COVID-19

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

March 30, 2021
Agenda

• What is this call about?
• Today’s speakers
  ▪ Karen L. Pinksy, MD
    – Chief medical officer, Chester County Hospital
  ▪ James A. Curtis, PharmD, MHA, BCPS, BCCCP
    – Director of clinical value optimization, Chester County Hospital
  ▪ Timmy Nelson
    – Volunteer, Chester County Hospital
    – NPFE-LAN Legacy Subject Matter Expert
• Title: Increasing Patient Positive Responses to the COVID-19 Vaccine
• Questions and answers (Q&A) from chat and Q&A panels
New COVID-19 Resource

- COVID-19: A Positive Test or Under Investigation? Being Prepared
- Provides questions to ask your dialysis facility.
- Lists suggestions for maintaining your emotional well-being.
  - Select “For Patients.”
What Is This Call About?

• Hear from experts who share tips for coping in a COVID-19 environment.
• Provide real-world experiences for others to put into use.
• Engage in bi-weekly calls on varying topics.
James Curtis, Pharm.D, MHA, BCPS, BCCCP
Director of clinical value optimization
Chester County Hospital
Increasing Patient Positive Responses to the COVID-19 Vaccine

James Curtis, PharmD, MHA, BCPS, BCCC
Director of clinical value optimization
Chester County Hospital

3/30/2021
Overview

- Vaccine review
  - Efficacy
  - Safety
- Public health impact of vaccination
- What’s next?
  - Duration of immunity
  - Impact of COVID-19 variants
Emergency Use Authorization (EUA)

- Under the EUAs, the following age groups are authorized to receive vaccination:
  - Pfizer-BioNTech: ages ≥16 years
  - Moderna: ages ≥18 years
  - Janssen: ages ≥18 years

- Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.
The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Dose volume</th>
<th>Number doses</th>
<th>Interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>30 µg</td>
<td>0.3 ml</td>
<td>2</td>
<td>3 weeks (21 days)</td>
</tr>
<tr>
<td>Moderna</td>
<td>100 µg</td>
<td>0.5 ml</td>
<td>2</td>
<td>1 month (28 days)</td>
</tr>
<tr>
<td>Janssen</td>
<td>5×10^{10} viral particles</td>
<td>0.5 ml</td>
<td>1</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Interchangeability With Other COVID-19 Vaccine Products

- Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated.
  - ACIP does not state a product preference.

- mRNA COVID-19 vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed-product series have not been evaluated.

- Both doses of the series should be completed with the same product.

mRNA = messenger ribonucleic acid; ACIP = Advisory Committee on Immunization Practices
People With Prior or Current SARS-CoV-2 Infection

- People should be offered vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

- Vaccination of people with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation.

- Reinfection is uncommon in the 90 days after initial infection, and vaccination may be safely deferred for at least 90 days.
People With Immunosuppression

- People with immunocompromising conditions or people who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19.

- The currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.

- Immunocompromised people can receive COVID-19 vaccination. Based on general best practices for vaccination of immunocompromised people, ideally COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the person’s risks related to their underlying condition.
Dialysis

**Patients receiving chronic dialysis**

- Dialysis units are high-risk locations for infection with SARS-CoV-2.

- Seroconversion after confirmed infection approaches 100% in the dialysis population, but the durability of this immune response and the extent to which it translates into protective immunity remains unclear.

- Some studies indicate that SARS-CoV-2 IgG titers decline substantially by 3 months after diagnosis.

Transplant Recipients

- The immunogenicity of SARS-CoV-2 vaccines in patients receiving other common immunosuppressive regimens requires further investigation.

- Among transplant recipients, the seroresponse to a trivalent influenza vaccination was significantly lower in those receiving mycophenolate mofetil.

- This finding might suggest that, in the future, such patients may need modification of vaccination regimens.

Renal Disease

- Based on the available data for inactivated vaccines such as those against influenza, one can reasonably assume that the safety of current SARS-CoV-2 candidate vaccines does not differ between individuals in the various registration studies and the CKD population.

- In the immunocompromised population, the response rates are expected to be lower than in the studies published so far. Potent vaccines, like all currently available in the United States, are important to produce a robust response.

- Dedicated prospective COVID-19 vaccine studies involving patients with advanced stages of kidney disease and kidney transplant recipients are needed and are likely to emerge in the near future.

CKD = chronic kidney disease
# Vaccine Components

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech (mRNA)</th>
<th>Moderna (mRNA)</th>
<th>Janssen (viral vector)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active ingredient</strong></td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein</td>
</tr>
<tr>
<td><strong>Inactive ingredients</strong></td>
<td>2((\text{polyethylene glycol (PEG)}\text{-2000})\text{-N,N-ditetradecylacetamide})</td>
<td>PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
<td>Polysorbate-80</td>
</tr>
<tr>
<td></td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>2-hydroxypropyl-(\beta)-cyclodextrin</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
<td>Citric acid monohydrate</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)azanediy1bis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate</td>
<td>Trisodium citrate dihydrate</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Tromethamine</td>
<td>Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
<td>Sodium hydroxide</td>
</tr>
<tr>
<td></td>
<td>Potassium chloride</td>
<td>Acetic acid</td>
<td>Hydrochloric acid</td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>Sucrose</td>
<td>Water for injection</td>
</tr>
</tbody>
</table>

Source: James Curtis
mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna)

- Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of 2 doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]).

- Approximately 80–89% of vaccinated persons develop at least 1 local symptom and 55–83% develop at least 1 systemic symptom following vaccination.

- Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset. These symptoms are more frequent and severe following the second dose and among younger persons compared to older individuals.


Viral vector COVID-19 vaccine (Johnson & Johnson)

- Preliminary data suggest an overall efficacy of 66.3% (95% CI: 59.9%, 71.8%) against symptomatic, laboratory-confirmed COVID-19 from ≥14 days after vaccination.
- Vaccine efficacy against hospitalization ≥14 days after vaccination was 93.1%.
- Fifty percent of vaccinated people experience at least 1 local symptom, with pain at the injection site most common, and approximately 55% experience at least 1 systemic symptom following vaccination.
- Most systemic post-vaccination symptoms are mild in severity and resolve within 1–2 days after vaccination. Overall, symptoms were more frequent in younger people than older people (ages ≥60 years).

Janssen—Efficacy

- **Prevention of hospitalization at 14 days—93%**
  - 31 COVID-19—associated hospitalizations were documented ≥14 days after vaccination.
    - 29 in the placebo group and 2 in the vaccine group (estimated efficacy = 93.1%; 95% CI = 71.1%–98.4%).

- **Prevention of hospitalization at 28 days—100%**
  - No COVID-19—associated hospitalizations occurred ≥28 days after vaccination in the vaccine group.
    - 16 occurred in the placebo group (vaccine efficacy = 100%; 95% CI = 74.3%–100.0%).

- **Prevention against symptomatic, laboratory confirmed COVID-19—66%**
  - 66.3% (95% confidence interval [CI] = 59.9%–71.8%) ≥14 days after vaccination.
  - 65.5% (95% CI = 57.2%–72.4%) ≥28 days after vaccination.
For some, the origin of cells is a religious or moral issue.

Adenovirus vaccines (like AstraZeneca or Janssen) have 3 components:
- Instructions—“Make the COVID19 spike protein.”
- A carrier—The carrier is another weakened virus called an “adenovirus.”
- A pathway—Paths for that vaccine to replicate in the body.

Creating the vaccine
- Modify the adenovirus by removing genes from the adenovirus so it can’t replicate in our body.
- Replace that deleted spot with a SARS-CoV-2 gene for the “spike protein.”
- Cells in the lab support the other deleted genes.
  - These cells originated from fetal stem cells in the 1980s.
Janssen—Concerns for Clotting?

- Numerical imbalances (not statistically significant) with more events in vaccine than placebo recipients were observed for the following serious adverse events in individuals receiving the vaccine or placebo, respectively:

  - **Deep vein thrombosis**
    - 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events (1 serious; 2 within 28 days of vaccination)

  - **Pulmonary embolism**
    - 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event (serious and within 28 days of vaccination)

  - **Transverse sinus thrombosis**
    - 1 event (serious and within 28 days of vaccination) vs. 0
AstraZeneca (AZ)—Up Next?

- 3/22—AZ releases preliminary trial data
  - 79% vaccine efficacy at preventing symptomatic COVID-19
  - 100% efficacy against severe or critical disease and hospitalization
  - Comparable efficacy result across ethnicity and age, with 80% efficacy in participants ages 65 years and over
  - Favorable reactogenicity and overall safety profile
  - AZ found no clotting events among 21,583 participants who received at least 1 dose of the vaccine in the United States.

- 3/23—National Institute of Allergy and Infectious Diseases (NIAID) Statement on AZ Vaccine:
  “Late Monday, the Data and Safety Monitoring Board (DSMB) notified NIAID, BARDA, and AstraZeneca that it was concerned by information released by AstraZeneca on initial data from its COVID-19 vaccine clinical trial. The DSMB expressed concern that AstraZeneca may have included outdated information from that trial, which may have provided an incomplete view of the efficacy data. We urge the company to work with the DSMB to review the efficacy data and ensure the most accurate, up-to-date efficacy data be made public as quickly as possible.”
Public Health Recommendations for Vaccinated Persons

For the purposes of this guidance, people are considered fully vaccinated for COVID-19 ≥2 weeks after they have received the second dose in a 2-dose series (Pfizer-BioNTech or Moderna), or ≥2 weeks after they have received a single-dose vaccine (Johnson and Johnson [J&J]/Janssen).

Fully vaccinated people can:

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing.
- Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing.
- Refrain from quarantine and testing following a known exposure if asymptomatic.
Public Health Recommendations for Vaccinated Persons

▶ For now, fully vaccinated people should continue to:
  • Take precautions in public, like wearing a well-fitted mask and physical distancing.
  • Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with unvaccinated people who are at increased risk for severe COVID-19 disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease.
  • Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households.
  • Avoid medium- and large-sized in-person gatherings.
  • Get tested if experiencing COVID-19 symptoms.
  • Follow guidance issued by individual employers.
  • Follow CDC and health department travel requirements and recommendations.
Source: CDC. 
Transmission of COVID-19 Post-Vaccination

- Early data suggest that the available vaccines are effective at reduction of asymptomatic disease.
  - Several sub-studies and press releases confirm a 50–95% reduced transmission after vaccination.

- Small sample sizes and variability in location/demographics make it difficult to draw too many conclusions.
Variants

- Viral mutations are expected.

- Key concerns stemming from the emergence of the new variants are impacts to:
  - Viral transmissibility.
  - Severity of disease.
  - Reinfection rates.
  - Vaccine effectiveness.
Variants

- B.1.1.7 (UK variant):
  - Estimated to be up to 82% more transmissible than previous variants.
    - People infected have considerably higher viral loads, which could explain the higher transmissibility.
  - Associated with a higher risk of death in the United Kingdom.
  - Modest decrease in neutralizing activity from previous native infection.
  - Modest decrease in neutralizing activity from vaccination.

- B.1.351 (South African variant):
  - Estimated to be up to 50% more transmissible than previous variants.
    - People infected have considerably higher viral loads, which could explain the higher transmissibility.
  - Associated with a 20% higher in-hospital mortality rate.
  - Complete escape from neutralizing activity in 50% previous native infections.
  - Significant decreases in neutralizing activity from vaccination.
Table: Summary Results on SARS-CoV-2 Vaccine Trails Efficacy and Viral Neutralization of the B.1.1.7, P.1, and 501Y.V2 variants, as Compared with Preexisting Variants.
Taken from N Engl J Med; New SARS-CoV-2 Variants — Clinical, Public Health, and Vaccine Implications, Published online 3/24/2021
Emerging Variants in the United States

- B.1.526—New York City ~20% of cases, most similar to B.1.351—reduction in response to neutralizing antibodies, plus increased rates of hospitalization.

- B.1.427/B.1.429/L452R—California variant, about 20% of all U.S. cases, more infectious, 4x times more likely to be admitted to ICU in some early studies.
Timmy Nelson
Chester County Hospital Volunteer
NPFE-LAN Legacy SME
Let Us Hear From You

• Q&As from chat and Q&A panels
What Kidney Patients Need to Know About the COVID-19 Vaccine

The CDC recommends:
- Get vaccinated to help prevent you and others from getting sick with COVID-19.
- People who have had COVID-19 should get vaccinated.
- Select Toolkits.

Some important things to know about the vaccine:
- COVID-19 vaccines DO NOT cause COVID-19 infection. None of the COVID-19 vaccines currently in development, or in use in the United States, contain the live virus that causes COVID-19.
- The COVID-19 vaccine can cause some side effects including redness, pain, muscle pain, fever. These symptoms are normal and are a sign that the body is building up its defenses against infection.
- Stay at least 6 feet away from others when you first get vaccinated.
- After getting a vaccine, continue to practice precautions.
Quality Assessment & Performance Meetings (QAPI)

• A tool to help you prepare for QAPI Meetings
• Learn what to expect and how to prepare:
  ▪ Before the meeting.
  ▪ During the meeting.
  ▪ After the meeting.
• Visit www.esrdncc.org/patients.
  ▪ Select “For New Dialysis Patients.”
  ▪ QAPI Meeting Resource.

Source: ESRD NCC
Where to Find Credible Information

Where to Find Credible Information About the Coronavirus 2019 (COVID-19)

During this pandemic, it’s especially important for everyone to take actions to keep themselves and others safe. To do this, let’s pause and think through how and where you can find credible, or trustworthy, information—especially as someone with kidney disease.

In stressful times, you may often turn to family and friends for support. Family and friends are great:

- Provide or receive emotional support.
- Connect with by phone call, video chat, or social media.

But your family and friends might not have the most up-to-date information on COVID-19, the best actions to take right now especially if you are on dialysis or have a kidney transplant. For this kind of information, you should turn to experts for credible information.

So, where can you find credible COVID-19 information? Start with these sites.

- Click on “For Patients.”

Credible Websites

Tips to identify credible websites on most mobile phone browsers

Source: ESRD NCC
The Kidney Hub

• The Kidney Hub—Mobile-friendly web tool created by patients, for patients.
• Links to new videos and helpful resources are now added.
  ▪ Newly added diet and nutrition section
• Let us know what you think.
  ▪ Email us at NCCinfo@hsag.com.
• Visit www.TheKidneyHub.org today!

Source: ESRD NCC
Our Next COVID-19 Webinar Events

• Save the dates for our next events.
  ▪ Provider-focused events:
    April 7 at 3 p.m. ET
  ▪ Patient-focused event:
    April 13 at 4 p.m. ET

Visit www.kidneyCOVIDinfocenter.com for information and to register.

Source: ESRD NCC
Thank You!

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

Additional COVID-19 resources for patients and providers:

www.thekidneyhub.org/covid19/
www.kidneyCOVIDinfocenter.com

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