Pandemic Preparedness: Lessons Learned

I. Context

The COVID-19 pandemic has been a life-altering experience for all of us – but those living with end-stage renal disease (ESRD) have borne a uniquely heavy burden. That reality is illustrated by data that show unusually high mortality rates for ESRD patients. The impact of COVID-19 on people with kidney failure has resulted in the first ever decline in the number of patients receiving dialysis in the United States in the 50-year history of the Medicare End-Stage Renal Disease Program.[1]

Those on dialysis, who often live with multiple comorbidities, have far higher risks of severe illness or death from COVID-19 than the rest of the population.[2,3] Moreover, ESRD occurs disproportionately among racial minorities who have likewise been in the crosshairs of COVID-19, particularly in more disadvantaged metropolitan statistical areas.[4] These trends have created a perfect storm of mortality, and have made ESRD an acutely dangerous condition to live with during the pandemic.

With this backdrop, the most striking lesson of the pandemic for members of the Alliance for Home Dialysis (Alliance) – which represents patients, providers, and innovators who seek to promote policies that facilitate treatment choices in dialysis care – is that there has never been a more critical time to address systemic barriers limiting access to home dialysis in the United States. Home dialysis, both peritoneal dialysis (PD) and home hemodialysis (HHD), not only offers patients significant quality of life advantages, including clinically meaningful physical and mental health improvements, but also allows these highly vulnerable patients to socially distance themselves and avoid potential exposure by traveling to the dialysis clinic or doctor's office.[5]

As Congress and the Biden administration, in collaboration with stakeholders, work to bolster our national pandemic preparedness resources in preparation for future health care emergencies, the Alliance offers for consideration the perspectives below on learnings from home dialysis patients' and their clinicians' experiences from COVID-19.

II. Prioritization of the ESRD Community

Supply Chain Challenges

As the pandemic has worn on, the healthcare industry has experienced wide-ranging supply chain challenges like most industries have. However, unlike in other sectors, patients' and providers' access to medical products can make the difference between life and death. These challenges have been particularly difficult for manufacturers of ESRD-related supplies, who have faced upstream supply challenges in securing raw materials and component parts, e.g., microchips, resins, polymers, and plastic

[1] https://www.asn-online.org/policy/webdocs/22.1.16JointNephrologyLettertoHHS_.pdf
[2] https://jasn.asnjournals.org/content/31/7/1409
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7314621/
[4] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html
[5] NX Stage. The Benefits of More Frequent Home Dialysis. NX Stage. 2021. https://www.nxstage.com/patients/benefits-of-home-hemodialysis.

derivatives. Healthcare stakeholders have struggled to compete with larger industries for access to these component parts, which adds to an already challenging environment. Dialysis providers did collaborate with CMS on efforts such as the Dialysis Community Response Network (DCRN); several stakeholders pointed to this public-private effort as the key to mitigating some of the worst supply constraints. As manufacturers and other dialysis stakeholders collaborate with federal partners to raise awareness and identify short-term solutions, a more thoughtful policy approach to sourcing the component parts necessary for life-saving and life-sustaining treatments should be developed for future pandemics. A widespread breakdown of the supply chain requires a whole-of-system approach to fix. As such, policymakers must prioritize the needs of medical equipment manufacturers, who are integral to vulnerable patients like those with ESRD, and create ample supply to ensure consistent access even when global markets are disrupted.

Access to Vaccines and Treatments

The swift development and production of effective COVID-19 vaccines and treatments curbed the transmission of the disease and reduced the likelihood of severe illness, hospitalization, and death.[6,7] However, when policymakers began determining the distribution of vaccines, they did not appropriately prioritize ESRD patients. The Alliance wrote to the Advisory Committee on Immunization Practices (ACIP) requesting that the U.S. Government include ESRD patients in the Phase 1 distribution of COVID-19 vaccines, including those who dialyze at home, and their health care providers, with particular focus given to staff in dialysis facilities.

Even so, the U.S. Government maintained its original determination. As a result, one of the most vulnerable groups of patients and their frontline providers waited for weeks longer than necessary for their vaccination. At the state level, logistical issues and a lack of alignment between state and federal policies kept vaccines unnecessarily out of reach for ESRD patients, putting them in harm's way for too long.[8] Further, state and federal policies suppressed clinicians' flexibility to provide the vaccine or treatments in a safe and timely manner. Future state and federal policies should recognize the severe vulnerability of this population and prioritize it more consistently.

Catheter and Vascular Access Placement

Patients who dialyze at home can receive either peritoneal dialysis or home hemodialysis. Peritoneal dialysis is a more common home modality and requires the insertion of a PD catheter.[9] Home hemodialysis patients often prefer a fistula for their permanent access, given the lower risk of bloodstream infections, although a catheter is also an option for HHD patients.[10] To prepare an individual for PD or HHD, the provider sends the ESRD patient home to train on the home modality and to schedule s surgery for a permanent access placement fistula, graft, or PD catheter.

Systemic barriers – which we discuss below – have long existed to the timely placement of PD catheters, and the pandemic has exacerbated these barriers. At the onset of the pandemic, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) issued guidance to urge the rescheduling of non-urgent elective surgeries. Though catheter placement and fistula surgery are necessary steps to ensuring many patients can get dialysis at home, the guidance did not designate these procedures as non-elective in the guidance, leaving them open to interpretation as

[6] https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness
[7] https://covid19.nih.gov/treatments-and-vaccines/covid-19-treatments
[8] https://fmcna.com/insights/field-notes/covid-vaccine-distribution/
[9] https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities, See Figure 1.13
[10] KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update - American Journal of Kidney Diseases (ajkd.org)

an "elective" or "low acuity" surgery. Some alternative surgical theaters, such as ambulatory surgical centers, closed entirely to preserve personal protective equipment (PPE) and mitigate labor shortages. The result was that hospitals postponed PD catheter and fistula procedures indefinitely, which undermined ESRD patients' ability to get permanent access placed and put many of them at risk. It is estimated that approximately 40% of access care in the United States was either delayed or canceled during the pandemic.[11]

In 2020, the Alliance wrote to CMS urging them to clarify that PD catheter placement is not an elective procedure, and CMS addressed this issue in later guidance. However, the delay in issuing the clarification resulted in widespread delays in PD catheter placements. Furthermore, some states were slow to align with the federal guidance, continuing confusion and adding an extra barrier to access. We encourage CMS and its state counterparts to provide more precise and earlier guidance on these issues in future health care emergencies so that patients who begin dialysis under adverse circumstances do not face unnecessary barriers to the access procedure and the modality of their choice.

Other barriers to PD catheter access include lack of trained staff, inadequate operating room space access, and the low reimbursement rate for PD catheter placement. These barriers should be addressed now. In addition to clear guidance, it is also paramount that surgeons know how to conduct a PD catheter placement surgery and receive the incentive to do so. While these barriers predate the pandemic, their worsening over the past two years underscores the urgency for our community to partner with policymakers to develop solutions. We know that CMS has recently asked for stakeholder comments about the feasibility of a demonstration project to incentivize access to PD catheter placement. We applaud this effort by the agency and would welcome the opportunity to help inform the framework for this model.

III. Telehealth and Digital Health

Telehealth

Telehealth has proven to be a valuable tool to preserve resources, promote social distancing, and provide flexibility for patients throughout the pandemic. We applaud CMS for acting quickly to allow dialysis patients to self-isolate and avoid group settings as much as possible during the public health emergency (PHE) through telehealth expansion. Access to telehealth services will continue to be critical, especially for educating pre-dialysis patients and ensuring competent, continuous care for beneficiaries who may not be able to travel to the clinic.

While the PHE granted new flexibilities for ESRD patients, virtual care is not new for this community. The 2018 CHRONIC Care Act increased telehealth access by designating a patient's home and dialysis facility as originating sites for home dialysis services without geographic restrictions and allowing some monthly virtual visits. The Coronavirus Aid, Relief, and Economic Security (CARES) Act implemented a provision that removed home dialysis patients' once-a-quarter in-person visit requirement for the duration of the PHE. In situations where video technology or broadband is unreliable, the PHE further allowed for physicians to be reimbursed for visits delivered by phone. Patients and providers who began using telehealth services during the pandemic may view the home dialysis experience as a successful example of managing chronic illness with virtual care as a tool.

[11] Agarwal AK, Sequeira A, Oza-Gajera BP, et al. Lessons learnt and future directions in managing dialysis access during the COVID 19 pandemic: Patient and provider experience in the United States. The Journal of Vascular Access. June 2021. doi:10.1177/11297298211027014

Still, as we contemplate the end of the PHE, providers and ESRD patients need clear guidance in the following additional areas:

- Audio-only visits: We believe CMS should continue to reimburse audio-only visits after the end of the PHE in exceptional circumstances. Furthermore, it is critical to ensure provider-documented guardrails for those calls, including: (1) attesting that a good faith effort for an audio-video call was inadequate to complete the visit; and (2) patients' relevant electronic medical records and dialysis treatment flowsheets should be visible and reviewed during the call. We recommend that patient participation in an audio-only evaluation and management (E/M) visit be sufficient for consent and that it fulfills the patient-initiated requirements.

- Digital tools: The standard of care for ESRD patients is evolving toward more patient-centered modalities, including digital tools to remotely monitor patients and enable providers to track the progress of disease. These tools can empower dialysis patients with the option to have their physiologic and therapeutic information monitored remotely, reducing the need for in-person visits. Under the current system, there is no separate reimbursement for new digital health technology such as RPM, artificial intelligence (AI), wearable technology, and clinical decision support tools. We believe that a more robust incentive would encourage the development, adoption, and use of innovative tools that improve ESRD patient experiences and outcomes.

- Patient-provider relationship: Patients should have the option to access their provider in person for each monthly visit if they prefer not to use telehealth.

- Waiver Guidance: Providers and patients need proactive, timely guidance from CMS on which telehealth waivers will continue and for how long.

IV. Mental Health Considerations for ESRD Patients

The pandemic has only exacerbated America's already extensive mental health crisis. Rates of anxiety and depression among U.S. adults were about four times higher between April 2020 and August 2021 than they were in 2019.[12] These alarming rates and associated struggles are particularly acute for dialysis patients who already must deal with a chronic disease that governs much of their daily lives and puts them at increased risk of severe illness and death. With that said, there is still more to learn about the lingering effects of pandemic isolation and risk on ESRD patients. Therefore, we stand ready to partner with policymakers to gather key information on this population and their unique struggles in hopes of providing them the resources they need now and in the future.

V. Conclusion

The ESRD community's experience over the last 2+ years has provided us with profound learnings that can be acted upon to create positive change for ESRD patients. By sharing our experiences and providing ideas, the Alliance hopes to inform policy changes that will continue to lower barriers to access to home dialysis and better protect individuals living with ESRD from future pandemics.

[12] https://www.cdc.gov/nchs/covid19/pulse/mental-health.htm