



FORUM OF ESRD NETWORKS

CMS / EDAC / FORUM LEADERSHIP CALLS

JUNE 2021 – OCTOBER 2021

The Executive Committee of the National Forum of ESRD networks has had a long-standing tradition of meeting with the leadership of the CMS Division of Kidney Health (DKH) to discuss a variety of topics related to the ESRD Program and activities led by the ESRD Networks. At the onset of the COVID-19 pandemic in the Spring of 2020, CMS/DKH invited Forum and Network leadership to begin meeting more frequently to discuss the concerns being seen in the kidney community and identify ways in which to work together to care for and keep kidney patients safe during the pandemic. The Forum and ESRD Networks are grateful for this ongoing commitment by CMS and the opportunity to work together as the COVID-19 pandemic continues to impact kidney patients and care providers.

Below are notes from calls convened in the Summer and Fall of 2021. Attendees of these calls include members of the Forum's Executive Committee, Executive Directors from the ESRD Networks, and CMS DKH leadership including Shalon Quinn, Director; Melissa Dorsey, Deputy Director; Todd Johnson, Regional Program Manager; Paul McGann, Chief Medical Officer; CMS Regional Office Staff and Contracting Officers.

CMS / EDAC / Forum Leadership Call: June 7, 2021

Weekly Net Change of COVID Positive Dialysis Patients & Vaccination Trends in the ESRD Population & Dialysis Staff

Mr. Brown reported weekly net change in national total covid positive patients since March 10 shows sustained suppressed numbers and in the last 2 weeks an increasing drop in cases. In the last week, there were only 213 kidney patients diagnosed with COVID 19 nationally. No state has hit a weekly high number since January 20, 2021. (Data source: weekly KCER ESSR reports)

Mr. Brown shared the Network 3 and 4 vaccination data as a representative national sample.

- The dialysis patient vaccination rate for Network 3 is currently 80% vaccinated, 9% declining and 11% unknown. Staff rate is correct (71%).
- The vaccination rate for Network 4 is 74% vaccinated, 14% declining, and 12% unknown. Staff rate is 59% vaccinated.
- The dialysis staff percent vaccinated compared to general population varies by state and Network. The staff declination is not known.

Kidney Patient Observations / Concerns

Dr. Atkinson shared that KPAC patients have recently discussed their concerns regarding the resistance to receive the vaccine, especially healthcare workers (25-30%). They have also expressed concerns with some staff relaxing on the use of masks and PPE. He encouraged the community, Networks and CMS to continue to encourage the messaging of safe environments and proper PPE use for the sake of our patients.

Transplant Metrics

Dr. Howard presented UNOS Transplant Data through 6/4/21 (data represents adults only). Total adult kidney transplants are well ahead of 2019 and 2020, still accounted for by DD transplants. LD transplants have improved in 2021, however still remain around 400 < in 2019, although well ahead of 2020. New weekly additions to the waitlist have completely rebounded. Holds related to COVID persist at approximately 0.7% of

the waitlist and still concerning is that the percent active on the waitlist remains approximately 5% < than in 2020, ie. more non COVID medical or non-medical holds.

CMS / EDAC / Forum Leadership Call: August 9, 2021

The questions sent to CMS leadership prior to the call were reviewed and Dr. Quinn provided the following responses.

Q: Does CMS have any information on the possibility of Federal Contractors being included if a vaccine mandate is required for Federal employees?

A: The Contracting Office was contacted about this question and at this time, there is no further guidance for Networks. Dr. Quinn is waiting for additional information and will provide an update when available.

Q: Can CMS check in with CDC on if there is any guidance that is forthcoming on booster vaccines for ESRD and immunocompromised individuals as is being mentioned in the media? If so, is there an expected timeline for release or date by which those decisions will be made?

A: CMS has been corresponding with CDC about boosters. The ACIP will be hosting a webinar on August 13th where we expect to receive additional information. <https://www.cdc.gov/vaccines/acip/index.html>

Q: NHSN is now tracking breakthrough infections in our ESRD population, will CMS be reviewing this data to provide recommendations for booster shots?

A: Yes, it was CMS' intent to use this data to monitor breakthrough cases. Both CMS and CDC are watching this closely.

Weekly Net Change of COVID Positive Dialysis Patients & Vaccination Trends in the ESRD Population & Dialysis Staff

Mr. Brown provided an overview of vaccination rates in the ESRD community, below are some highlights.

- As of 07/27/2021, 66.7% of dialysis patients are fully vaccinated. Rates by state range from 83.9% to 57.7% fully vaccinated.
- Comparing vaccination rates by state in the dialysis population versus the total population, all states (except Guam) have higher vaccination rates among the dialysis population versus the general population.
- Staff vaccination rates are less than patient vaccination rates in all Networks, ranging from 9.1% to 18.7% difference by Network.
- Weekly net change in COVID positive patients is increasing again since late June, with this week's rate the highest since March 4. Four states account for the most significant increases (FL, TX, CA, LA). However, correlating the vaccination rates and COVID positive patients by state, only 3 of these 4 states fall below the national average.

Kidney Patient Observations

Kidney patients continue to be concerned with the rising infection rates and have questions about when boosters will be available for transplant patients. Dialysis patients are also expressing concern about the Delta variant and whether a booster would provide additional protection for them. Mr. Forfang shared the KPAC is considering the drafting of a letter or flyer to send to providers sharing patient concerns about the low vaccination rate for staff and protecting their patients from the virus. He also inquired about whether CDC is tracking the type of vaccination patients are receiving and whether those patients who received the J&J vaccine will be a higher priority for the booster knowing the original efficacy rates was slightly lower.

Ms. Edwards shared concerns from patients about the CMS initiatives to move more patients to home therapies (50% by 2025) and the lack of support available. It was noted that patients with Medicare, versus

Medicaid, have more barriers to receiving the in-home support they need to be success home dialysis patients. This is an equity of care issue and a barrier for many Medicare patients.

Transplant Metrics

Referencing UNOS data as of 08/08/2021, Dr. Howard provided an overview of adult kidney transplant data trends. Total transplants have rebounded from 2020 to pre COVID (2019) levels driven by DD transplants. LD transplants continue to lag behind 2019 although are ahead of 2020. Additions to the waitlist have rebounded from 2020 although there is significant heterogeneity among UNOS regions.

Network Observations

During the 08/06/2021 KCER call with Networks, several Networks reported receiving notifications from facilities that they are closing permanently due to staff shortage. It was also noted that some facilities are eliminating shifts due to staff shortages. There are concerns this may become a trend and an access to care issue in the future. This may also have an impact on whether providers will be able to cohort COVID+ patients if COVID positivity rates continue to increase.

Dr. Quinn inquired about whether this has become an access to care issue, especially in rural areas.

Ms. Vinson shared that the current closures didn't seem to be impacting access to care presently. However, several Networks have reported hearing dialysis staff being drawn away from the dialysis facilities by local hospitals who are offering higher salaries and bonuses to fill vacancies and some LDOs offering increased salaries to rural facilities to help mitigate this issue.

Ms. Edwards shared that from a patient perspective, a facility closure can be quite traumatic for patients, forcing them to find a new facility and establish new relationships with staff and care providers.

CMS / EDAC / Forum Leadership Call: August 30, 2021

Questions sent to CDC (via CMS) from the ESRD Networks & Forum Leadership

1. Will the CDC issue recommendations on which group should receive COVID boosters next after immunocompromised patients? Healthcare workers and Nursing Home Residents were amongst 1st group to receive initial vaccines in December-January, and preliminary information suggests individuals should receive booster 8 months after completed series, which may mean September for these groups.

At the recent ACIP meeting (on 8/31/21), the latest data around boosters and possible recommendations were discussed and focused on the highest risk individuals and internal since receipt of last dose. ACIP will meet again later in September to review the latest data on safety and immunogenicity of booster doses, and thoroughly evaluate effectiveness, breakthrough infections and epidemiology data. After FDA regulatory action on booster doses, ACIP will meet to make recommendations on the use of a booster dose after thoroughly reviewing the evidence.

2. Would CDC consider specifically adding dialysis patients as immunocompromised patients in whom COVID boosters are now recommended?

The succinct summary is that dialysis in and of itself is not thought to be moderately-severely immunocompromising. However, some patients may be deemed by their providers as being moderately-severely immunocompromised due to other comorbidities or conditions. As such, a blanket recommendation that all dialysis patients should receive a 3rd/additional dose was not made; however,

providers can evaluate patients and make their own determinations on whether a third/additional dose is needed taking into account the patient's entire clinical picture.

- At this point a third additional dose meant to supplement a primary vaccine series is not being recommended for all people because the clinical benefit is not known
- Dialysis patients as all-comers are not a listed category on moderate-severe immunocompromised
- Data from several studies suggest that many dialysis patients mount a fairly robust immune response after receiving a 2-dose primary mRNA COVID-19 vaccine series
- With few exceptions, administration of other vaccines in this patient population follows the standard vaccination schedule
- Some dialysis patients may have characteristics that place them in a category of moderate-severe immunocompromised
- The patient's clinical team is best positioned to assess the degree of altered immunocompetence in an individual patient

There is an FAQ posted here [COVID-19 Vaccine Indications for Patients Who Are Immunocompromised | CDC](#) that can also be shared with providers and facilities.

My practice serves many dialysis patients. Should dialysis patients receive an additional mRNA COVID-19 vaccine dose to supplement a 2-dose primary mRNA COVID-19 vaccine series?

CDC recommends an additional mRNA vaccine dose for dialysis patients who are moderately to severely immunocompromised (from a medical condition, medication, or treatments). Treatment with hemodialysis, on its own, may not result in moderate to severe immune compromise. [Data from several studies](#) suggest that the vast majority of dialysis patients develop an immune response after receiving a 2-dose primary mRNA COVID-19 vaccine series. An additional dose is not recommended for immunocompetent dialysis patients.

Some dialysis patients have health conditions or take medications that may result in moderate to severe immune compromise. For example, a dialysis patient awaiting organ transplantation or who is post-organ transplant may be immunocompromised. The patient's clinical team can assess the degree of altered immunocompetence and whether the patient should receive an additional dose of mRNA COVID-19 vaccine.

See [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#) for more information.

3. For patient safety, should dialysis facilities mandate vaccinations for healthcare workers with direct contact to ESRD patients?

An organization must consider many factors when deciding whether it will mandate vaccine for healthcare personnel including state and other applicable laws. CDC continues to emphasize it is critical to ensure everyone eligible receives the primary COVID vaccine series. CDC has many resources available to help improve vaccine hesitancy and is available to provide assistance to organizations and health departments looking to increase vaccine uptake.

4. Is data being gathered by CMS or CDC to correlate breakthrough infections with hospitalizations and outcomes in ESRD Patients? Are dialysis or transplant patients experiencing more severe breakthrough infections leading to hospitalization?

The Dialysis Safety Team in the Division of Healthcare Quality Promotion at CDC is currently collecting breakthrough case reports from dialysis organizations. We are in the process of summarizing the data. This project doesn't specifically focus on transplant patients. However data collection from other sources has shown that immunosuppressed individuals, which would include transplant patients, make up a large percentage of patients hospitalized with breakthrough infections.

5. Have any of the large dialysis organizations talked with CMS or CDC about offering boosters in their clinics for their patients? Or will patients be expected to get boosters in their communities?

Since March, CDC has supported the Dialysis Partners COVID-19 Vaccination Effort <https://www.cdc.gov/vaccines/covid-19/planning/dialysis-partners-jurisdictions.html>.

Fresenius and DaVita are enrolled as federal vaccine providers and can order vaccine to administer in their clinics. They also support other dialysis organizations ordering vaccine through the network administrator program. Administration of an additional dose of COVID-19 vaccine that falls under EUA and ACIP interim recommendation is permitted within the Dialysis Partners COVID-19 Vaccination Effort, including for vaccine providers within the Network arrangement. The vaccine ordered by dialysis providers through this program can be administered onsite in their clinics.

Weekly Net Change of COVID Positive Dialysis Patients & Vaccination Trends in the ESRD Population & Dialysis Staff

Referencing data available to Networks through EQRS and the Dashboard, Mr. Brown provided an update on the COVID positivity and vaccination rates in the ESRD population. Below are some of the highlights:

- The national average of ESRD patients fully vaccinated is 68.7%. States vary from 87.0% to 57.9%.
- Dialysis rates of vaccination, compared to the general adult population by state: on average, vaccination rates in the dialysis population are 7.9 percentage points higher than that of the adult state population, with a state range of 2.8 – 27.2 points. There are 5 exceptions where the state rate is higher than the dialysis population (NY, GU, WA, NM, AK).
- On average, the patient vaccination rate is 13.8 percentage points higher than the staff rate in each Network, with a range of 7.1 – 19.6.
- The dialysis staff vaccination rate in each state compared to the state rates: 39 states show the dialysis healthcare personal vaccination rate is lower than the overall state rate.
- The weekly net change in the national total number of COVID+ dialysis patients is the highest since February 17, 2020, with 1667 new positive cases the week of August 24, 2021.
- Of the top 10 states with the highest 4-week moving average of new COVID+ cases, 8 of those 10 also had lower than national-average vaccination rates. The 2 exceptions were IL and NJ.

Q, Quinn: Have the Networks seen an increase in vaccination rates since the FDA approval of the Pfizer vaccine? Have Networks changed their messaging in light of the FDA approval?

A, Brown: Yes, Networks have adjusted the messaging and have seen some uptick in the partially vaccinated rate in the last couple weeks.

Q, Edwards: Within the patient populations, are we able to see the number of patients getting COVID who have already been vaccinated? Are breakthrough rates available?

A, Brown: Each Network can see their own data. NHSN does track partially/fully vaccinated along with the positivity data. We hope this data will be available soon on the national dashboard and when that happens, we can share the data. Agree, this is important information.

Q, Kalantar: This data highly educational and, especially the last 2 slides, so convincing why we need to increase vaccination, is there a way to carefully bring this to a peer review report?

Brown: The vaccination rates by state are now on the CDC website.

Molony: Even with the data on the CDC website, very few people go there to review the data. It would be nice to have the data available easily for healthcare providers and quickly accessible.

Brown: More data will be available soon, including the number of boosters given to patients.

Molony: Will we be able to trend the booster data by modality (dialysis vs transplant) and by age?

Observations from the ESRD Networks

During the EDAC's month call in August, Networks shared concerns regarding the increase in infection rates and how this is impacting the QI projects. While continuing to provide COVID TA, attention is pulled away from the QI projects, below are some of the Network observations.

Ms. Albin shared observations from Networks 8 and 14:

- Facilities are reporting they don't have enough staff to take care of patients. Facilities reaching out to tell us that they are reducing shifts and going to 3-days from 6-days because they don't have enough staff. Nurse managers who typically have 4-5 facilities to oversee are now working the floor at multiple shifts because of the staff shortage.
- Texas has very strict regulations regarding staff and while they have waivers under the emergency order, it has made it increasingly difficult for workers and many have quit or taken early retirement because of the stress and burden.
- LDO facilities were working to provide specific data regarding these staffing issues, but due to the hurricane they were unable to meet today's deadline. We hope to have data soon to share.

Ms. Quinn reported that CMS is tracking facility closures and staying in contact with the survey divisions.

Ms. Albin shared that CMS may not see the full impact of closures in EQRS because facilities are only closing temporarily until they can recruit staff to open again. Networks 8 and 14 are tracking this information.

Dr. Molony shared he is seeing this in the Houston area, closing shifts and moving patient to different facilities. Also seeing challenges placing patients in facilities who are being discharged from the hospital. We expect the burden to increase with the addition of patients leaving LA after the hurricane.

Dr. Kalantar shared an idea on developing guidance for facilities about how to care for patients during COVID surges, sharing best practices and successful actions that Networks have seen in their regions.

Ms. Rose shared observations from Network 7:

- Similar challenges being seen in Florida. Biggest issue today is patients not having a COVID unit to be discharged to.
- Recently received notification from very large healthcare systems that they are sending patients into the community and telling them to come back to the ER for dialysis.
- One nursing home is transporting patients back and forth to the ER for dialysis treatments because the local facilities don't have capacity or space in the cohort clinic.
- Staffing shortages are being seen in the cohort clinics. DaVita has stepped up to open cohort facilities in the Tampa Bay and Jacksonville areas to help with these hard-hit areas.
- It's challenging to get facilities to focus on QI activities when they are dealing with these issues. A Feel like Networks need to support facilities and work within their bounds of staffing to get any other work done.

Dr. Quinn thanked members for sharing their observations. CMS has fielded some questions recently about hospital discharges and shared information about the ESRD Networks to help with placement. The staffing issues are new, and CMS would appreciate additional conversations and information about what Networks are seeing.

Ms. Cash reported seeing similar trends in Network 9, noting the impact of this surge is affecting facilities different than in 2020. People are not there to do the work in the facilities, managers are on the floor, and we don't have cohort facilities and the staff to stretch to cohort shifts.

Ms. Vinson shared that Networks are working to quantify the impact of these challenges to provide more detail to CMS on the next Office Hours call. Networks are not seeing permanent closures, rather shift changes and staffing shortages.

Dr. Quinn thanked members and Networks for the work they are doing. She inquired about what the root-causes might be and how to address those issues.

Dr. Molony shared that he is seeing staff burnout, working hard non-stop without breaks, and competing options for employment (less stress and higher salaries).

Ms. Albin shared that senior staff who are close to retirement have decided to just get out, they have been overburdened for 18+ months.

Dr. Henner shared that dialysis staff are skilled staff, it takes time to train them to take care of patients, they can't be replaced overnight.

Huff: Are there observations regarding the impact to patient, in particular, missed treatments or shorter time on treatment?

Edwards: Transferring to a new facility puts an enormous amount of pressure on patients, many patients already suffer from depression, and this adds to that anxiety. Patients will have concerns about new staff treating them and are they vaccinated, added distance from home and maybe new transportation, adjusting childcare or work schedules to accommodate a new treatment schedule or travel time, or adjusting other health appointments around the new facility schedule. New variables to a routine can cause a feeling of vulnerability and lack of security.

Molony: CMS could possibly influence the transportation issue by making it more flexible and allow for more rapid changes.

Observations from Forum Physician Leaders & KPAC Members

Dr. Kalantar: Seeing some improvement in trends, appears the surge may be plateauing in recent days.

Dr. Wagner: Good discussion today. NY is doing OK for now regarding ESRD management but the recent COVID vaccination mandate for healthcare staff may impact this.

Dr. Molony: Patients continue to ask about when they are going to get their booster, we need more information about this and need to get it into the dialysis facility to help reduce anxiety.

Mr. Forfang: When will facilities mandate the vaccine? Kidney patients shouldn't feel safer talking to the airline pilot or the mouse as Disney World than being treated in the dialysis facility. We deserve to be safe. Members considered a suggestion that the Forum (KPAC/MAC) develop a carefully worded memo or poster encouraging healthcare providers to get the vaccine to help keep patients safe.

Mr. Forfang: We need to support the patients who don't have a choice about going to the dialysis facility.

Ms. Edwards: KPAC members talked about this recently in relation to hepatitis and how patients are treated under those circumstances. Patients are demanding that more care is taken in this area.

Dr. Molony: The Forum MAC (Medical Advisory Council) would endorse this in support of patients.

Dr. Quin supported this initiative but cautioned members to be careful not to imply any CMS or CDC endorsement in the absence of a formal CMS or CDC policy regarding vaccination mandates.

Transplant Metrics Update

Referencing UNOS data as of 8/29/2021, Dr. Howard provided an overview of transplant data trends. Total kidney transplants continue well ahead of 2019 (pre-COVID) and 2020. The past few weeks have demonstrated a significant decline in the volume of both DD and LD transplants, not surprising given the strain on hospital capacity in so many parts of the country. This is the first time in 2021 that a significant reduction in weekly

additions to the kidney transplant waitlist have been seen. Dr. Howard recognized CMS for making adjustments to the QIP in 2020 due to the PHE and asked that consideration be given in 2021 considering the impact being seen in recent weeks.

Dr. Quinn reported the TAQIL contract has been awarded to HSAG and the work is kicking off this week.

Huff: Regarding waitlist related to vaccination, is anyone making vaccination an issue for staying on waitlist, does it impact donation?

Howard: Unsure at this time.

Molony: I am aware of transplant programs who are not transplanting without a vaccination.

Edwards: Personally, working on getting waitlisted and my transplant center suggested I come in for a booster.

Vinson: Network 5 has been working with transplant centers, asking them to draft a letter that could be given to dialysis providers who had patients waitlisted, encouraging them to get vaccinated.

CMS / EDAC / Forum Leadership Call: September 27, 2021

Questions for CDC from the ESRD Networks & Forum Leadership

Priti Patel, MD, MPH, Medical Officer, CDC and Ana Cecilia Bardossy, MD, CDC were invited guest attendees of this call. Dr. Patel provided an overview of the new recommendations for boosters, restating these recommendations are different than those for the 3rd/additional vaccine for people with severe immunocompromised conditions.

Discussion and Q&A:

Patel: Information presented today was for the Pfizer vaccine. CDC expects to have more information about recommendations for the Moderna and J&J vaccine in a few weeks.

Q: For kidney transplant patients who received both dosages while on immunosuppression meds, do they need to wait 6 months, or can they get the 3rd dose earlier?

A: If the patient is immunocompromised, they should get the 3rd vaccine 28 days after the 2nd dose, rather than waiting for the booster. The 3rd vaccine should be the same type as the initial dose.

Q: We are seeing in NHSN data that about 1500 dialysis patients in our Networks have received the 3rd dose. Will CDC track the difference between the booster and the 3rd dose in NHSN?

ACTION: CDC will need to review this with the NHSN team and report back to the group.

A: As a kidney patient working through the steps to get on the transplant waitlist, I received a letter from my transplant center recommending I get the booster. Is this a recommendation for all waitlisted patients?

A: If the patient received the Pfizer vaccine and it's been 6 months since the 2nd dose and they meet the criteria, they should get the booster.

Q: Regarding the mandate for healthcare workers to be vaccinated, is this for the initial doses or are boosters necessary to be considered 'complete'?

A: We are just focusing on the primary vaccination series and not the booster dose as part of that mandate.

Comment: From the Network perspective, the recent Network Contract Mod requires 80% of staff receive the booster which does not align with the above recommendation.

ACTION: Dr. Quinn will seek clarification from the CMS team and send out some guidance to the Networks.

Follow-up to the CDC Q&As from the August 30, 2021 call:

Adding dialysis patients to the list of immunocompromised people:

Patel: We were pleased to see that dialysis patients and people with CKD were included in booster recommendations. The recommendation for the 3rd dose was to ensure people with compromised immunity (i.e. transplant patients) were responding to the initial doses as expected. The booster is intended to address the waning immunity from the initial doses. Based on data we're seeing; dialysis and CKD patients seem to be responding well to the initial dose. While we appreciate the boosters are important, we still have work to do to get the initial dose to everyone.

Is data being gathered by CMS or CDC to correlate break through cases with hospitalization for dialysis/CKD patients?

Bardossy: The CDC is collecting breakthrough data on dialysis patients (not transplant patients) and is in the process of analyzing and summarizing the data.

Q: Is there any guidance from CDC regarding the use of titration to determine whether a booster is needed? Does CDC have recommendations for the use of monoclonal antibodies for dialysis and kidney transplant patients?

Patel: Many studies have been published regarding the antibody titers post vaccination, all of them acknowledged we don't know what the correlate is. While its useful information for scientific exploration, our recommendations are not based on post-vaccination titer data.

ACTION: We will gather more information about the use of monoclonal antibodies for CKD/ESRD patients and follow-up.

Is CMS/CDC communicating with LDOs about offering boosters in the dialysis setting?

Patel: The CDC is in communication with DaVita and FMC leaders, and they are planning to provide booster doses to patients in their facilities. We are working with them to understand how many other facilities (non-LDO) are in their Networks and what their needs are for booster doses.

Q: Has a timeline been discussed with LDOs?

Patel: CDC requested data by the end of the week; the number of doses needed to give boosters to patients in their facilities and the non-LDO facilities in their service Networks. We'll make sure there's sufficient doses and try to meet the 6-month timeline, we are planning for October.

Q: Do you know how many facilities are in their service Network? If this information could be shared with the ESRD Networks, it would help us with our technical assistance, help us to focus on the gaps, and connect those facilities not in the Network with community services offering the booster.

ACTION: We don't know this but can get the information to the ESRD Networks.

Comment: Many patients have received doses in a facility, however some declined, could this be an opportunity to offer initial doses to those that declined it previously? Can we ask the LDOs to include these patients in their counts?

Patel: Agree and we encourage them to keep these people on the radar when asking for total doses.

Q: Does the CDC have guidance or recommendations on getting more than one vaccination in a sitting for dialysis and transplant patients (i.e. pneumococcal, influenza and COVID)? And also for healthcare workers?

Patel: Short answer is yes. People can get more than 1 vaccine in a sitting. Care providers should balance the pros and cons of this for dialysis patients who are seen 3x week vs those they may lose as lost to follow-up.

Agree it would be helpful to get language about this and will follow-up with this. **ACTION**

Weekly Net Change of COVID Positive Dialysis Patients & Vaccination Trends in the ESRD Population & Dialysis Staff

Mr. Brown provided an update on national COVID positivity rates and vaccination rates:

- The weekly net change in the national total number of COVID+ dialysis patients has declined since the last call on August 30, with 1357 new positive cases the week of September 14, 2021. It was noted that Alaska and Idaho had significant peaks in positivity rates over the past 2 weeks.
- Some states have recently reached a new weekly pandemic high after several weeks of lower numbers, including Alaska, Florida, Guam, Hawaii, Oregon, and West Virginia.

- The national average of ESRD patients fully vaccinated is 70.8%, up from 68.7% on August 17. States vary from 89.7% to 57.1%.
- In 48 of the 54 states/territories, patient vaccination rates exceed staff vaccination rates. The national average of staff fully vaccinated is 60.3% with state variations from 95.4% to 30.8%.
- Comparing the % of fully vaccinated dialysis patients to the overall state vaccination rate, only 6 states have lower rates of dialysis patients vaccinated than the overall state population.
- Comparing the % of fully vaccinated dialysis staff to the overall state vaccination rate, 34 states have lower rates of staff vaccinated than the overall state population.

Mr. Brown shared that when the state of NJ mandated vaccinations for dialysis staff, the rate of vaccinations did improve significantly after remaining relatively unchanged for several weeks.

Transplant Metrics Update

Referencing UNOS data through week 34 for 2021, Dr. Howard provided an overview of the trends. Total kidney transplants in 2021 continue to remain ahead of 2020 and 2019, this trending is primarily due to deceased donor transplants which are trending ahead of 2019 and 2020. Data for the past 6 years shows that deceased donor transplants continue to run ahead of previous years, while living donor transplants are lagging previous years. Waitlisting total additions were increasing each year, rates have rebounded since 2020 but haven't caught up to 2019 to date.

Observations from Forum Physician & ESRD Networks

On behalf of the ESRD Networks, Ms. Vinson thanked Ms. Quinn for her assistance in inviting CDC leaders to the call.

On behalf of kidney patients, Ms. Edward thanked CMS and CDC for their continued support and work to keeping patients, and for sharing the information today.

A suggestion was made to summarize the vaccination information presented during the call and to share with patients.

Ms. Quinn thanked attendees for their work.

CMS / EDAC / Forum Leadership Call: September 27, 2021

Guest Presentation by John J. Sim, MD, Kaiser Permanente of Southern California

Dr. Kalantar introduced Dr. Sim, referring members to several recent articles authored by Dr. Sim and his colleagues.

<https://pubmed.ncbi.nlm.nih.gov/?term=Sim%2CJohn+J&sort=date&size=200>

<https://pubmed.ncbi.nlm.nih.gov/33251507/>

Dr. Sim shared findings from data pertaining to COVID infections in the kidney CKD and ESRD population served by the Kaiser Permanente system, below are a few of the highlights:

- ESRD patients on dialysis at KP between March 1-June 30, 2020, they found this population had a 20x greater mortality rate due to COVID than the general population.
- As of 10/15/2021, the mortality rate for KP COVID+ patients receiving dialysis is 22% and those with functioning kidney transplants is 12%.
- KP patients with COVID AKI initiating renal replacement therapy: 68% (114 of 214) of these patients died and 31.7% are alive but still requiring RRT.
- Mortality rates for AKI patients with eGFRs within normal range were much higher than for those with less than 30.

Dr. Sim also discussed the absence of kidney patients included in COVID clinical trials. He recognized that CKD patients are excluded because they tend to be sicker, have more confounding issues and may be higher risk for adverse reaction to new therapies (i.e. toxicity). COVID therapies proven to reduce mortality (i.e. Remdesivir) were not approved for dialysis patients or for people with eGFR <30. However, Dr. Sim suggested that if these therapies were reducing COVID mortality, and mortality in the ESKD population was highest in the population with eGFR >30, these data should be looked at more carefully and therapy options given consideration for the ESRD population. Across the 14 KP facilities during May 2020-Jan 2021, 23% of ESKD patients with COVID-19 and hospitalized, received Remdesivir with only a small portion having liver injury (comparable to those not receiving Remdesivir).

Q&A and Comments:

- Dr. Quinn thanked Dr. Sim for sharing and presenting the data.
- This data is very representative of the middle population with CKD/ESRD, it shows the impact to this population is profound.
- How do these KP outcomes compare to other sources? JS: We found AKI rates are similar to other sources. Mortality rates at KP are lower here than at others.
- What was/is the KP indications for COVID testing (i.e. only with symptoms)? JS: KP has a very low threshold for testing and continues to screen patients closely. If a patient is suspicious for COVID they are isolate and tested. Because of this we feel our denominator and data are very accurate and inclusive.
- Have you looked at your transplant population and the use of Remdesivir? JS: No, we don't have that data, we were going by eGFRs.

Questions for CDC from the ESRD Networks & Forum Leadership

Dr. Shannon Novosad (CDC) shared information regarding the COCA call which will convene on October 26, 2021, "What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID-19 Boosters." The COCA call will provide an overview of the most recent recommendations for administering COVID-19 booster vaccines. The Centers for Disease Control and Prevention will provide updates about the latest recommendations and clinical considerations for administering COVID-19 boosters, including an update on early safety monitoring for additional COVID-19 vaccine doses.

Referencing the Q&As from previous calls, Dr. Henner shared the Forum KPAC would like the CDC to clarify the definition of booster vs 3rd shot, sharing that there has been a lot of confusion around this topic. Dr. Novosad acknowledged the concern and shared the following:

- Additional/3rd dose: intended for someone who didn't respond as expected to the initial doses (i.e. patients who may be immunocompromised)
- Booster: intended for people who received the initial doses and responded as expected but where the immunity wains over time.

During the September CMS/Forum Leadership call, the Forum KPAC was asked to develop a patient flyer highlighting the new vaccination guidelines. This request was brought to the KPAC and was met with several questions including the above clarification regarding additional vs. booster. KPAC members were also unclear about recommendations for dialysis versus transplant patients and whether recommendations for the Moderna and J&J vaccine will be the same as the Pfizer recommendations. Dr. Novosad recognized these concerns and the changing recommendations as data is reviewed and updates are received. A recommendation was made to consider developing a more general flyer with the most important key concepts and a reference to a website where the detailed information (which is likely to change over time) can be accessed. Members agreed. Mr. Forfang asked if a CDC representative would be available to join the KPAC workgroup to assist them in developing the flyer. Dr. Novosad agreed and will work with the KPAC to identify a CDC rep to join the workgroup.

ACTION: Forum/ KPAC leaders will follow up with Dr. Novosad to identify a CDC volunteer to join the KPAC workgroup.

Weekly Net Change of COVID Positive Dialysis Patients & Vaccination Trends in the ESRD Population & Dialysis Staff

Mr. Brown provided an update on national COVID positivity rates and vaccination rates:

- The weekly net change in the national total number of COVID+ dialysis patients continue to decline with about 600 new positive cases the week of October 19, 2021.
- While the patient vaccination rates remained about the same (71.6%), staff vaccination rates have increased slightly from 65.5% to 67.6%.
- In those states where vaccinations are mandatory for healthcare workers, some are showing staff vaccination rates have exceeded patient vaccination rates.

Q: Is data available regarding the booster shots?

A: Yes, Networks have access to their state data and are seeing good rates.

Transplant Metrics Update

Referencing UNOS data through week 40 for 2021, Dr. Howard provided an overview of the trends:

- The combined (DD/LD) transplant rate has rebounded from 2020 and remains greater than 2019, driven by continued increase in DD transplant rate.
- LD transplant rate improved from 2020, however, it remains well behind that seen in 2018 and 2019 and appears to be progressively worsening as the year progresses.
- The waitlist rate significantly improved from 2020, although has not rebounded to that seen in 2019.
- The LD transplant rate and waitlist rate will impact performance on the mandatory ETC model (MY 1/1/2021-23/31/2021, BY1 7/1/2019-6/30/2020).

Q: Is there any indication of the impact of vaccination status on any of these trends?

AH: No, but we can try to find information about this and share during the next call. Many transplant centers are encouraging and mandating patients on the waitlist get the vaccine.

Observations from Patients & Community

Dr. Henner shared that he recently tried to find a dialysis facility in the Philadelphia area who could accept a patient for a transient treatment while the patient was visiting the area for a medical appointment. They could not locate an open chair in the area and were forced to search outside the immediate area for availability. He is seeing this scenario increase in recent weeks due to staffing shortages.

Mr. Forfang shared the KPAC has also seen this trend and shared stories during their monthly KPAC calls. Some KPAC members are also seeing a slowdown or lack of progress in the waitlist referral process. Patients are vaccinated and wanting to visit family and friends they have not seen in a very long time; they are having difficulties finding facilities that will accept them for transient treatments.

Physician leaders report having to hire travel nurses to fill vacancies which is expensive and from the patient's perspective, causing anxiety and safety-concerns for patients. Mr. Forfang recognized the steep learning curve for dialysis nurses and expressed concern about increased rates of infection and accidents with the use of travel nurses who are unfamiliar with dialysis.

Dr. Quinn acknowledged these concerns and shared that CMS is hearing similar stories about the impact of staffing shortages. While CMS has access to facility closures, they do not have data regarding staffing

shortages and shift changes. She encouraged attendees to consider ways to quantify these experiences, which would help identify actionable steps to be taken to support the Networks and facilities.

During a recent call with LDO leaders representing his Network, Dr. Molony asked LDOs to share data regarding the number of unoccupied or empty chairs. He will forward if the data is made available.

Mr. Forfang expressed a desire for the community (Networks, facilities, CMS) to work together to collaborate to address these issues for the safety and quality of care for patients.