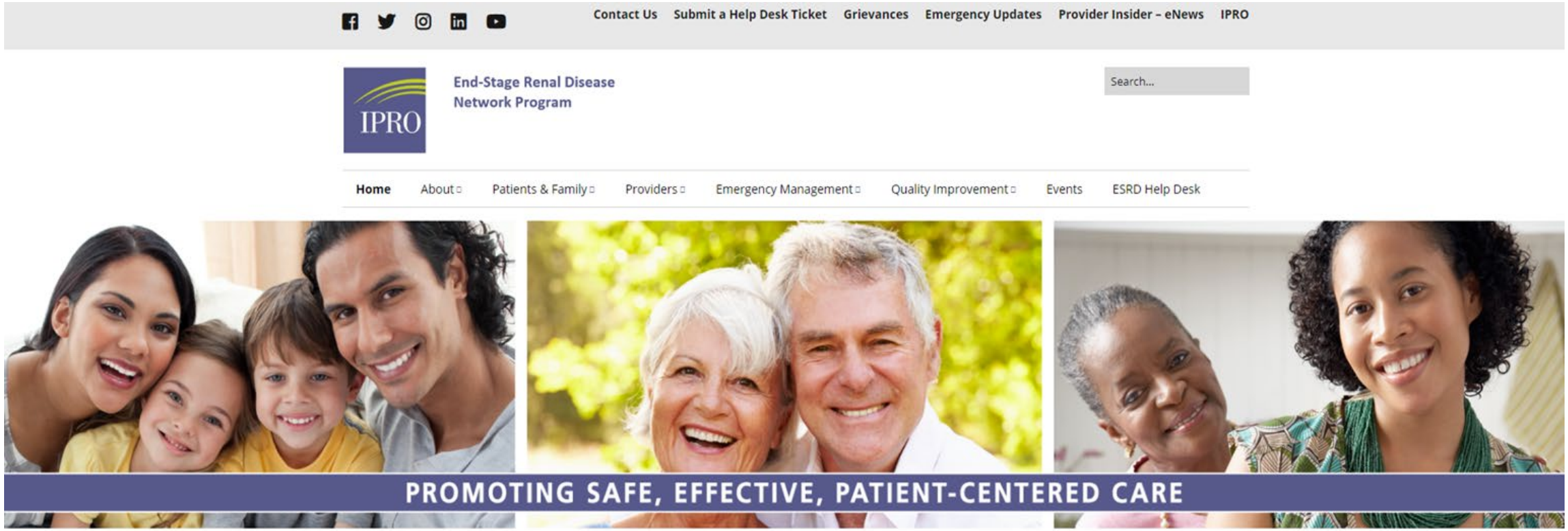
- Complete Post-Event Evaluation – we value your feedback!
- Look out for PAC Newsletter: *PAC Matters-Connecting the Community*
- Join the IPRO ESRD Network Program's Virtual Patient Support Group
  - Next Meeting Thursday, 2/25 at 5:00PM
  - Dial 1-855-797-9485, Access Code: 616 535 334
- Follow IPRO ESRD Network Program on Social Media
  - https://www.facebook.com/groups/IPROESRDPAC
  - https://www.facebook.com/ESRDNetwork1
  - https://www.facebook.com/ESRDNetwork2
  - https://www.facebook.com/NW6ESRD
  - https://www.facebook.com/ESRDNetwork9
  - https://twitter.com/IPROESRDNetwork
  - https://www.instagram.com/ipro_esrd_network/
- Check out Network Program Website for Resources https://esrd.ipro.org/
- Get Prepared for Winter Emergencies: https://www.kcercoalition.com/en/patients/
- Talk to your healthcare team about COVID Vaccine availability in your State

Social Media - Join Our Facebook Group!

https://www.facebook.com/groups/IPROESRDPAC



Visit the IPRO ESRD Network Website! https://esrd.ipro.org/



The mission of the End Stage Renal Disease (ESRD) Network Program is to promote health care for all ESRD patients that is safe, effective, efficient, patient-centered, timely, and equitable.

Final Questions or Comments?

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Thank you to our guest speakers!

Thank You for Attending!
For questions and assistance please contact:

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