COVID-19

An End Stage Renal Disease (ESRD) National Coordinating Center (NCC) Professional Education Webinar

January 27, 2021

COVID-19 = Coronavirus Disease 2019

ESRD NCC NATIONAL COORDINATING CENTER

Agenda

- What is this call about?
- Today's speakers:
  - Lance Salazar, PharmD, Clinical Pharmacy Coordinator, Sutter Health System
  - Jeffrey Silvers, MD, Medical Director of Pharmacy and Infection Control, Sutter Health System; Member, California Department of Public Health (CDPH) COVID-19 Drafting Guidelines Workgroup
- Topic: COVID-19, Renal Disease and Vaccination
- Questions and answers (Q&As) from chat and Q&A panels

What Is This Call About?

- Hear from stakeholders and peers in the ESRD community who are adapting to COVID-19.
- Share examples and provide real-world strategies for facilities to use.
- Engage in bi-monthly calls on varying topics.

The mRNA COVID-19 Vaccines and Healthcare Workers

Jeffrey Silvers, MD
Medical Director of Pharmacy and Infection Control, Sutter Health
Member CDPH COVID-19 Drafting Guidelines Workgroup

Lance Salazar, PharmD
Clinical Pharmacy Coordinator, Sutter Health

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DEFINITIONS

- SARS-CoV-2 is the virus that causes COVID-19
- COVID-19 is the disease caused by the SARS-CoV-2 virus

COVID CASES 1/14/21 14:54

- WORLD
  - CASES 92,850,683
  - DEATHS 1,988,290
- USA
  - CASES 23,253,252
  - DEATHS 387,910

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CDC List of Adults Who **Are at Increased Risk** of Severe Illness From COVID-19

- Cancer
- Chronic Kidney Disease (CKD)
- Cancer
- Chronic Obstructive Lung Disease
- Down's Syndrome
- Heart conditions, not just hypertension
- Weakened immune system from solid organ transplant
- Obesity (BMI $\geq$ 30 kg/m^2)
- Pregnancy
- Sickle Cell Disease
- Smoking (Present or history of)
- Diabetes (type 2)

CDC = The Centers for Disease Control and Prevention; BMI= body mass index

What Is the Risk of Chronic Kidney Disease?

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OpenSAFELY

OpenSAFELY DATA

- Williams EJ, et al. Factors associated with COVID-19-related death using OpenSAFELY. Nature 2020; 584:430–436
- 17,278,392 adults ≥18 years old
- Covers 40% of all patients in the United Kingdom
- ≥ 12-month follow-up (started 2/20)
- 10,926 deaths
- CKD is second most common risk factor for dying from COVID-19 after age

OpenSAFELY DATA

- Hazard Ratio, fully adjusted model for age

Condition	Hazard Ratio
Dialysis	3.69
Renal Transplant	3.53
CKD 4–5 Combined	2.52
Diabetes	1.31–1.95 (depends on control)

CKD Is a Key Risk Factor for Severe COVID-19

- CKD is among the most prevalent conditions that increase the risk of severe COVID-19
- CKD is the condition most strongly associated with the risk of severe COVID-19 (not counting age)
- Nephrology, Dialysis, Transplantation (2021) 36:87–94

COVID-19 Hospitalization and Death by Age

CDC Updated August 18, 2020

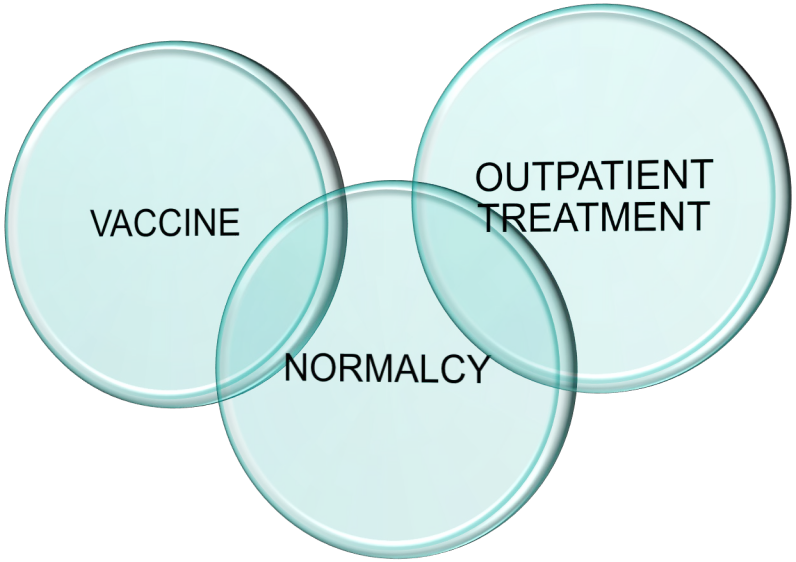
Rate ratios compared to 18-29 year olds

	Hospitalization[1]	Death[2]
0-4 years	4x lower	9x lower
5-17 years	9x lower	16x lower
18-29 years	Comparison Group	Comparison Group
30-39 years	2x higher	4x higher
40-49 years	3x higher	10x higher
50-64 years	4x higher	30x higher
65-74 years	5x higher	90x higher
75-84 years	8x higher	220x higher
85+ years	13x higher	630x higher

Source: CDC.

Vaccinating Against COVID-19
We Want Our Lives Back!

STEPS TO A POST-COVID NORMAL LIFE



Source: Sutter Health

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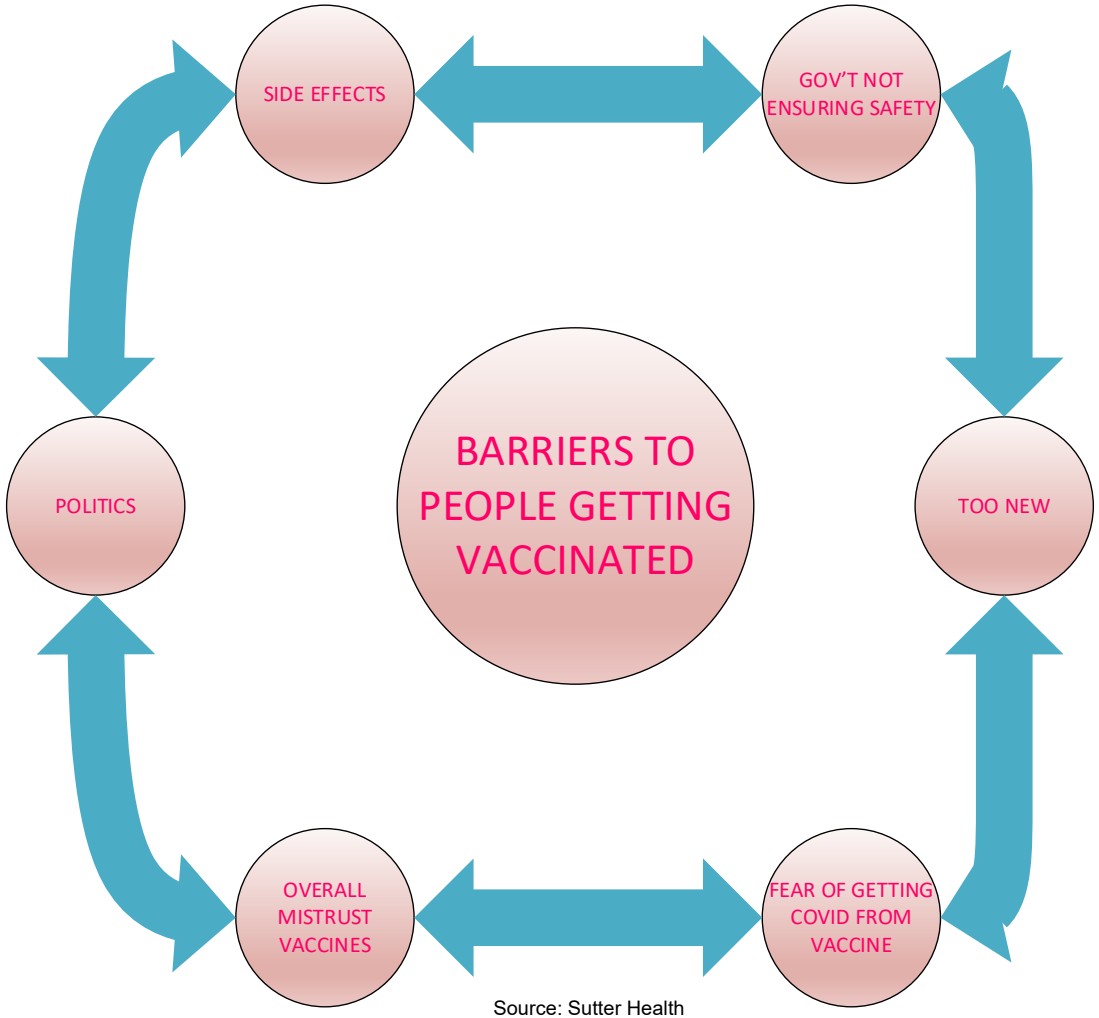

Source: Sutter Health

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HISTORY BEING MADE

Source: Sutter Health

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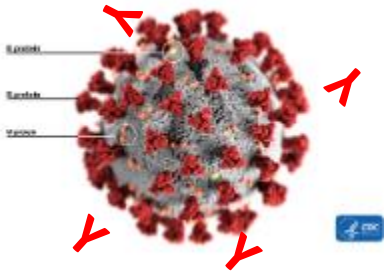
MECHANISM OF ACTION

VACCINE DEVELOPMENT 2020



Source: CDC

1. Find the protein of the pathogen that you need to counter
2. Code the sequence of the gene making that protein
3. Create a vaccine using that code

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IMPORTANT POINTS

- Not a live vaccine
- Does not contain a whole virus
- Does not enter the nucleus of the cell
- Degrades quickly by normal cellular processes
- Does not use any fetal cells during the development or production

DEMOGRAPHICS

- ♂=♀
- 83% white
- 20–25% Latinx
- 10% Black or African-American
- Younger/Older 60/40
- 1/3 BMI $\geq$30 kg/m^2 Moderna used $\geq$ 40 kg/m^2
- 1 in 5 with other co-morbidities
  - 8% DM or pulmonary disease
- Pregnancy and lactating women excluded

DM = diabetes mellitus

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RESULTS—PFIZER

- 170 Participants developed disease
- 162 Placebo
  - 9 cases severe disease
- 8 mRNA
  - 1 case severe disease
- COVID-19 between dose #1 and #2
  - 39 Vaccine (10 severe)
  - 82 Placebo (9 severe)
  - 52.4% efficacy
- Efficacy consistent across age, gender, race and ethnicity
- Older adults tended to report fewer, milder adverse events

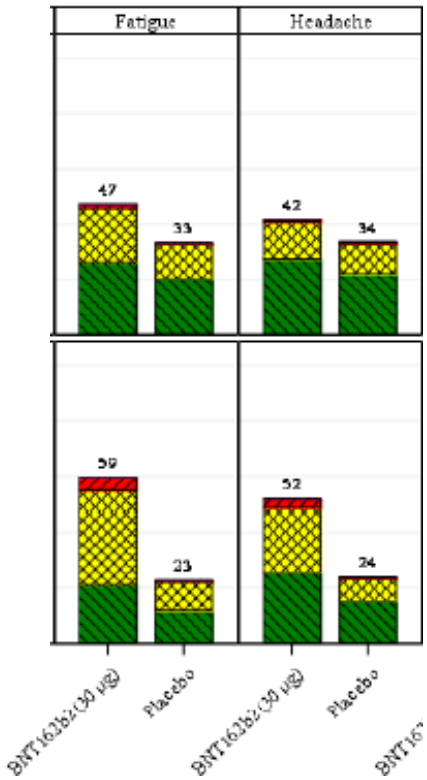
mRNA = messenger ribonucleic acid

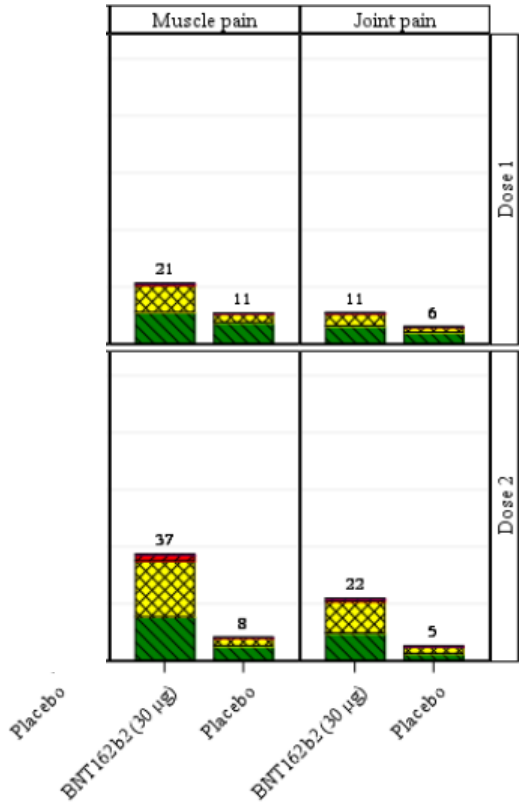
SIDE EFFECTS—PFIZER

- Pain (mild–moderate) at injection site 75–85%
  - <6% swelling or redness
- Systemic events more common second dose and in persons ≤ 55 years old versus > 55 years old
- Median onset calendar day #2–3
- Median duration 1 day
- https://www.fda.gov/media/144246/download

SIDE EFFECTS

- Fatigue and headache are the most common after local site tenderness
- Muscle pain and/or joint pain—higher second dose
- Placebo is saline





FDA. Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years. Accessed on January 14, 2021. Available at https://www.fda.gov/media/144246/download.

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TWO DOSES ARE IMPORTANT

- Pfizer data
- COVID-19 between dose #1 and #2
  - 39 Vaccine (10 severe)
  - 82 Placebo (9 severe)
  - 52.4% efficacy
  - May not protect against severe disease after 1 dose

CONTRAINDICATIONS

- 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 [PEG])
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

HELP DIFFERENTIATE

Symptom	Anxiety	Vasovagal	Allergy
Interval after injection	May start before or any time after vaccination	May start before injection, usually within a few seconds to a few minutes after shot	Generally start within 30 minutes, always within a few hours
Consciousness	May feel faint or lightheaded	May feel faint, lightheaded, can progress to LOC	Anxiety, can progress to lightheadedness and LOC
Respirations	Typically, fast, shallow, hyperventilation	Typically, slow, may have periods apnea	SOB, wheezing, cough, stridor
Pulse	Normal to elevated, regular	Slow and weak, but regular	Rapid, weak, may be irregular
Blood pressure	Normal to elevated	Normal to low	Normal to low
Skin	Can be flushed, diaphoresis	Pale, clammy, diaphoresis	Warm, flushed, can progress to clammy and pale. Itching, hives Swelling face, tongue
Treatment	Reassurance Place patient in recumbent position	Reassurance Place patient in recumbent position Place cool, damp cloth on face	Benadryl or Zyrtec for rash, itching, hives. Epinephrine IM for dyspnea, cough, SOB, swelling of tongue or throat, hypotension or LOC
Subsequent vaccine	Yes, with observation 15–30 minutes	Yes, with observation 15–30 minutes	No. Refer to allergy for evaluation

LOC = loss of consciousness; SOB = short of breath

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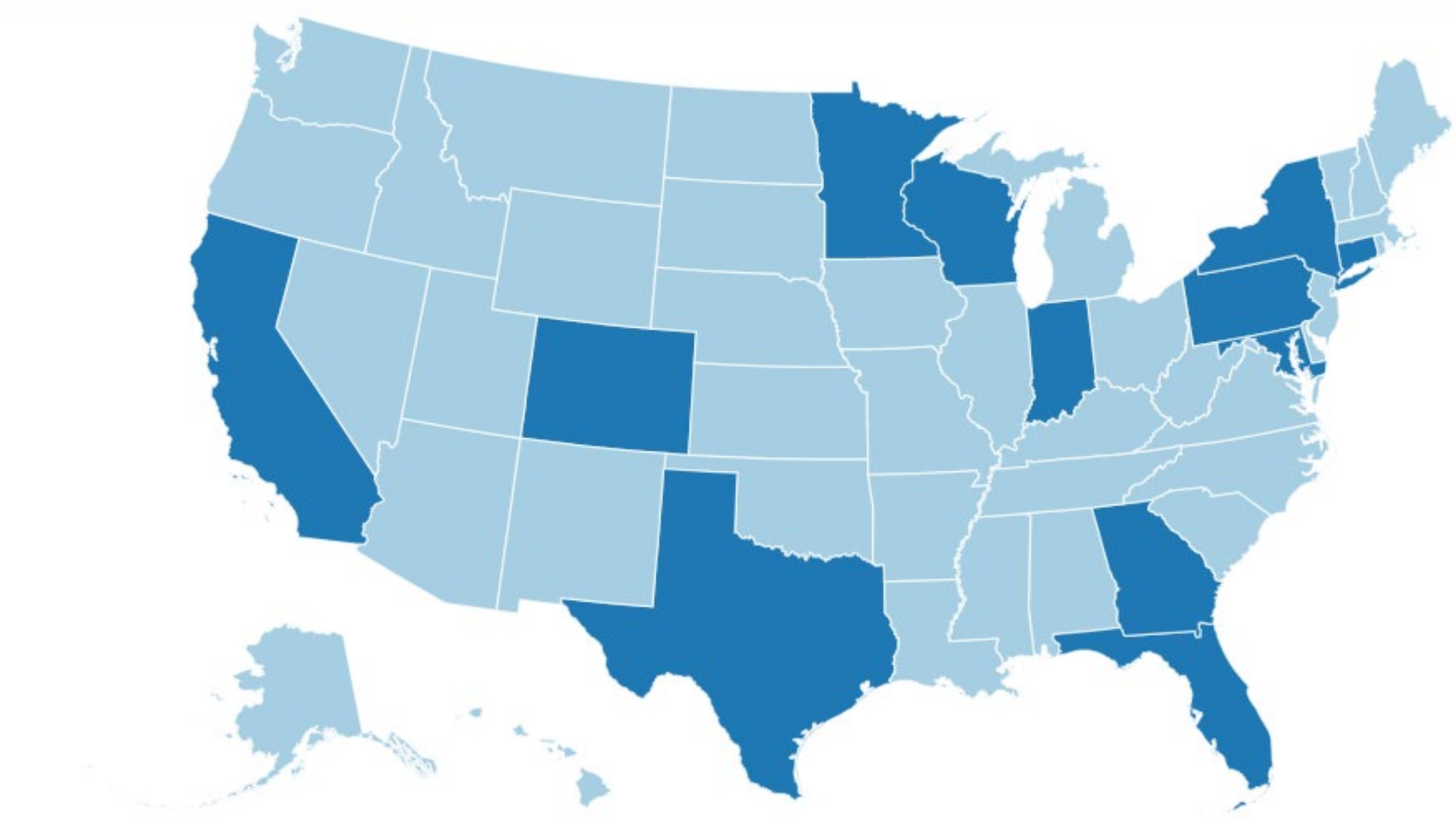
CDC as of 1/13/21. Detected by Random Genomic Sequencing

B.1.1.7 Lineage Cases in the United States*† Total Cases: 76



Source: CDC

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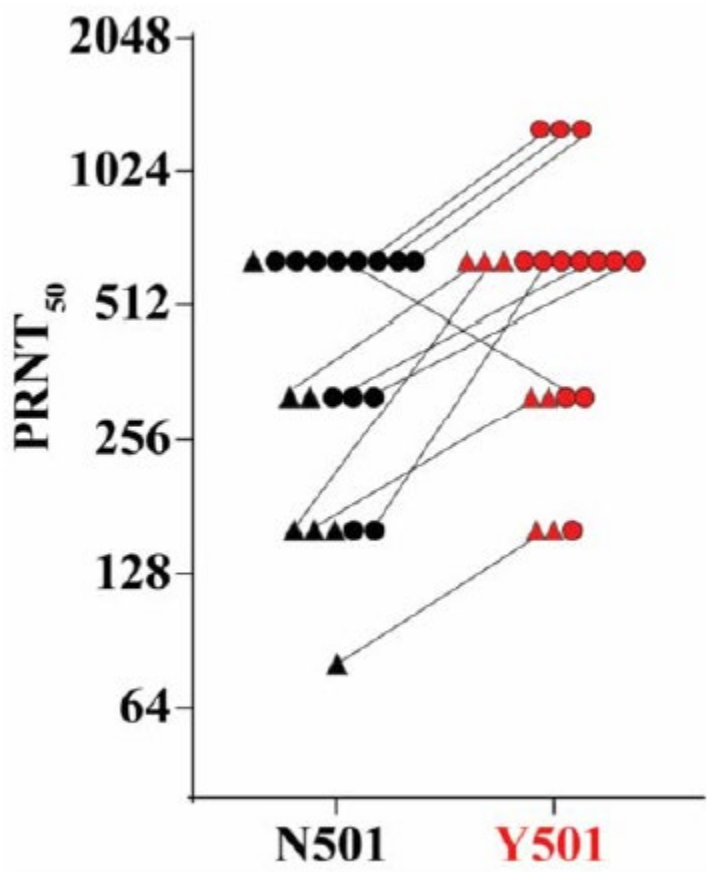
N501Y—Also Called B117

- Investigation of novel SARS-CoV-2 variant: Variant of Concern 202012/01 (publishing.service.gov.uk)
- 30–50% more contagious
- At least 45 countries so far
  - South Africa strain shares this N501Y mutation
- Increases binding to the ACE2 receptor
- Sera from 20 vaccine recipients had equivalent neutralizing tiers to the N501 as the Y501
- 2021.01.07.425740v1.full.pdf (biorxiv.org)

ACE2 = angiotensin-converting enzyme 2

50% Plaque Reduction Neutralization Titers of 20 Vaccine Recipients Against N501 Versus Y501



△ 2 wks post 2nd dose
○ 4 wks post 2nd dose

Source: bioRxiv preprint doi: https://doi.org/10.1101/2021.01.07.425740; this version posted January 7, 2021.

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FREQUENTLY ASKED QUESTIONS

ARE THE MODERNA AND PFIZER VACCINES EQUIVALENT?

- Yes, both products are about 95% effective after two doses
- This is outstanding efficacy for a vaccine
  - Flu vaccine is about 40–60%

WHAT IS THIS VARIANT STRAIN AND WILL THE VACCINE STILL WORK?

- SARS-CoV-19 mutates, more frequently because it is everywhere
- The mutant strain initially identified in the UK is more contagious (30–50%)
- It does not pose more risk of severe disease than the other circulating strains
- Now found in at least 45 countries
- Data shows that the vaccine should still work

OUTSIDE OF WORK, IF EVERYONE HAS RECEIVED 2 DOSES OF THE VACCINE, DO WE STILL NEED TO SOCIALLY DISTANCE AND MASK?

- At this time, widespread vaccination against COVID-19 may not be achieved until mid-2021
- Social distancing and masking practices are still necessary until it is determined we can safely reduce our current guidelines
- <u>To lessen the time that social distancing and masking is necessary, get fully vaccinated as soon as possible</u>

I DEVELOPED COVID-19 AFTER MY FIRST DOSE OF THE VACCINE. WHY DIDN'T IT WORK?

- The COVID-19 vaccine provides almost no protection for the first week after the first dose
- Vaccines may be only 50% protective between the next few weeks before the second dose

IF I HAVE HAD THE VACCINE, CAN I STILL ACQUIRE COVID-19?

- Small numbers of otherwise healthy people can still get COVID-19 as no vaccine is perfect
- We do not have enough data on patients with chronic kidney disease to say whether the vaccine works exactly the same in that population, so your risk of getting COVID-19 might be higher with that disease

CAN I BE VACCINATED IF I HAVE SEVERE REACTIONS TO OTHER THINGS?

- The following groups can still be vaccinated:
  - Individuals with a history of food (e.g. shellfish, peanuts, strawberries), pet, insect, venom, environmental, latex, or other allergies unrelated to vaccines or injectable therapies
  - History of allergy to oral medications
  - Non-serious allergy to vaccines or injectables
  - Family history of anaphylaxis
  - History of anaphylaxis not related to vaccines or injectable therapy
- Patients with a history of these types of allergies should be observed for 30 minutes after vaccination

WHO SHOULD NOT RECEIVE AN mRNA VACCINE?

- 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 [PEG])
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

WHAT ABOUT THE VACCINE AND PREGNANCY, BREAST FEEDING, AND FERTILITY?

- While the data is limited, the vaccines are likely to be safe in all stages of pregnancy and should not affect fertility
- The antibodies developed after vaccinations usually get into breastmilk and are a source of protection for breastfeeding babies.
- CDC and the major women's health medical societies support use of the vaccine in all of these populations.

IF I HAD COVID, HOW LONG DO I WAIT TO GET VACCINATED?

- You should wait to get vaccinated until after the illness has resolved and you are no longer in isolation
  - A minimum of 10 days from onset of symptoms and
  - No fever without taking any medications to reduce the temperature for at least the last 24 hours and
  - Improved symptoms
- If you never had any symptoms, it is a minimum of 10 days from when the first positive test was collected

IF I HAD COVID, HOW LONG DO I WAIT TO GET VACCINATED?

- Immunosuppressed patients (e.g. kidney transplant patients should wait up to 20 days [should discuss with your local expert])
- If you were treated with the antibody medications in your veins, you should wait 90 days after receipt

WHAT I WANT YOU TO TAKE HOME

REMEMBER

- We are now into the next phase of a historical pandemic
- Patients with kidney disease are at increased risk to have severe COVID-19 and be hospitalized, requiring mechanical ventilation or die
- Now is our opportunity to put all of our work into action

UNDERSTAND

- The mRNA vaccines have proven effective
- There is no living virus in the vaccines
- Pregnancy, breast feeding, and fertility should be unaffected by these vaccines
- Short-term symptomatic reactions to the vaccine are frequent but are clearly outweighed by benefit of vaccination

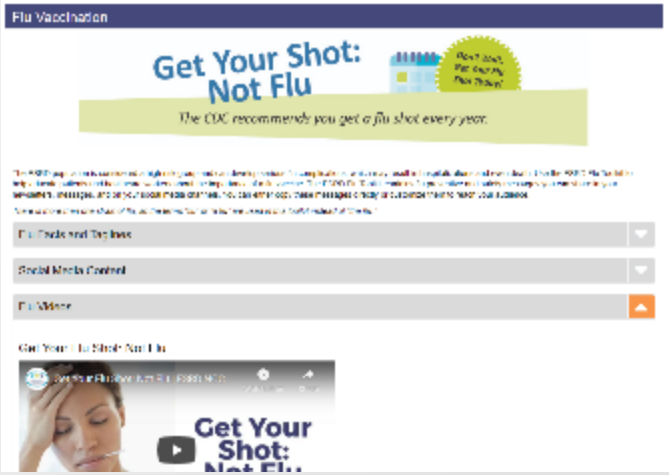
Let Us Hear From You

- Q&As from chat and Q&A panels

Flu Vaccination Toolkit

Influenza toolkit for providers featuring:

- Flu facts and taglines
- Social media content
- Flu videos
- Print-ready materials
- On-demand training and educational events
- Visit esrdncc.org/flu today!



Inspirational Posters

- Evidence-based 12” x 18” posters
- PDF format for on-demand printing
- Focus on psychological/physical health, emergency preparedness, and COVID-19.

To view, visit https://esrdncc.org/professionals/inspirational-posters/.

The Kidney Hub

- The Kidney Hub—Mobile-friendly web tool created with patients, for patients
- Links to new videos and helpful resources added.
- Visit www.TheKidneyHub.org today!

***Home Dialysis**: Choosing Home Dialysis*

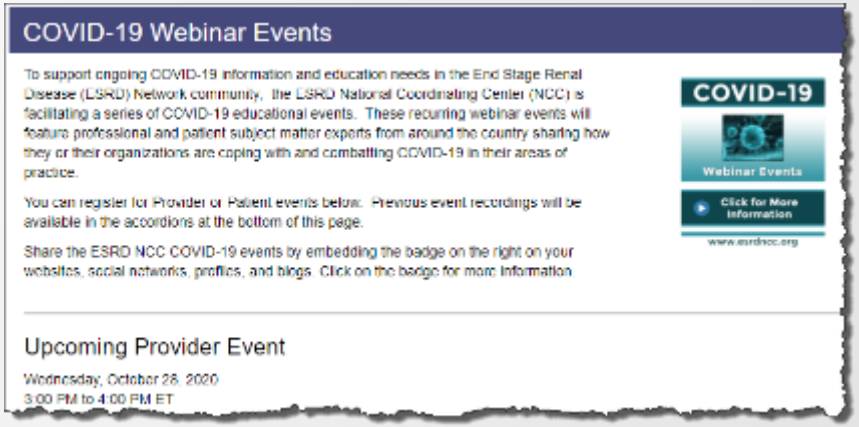
***COVID-19:** Your Guide to Using Telemedicine*

***Transplant**: Turning Negatives Into Positives*

Diet and Nutrition Resources Added!

Our Next COVID-19 Webinar Events

- Patient-focused event: February 2, 2021, 4 p.m. ET
- Provider-focused event: February 10 , 2021, 3 p.m. ET



COVID-19 Webinar Events

To support ongoing COVID-19 information and education needs in the End Stage Renal Disease (ESRD) Network community, the ESRD National Coordinating Center (NCC) is facilitating a series of COVID-19 educational events. These recurring webinar events will feature professional and patient subject matter experts from around the country sharing how they or their organizations are coping with and combatting COVID-19 in their areas of practice.

You can register for Provider or Patient events below. Previous event recordings will be available in the accordions at the bottom of this page.

Share the ESRD NCC COVID-19 events by embedding the badge on the right on your websites, social networks, profiles, and blogs. Click on the badge for more information.

COVID-19

Webinar Events

Click for More Information

www.esrdncc.org

Upcoming Provider Event

Wednesday, October 28, 2020
3:00 PM to 4:00 PM ET

Visit kidneyCOVIDinfocenter.com to register.

Thank You!

NCCinfo@hsag.com
844.472.4250
813.865.3545
www.esrdncc.org

Additional COVID-19 resources for patients and providers:

https://www.kcercoalition.com/en/covid-19/

www.kidneyCOVIDinfocenter.com

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