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Policy and Pandemic: The Changing Practice of Nephrology During the Coronavirus Disease-2019 Outbreak



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The coronavirus (coronavirus disease-2019) pandemic has changed care delivery for patients with end-stage kidney disease. We explore the US healthcare system as it pertains to dialysis care, including existing policies, modifications implemented in response to the coronavirus disease-2019 crisis, and possible next steps for policy makers and nephrologists. This includes policies related to resource management, use of telemedicine, prioritization of dialysis access procedures, expansion of home dialysis modalities, administrative duties, and quality assessment. The government has already established policies that have instated some flexibilities to help providers focus their response to the crisis. However, future policy during and after the coronavirus disease-2019 pandemic can bolster our ability to optimize care for patients with end-stage kidney disease. Key themes in this perspective are the importance of policy flexibility, clear strategies for emergency preparedness, and robust health systems that maximize accessibility and patient autonomy.

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The coronavirus disease-2019 (COVID-19) pandemic has disproportionately affected older patients with comorbidities.¹⁻³ Patients with end-stage kidney disease (ESKD) are particularly vulnerable. Some studies report mortality rates as high as 13% in the hemodialysis population.⁴ The first reported death from COVID-19 in the United States was a patient receiving hemodialysis in Seattle, Washington.⁵ In response, the dialysis organization rapidly established education, screening, and testing protocols to safely cohort and dialyze patients. Managing a complex and vulnerable dialysis population amidst a rapidly evolving crisis requires a nimble response. Federal policy, then, plays a critical role in alleviating the difficulties faced by nephrologists and dialysis facilities whose attentions are monopolized by the pandemic. In this perspective, we summarize new policies shaping ESKD care during the COVID-19 pandemic, propose next steps for policy makers and the nephrology provider community, and speculate on the impact of these policies on nephrology care after the COVID-19 pandemic (Table 1).

CHANGES IN POLICY AND DELIVERY OF CARE

Resource Management

Healthcare facilities in the United States rarely contend with resource scarcity on the scale seen during the

COVID-19 pandemic. The nephrology community has had to address shortages of continuous renal replacement therapy (CRRT) solutions, dialysis machines, staffing, and personal protective equipment (PPE).⁶⁻⁸ Shortages of CRRT dialysate and dialysis machines have anecdotally led to increased use of intermittent hemodialysis instead of CRRT, shortened treatment times, and rationing of dialysis altogether. To address these challenges, the Centers for Medicare and Medicaid Services (CMS) has been working closely with the US Food and Drug Administration to increase dialysate manufacturing and strengthen supply chains.⁹

The Centers for Disease Control and Prevention (CDC) has also released recommendations on strategies to mitigate staffing shortages. These include outlining contingency and crisis strategies, considering alternate care sites (including “siloeing”) for treating patients with COVID-19, and implementing return to work criteria for providers contracting the virus.¹⁰⁻¹² Identifying effective strategies to optimize staffing is particularly important in dialysis care, as nurses are highly specialized, have high exposure risk, and work with a vulnerable population that requires frequent, routine care. Staffing shortages would significantly cut a medical facility’s ability to dialyze patients both in the inpatient and outpatient settings. Finally, the CDC has released guidelines for optimizing PPE use, including distributing stockpiled N95 respirators, purchasing PPE from other countries, decontaminating N95 respirators for reuse, and creating a PPE burn rate calculator.¹³ N95 respirator decontamination techniques—ultraviolet irradiation, microwave-generated steam, warm moist heat, and hydrogen peroxide vapor—were extensively studied in anticipation of an influenza pandemic and implementation of these techniques has materially relieved PPE shortages in hard hit COVID-19 areas.¹⁴⁻¹⁸

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Telemedicine

Telemedicine offers the advantage of continuity of care without person-to-person contact. Although rudimentary

infrastructure for telehealth existed in large health systems even before the pandemic, the use of telehealth has dramatically increased after the CMS' decision to waive onerous requirements restricting its use.¹⁹ Previously, only patients using home dialysis modalities had the ability to use telemedicine and only with approved, encrypted devices and software.^{20,21} The CMS relaxed requirements for telemedicine requiring both audio and visual inputs as dictated by the Coronavirus Aid, Relief, and Economic Security Act.²² Because many patients do not have access to online video devices, this has allowed clinicians to use audio-only devices for patient encounters without taking large reimbursement cuts. The CMS also removed restrictions on the types of practitioners who could bill for telemedicine encounters, expanding the scope of essential nephrology care. One robust system experienced with telemedicine and nephrology care is the Veterans Affairs health system, which has substantially increased access to care to patients living in rural areas, many of whom have CKD.²³ The Veterans Affairs has more than 150 medical centers serving as "hubs" for community-based outpatient clinics, which can deliver multidisciplinary care in conjunction with nutritionists, surgeons, and interventional radiologists.²³

A long-term perspective for telemedicine would behoove policy makers. Should care-coordination improve in the status quo, the CMS could consider extending waivers beyond the COVID-19 pandemic. Even before the pandemic, the CMS proposed voluntary payment models that relaxed regulatory requirements for telehealth to promote different avenues for delivering multidisciplinary care. The nephrology provider community should aim to work alongside these efforts to train and accredit health professionals in telemedicine, which will maximize providers' likelihood of success.²⁴ A close monitoring effort during the pandemic could help policy makers determine whether an expanded telemedicine benefit remains appropriate after the pandemic subsides.

Dialysis Access Procedures

Reports indicate that many centers have deferred vascular access procedures including arteriovenous fistula (AVF) and arteriovenous graft (AVG) placement during the COVID-19 crisis.²⁵⁻²⁷ Although early delays may have stemmed from the initial CMS guidance recommending deferral of nonessential surgical procedures, delays remain widespread despite the CMS' clarification that dialysis access procedures are essential.²⁸ Some delays may be justified, especially in areas with high COVID-19 caseloads. Hospital administrators must weigh the potential benefits of placing permanent vascular accesses earlier against the downsides of potentially exposing patients to the virus and of consuming valuable resources, including

facilities, personnel, and PPE. Short-term delays of vascular access procedures may be safer for some patients. Delaying dialysis initiation until absolutely necessary is always recommended but could also help alleviate the need to place vascular accesses.²⁹ However, nephrologists should remain vigilant that many patients have delayed seeking urgent medical care owing to COVID-19 fears, and nephrologists should not hesitate to initiate dialysis when indicated.³⁰⁻³³

In regions with already low COVID-19 prevalence, transitioning from a crisis management stance to 1 that plans for eventual sequelae of delayed vascular access procedures may yield dividends. Finding safe opportunities to place permanent vascular accesses could stave off life-threatening bloodstream infections and thromboembolic complications associated with long-term dialysis catheter use.³⁴⁻³⁶ Doing so may not be easy. Globally, the 12-week cancellation rate for elective, nononcologic surgeries is 82%, leading to a backlog of cases projected to take a median of 45 weeks to clear.³⁷ As hospitals fill operating room schedules with semielective and elective cases, patients undergoing hemodialysis may find it difficult to schedule a procedure. Although the American College of Surgeons has published principles for prioritizing elective

procedures, operationalizing these principles in a way that is "sensitive to the institution's resources, priorities, and patient needs" remains a challenge.³⁸ Given large revenue shortfalls due to cancellations, hospitals may be tempted to prioritize high-revenue procedures rather than those most likely to positively improve patient outcomes, such as timely permanent dialysis access

placements.^{39,40} Relieving the bottleneck will likely require a combination of policies: (1) guidance on prioritizing procedures that prevent downstream complications (ie, AVFs to prevent line infections), (2) additional rounds of legislative stimulus aimed at alleviating accumulating hospital debt, and (3) potentially increasing reimbursements for fistulas and grafts. The CMS and policy researchers should study whether preventing expensive bloodstream infections could offset costs from higher reimbursements.

Percutaneous AVF placements, performed endovascularly using thermal energy or radiofrequency, were approved by the US Food and Drug Administration in 2019.⁴¹ Because they can be performed in an office-based fluoroscopy laboratory, they could alleviate the mounting backlog. They can also be placed under local or regional anesthesia, avoiding aerosol-generating intubation from general anesthesia. Concomitant assessment of vasculature during the procedure could further streamline the process by obviating preparatory vascular mapping that was likely delayed during the outbreak. The CMS could temporarily increase office-based reimbursements for percutaneous AVFs to incentivize their use. Because the

CLINICAL SUMMARY

- Existing policies have relaxed administrative burdens such as quality reporting and have eased patient care such as telehealth waivers in end-stage kidney disease care.
- There is a critical need to address current delays in dialysis access procedures and a future backlog in procedures.
- Although home dialysis may alleviate some of the risks of coronavirus disease-2019, challenges in peritoneal dialysis catheter placements and remote training persist.

CMS does not have to reimburse for facility fees, this option could simultaneously be cheaper than routine AVFs. Caution is warranted, however. Percutaneous AVFs are a relatively new technology, and although early results are promising, robust data on their efficacy remain limited.⁴²

Home Dialysis

Home dialysis has gained appeal during the pandemic because patients can minimize their exposure to others. In addition, peritoneal dialysis (PD) using percutaneously placed catheters can decrease the need for AVFs and AVGs and can provide another outlet for delayed vascular access procedures with the added benefit of being able to start dialysis urgently. Just before the COVID-19 pandemic, the CMS proposed measures to expand home dialysis use through the Advancing American Kidney Health initiative, which aims to have 80% of patients with new kidney failure use a home dialysis modality or obtain a transplant by 2025.⁴³ Even before the pandemic, the task of building the necessary infrastructure to drastically increase home dialysis modalities, including the training of nephrologists, nurses, and dialysis staff, was daunting.⁴⁴ Only 14% of patients with incident ESKD use a home dialysis modality or receive a transplant.⁴⁵ COVID-19 has made infrastructure investments in home dialysis substantially more challenging. Notably, the American Society of Nephrology has created a multidisciplinary COVID-19 Home Dialysis subcommittee with representatives from the Nephrologists Transforming Dialysis Safety initiative, the CDC, dialysis organizations, home dialysis vendors, nurses, and patients. The subcommittee has a broad set of aims, including advocating for increased access procedures, addressing staffing shortages, exploring urgent-start PD, expanding home telehealth capabilities, and ensuring adequate supplies.⁴⁶

The steepest barrier to successfully expanding home dialysis during the COVID-19 pandemic is arguably the training, which could expose available staff to patients with COVID-19. As CRRT solution shortages have led to increased attention toward urgent-start PD, consideration should be given to increasing the capacity of staff able to support patients on home dialysis, including home dialysis training. Telemedicine could provide an alternative avenue for home dialysis training. Effective remote training methods do not yet exist, however. Although educational resources about dialysis options can readily be extended through applications and websites, home dialysis training involves teaching a physical skill, and the tactile experience is challenging without in-person supervision. Remote training does not come without risks, and programs would require close monitoring to ensure they do not lead to early complications of peritonitis and technique failure. Still, policy makers should consider whether the pros of reducing center-based dialysis might outweigh these risks.

For nephrologists and their established patients using home dialysis, the expanded telehealth benefit during the COVID-19 crisis has been a welcome addition. The expansion builds on the Bipartisan Budget Act of 2018 (HR-1892), which allowed patients on home dialysis to

receive their monthly clinical assessments via telehealth, with required face-to-face quarterly assessments.⁴⁷ The COVID-19 pandemic led the CMS to suspend the quarterly face-to-face requirement and to allow dialysis facilities certified in home training and support services to furnish home dialysis at long-term care facilities.^{48,49}

For patients with acute kidney injury, acute PD may confer additional advantages when patients experience difficulties with hemodialysis or CRRT because of coagulopathies related to COVID-19 or when hemodialysis and CRRT resources have been exhausted,⁵⁰ challenges that exacerbate supply and personnel shortages in areas with high COVID-19 burden.⁵⁰⁻⁵² Despite these potential advantages in the acute setting, Medicare currently has no payment mechanism to extend PD for acute kidney injury in the outpatient setting.⁵³ Policy makers at the CMS and in Congress should note that promoting home dialysis infrastructure could translate into a sustained impetus for home dialysis use even after the pandemic has subsided.

Relieving Administrative Burdens

To allow healthcare providers greater time and flexibility to address this national emergency, the CMS has relaxed administrative burdens on providers. While some efforts preceded the COVID-19 pandemic with the CMS' "Patients over Paperwork" initiative, the pandemic has accelerated these changes.^{48,54} Before COVID-19, the CMS issued the Omnibus Burden Reduction (Conditions of Participation) Final Rule to "reform Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome."^{55,56} In response to the pandemic, the CMS also postponed deadlines for routine auditing and reporting scheduled after March 1, 2020.^{48,57} For dialysis centers, this includes audits of water/dialysate equipment operators, inspections of equipment and fire safety, and cardiopulmonary resuscitation certification.⁴⁸ These flexibilities not only free up time for providers to develop COVID-19 response measures but also mitigate unnecessary exposures to nonessential personnel. However, policy makers and nephrologists should be aware that postponement of routine audits and reporting increases the risk of not detecting waterborne pathogens, equipment malfunction, and other safety violations.

Reevaluating Quality Measures

The CMS has relaxed reporting requirements for quality payment programs such as the Merit-Based Incentive Payment System (MIPS) (a value-based purchasing program that evaluates clinicians on 4 dimensions of care: quality, cost, improvement activities, and using an interoperable electronic health record) and the Quality Incentive Program (QIP) (a program that evaluates dialysis facilities on the quality of their dialysis care).^{58,59} The deadline for submission of 2019 MIPS data was pushed back 30 days from March 31 to April 30, 2020.⁶⁰ In addition, the CMS made MIPS reporting for clinicians reporting as individuals optional without any penalties. Clinicians reporting as groups could apply for an "Extreme and Uncontrollable Circumstances" exemption, which allows qualifying

Table 1. Policy Initiatives During the COVID-19 Crisis and Proposed Future Directions

	Pre-COVID-19 Policy Infrastructure	Response to COVID-19	Future Directions
Resource management		<ul style="list-style-type: none"> • Increased dialysate manufacturing • Contingency and crisis strategies with return to work criteria • PPE burn rate calculator 	<ul style="list-style-type: none"> • Strengthen supply chains • Increase capacity of staff to support patients on home dialysis
Telemedicine	<ul style="list-style-type: none"> • Only for home dialysis • Requires HIPAA-compliant, HIPAA-approved, encrypted devices and software • Requires audio and video 	<ul style="list-style-type: none"> • Any patients may use telemedicine • May use standard software, not HIPAA compliant • Waived requirements for both audio and visual input 	<ul style="list-style-type: none"> • Train more providers in telemedicine • Consider relaxed requirements for telehealth use, expand to multidisciplinary care
Dialysis access	<ul style="list-style-type: none"> • Quality incentives for timely arteriovenous fistula or graft placements 	<ul style="list-style-type: none"> • Access procedures clarified as essential 	<ul style="list-style-type: none"> • Address bottleneck of elective procedures • Consider additional reimbursement to offset competition with high revenue procedures • Pathways for percutaneous access placements
Home dialysis	<ul style="list-style-type: none"> • Patients using home dialysis may use telehealth • Face-to-face assessments required quarterly 	<ul style="list-style-type: none"> • Suspended quarterly face-to-face requirement • Dialysis facilities allowed to furnish home dialysis at long-term care facilities 	<ul style="list-style-type: none"> • Increase home dialysis infrastructure support • Increased access to telehealth • Consider financial pathway for using outpatient PD for AKI
Administrative burden	<ul style="list-style-type: none"> • Patients over paperwork Omnibus Burden Reduction (Conditions of Participation) Final Rule 	<ul style="list-style-type: none"> • Deadline extensions for routine auditing, equipment inspections, and CPR certification 	<ul style="list-style-type: none"> • Balance reduction of regulatory burden with patient safety
Quality measures	<ul style="list-style-type: none"> • MIPS • QIP 	<ul style="list-style-type: none"> • Extended MIPS reporting deadline, optional reporting for individuals • January 1, 2020 to June 30, 2020 exempt from QIP 	<ul style="list-style-type: none"> • Monitor vascular access outcomes, transplantation, and hospitalization rates • Consider delayed measure implementation

Abbreviations: CPR, cardiopulmonary resuscitation; MIPS, Merit-based Incentive Payment System; QIP, Quality Incentive Program; CMS, Centers for Medicare and Medicaid Services; PPE, Personal Protective Equipment; PD, peritoneal dialysis; AKI, acute kidney injury; CARES Act, Coronavirus Aid, Relief, and Economic Security Act; HIPAA, is Health Insurance Portability and Accountability Act.

groups to forego data submission. Providers participating in a COVID-19 clinical trial may now also report it as a high-weighted improvement activity.⁶⁰

Similarly, the CMS will not include data from the first 2 reporting quarters, from January 1, 2020 to June 30, 2020, for dialysis QIP reporting.⁶¹ While high QIP performance is associated with superior patient outcomes under normal circumstances, the COVID-19 outbreak has confounded the CMS' ability to reliably measure high-quality care and could distract providers from responding adequately to the crisis.⁶² Although QIP data from January 1, 2020, to March 1, 2020, were likely not impacted by the pandemic, the CMS has indicated that providers should not focus on data reporting during the crisis. Because different regions of the country have experienced varying severities of the outbreak, standardizing quality measures across the country has become virtually impossible.

Furthermore, the crisis will undoubtedly lead to large reductions in performance of some QIP measures in the

short and medium term. However, the CMS still has not announced further postponements to QIP reporting. As previously discussed, AVFs and AVGs have undergone substantial delays, which will inevitably affect quality measures regarding vascular access. Because AVFs can take 6 months or longer to mature, the CMS should anticipate poor performance beyond the COVID-19 pandemic and should consider delaying evaluation of vascular access measures even after the crisis has abated. Likewise, delays in transplant evaluations will impede facility performance on kidney transplant waitlist measures and reduce the overall transplantation rate. Eighty percent of deceased-donor kidney transplant programs surveyed in the United States are operating with some restrictions.^{63,64}

Regional variability in COVID-19 emergency room and hospitalizations rates will also unpredictably change the standardized hospitalization and readmission ratios.⁶⁵ Given the rapidly evolving crisis, the CMS should closely monitor vascular access outcomes, transplantations, and

hospitalization rates alongside COVID-19 cases, so it can determine when and how the QIP can be appropriately reinstated.

CONCLUSION

The COVID-19 pandemic has brought unprecedented challenges to the delivery of health care to patients with ESKD. Policy and healthcare infrastructure have been transformed in response to these challenges and include strategies for resource management, an expansion of telemedicine and home dialysis modalities, refined guidance on dialysis access procedures, extra measures to relieve administrative burden, and a reevaluation of quality metrics. Continued exploration of creative ways to implement dialysis access procedures, telemedicine, and home dialysis modalities are particularly relevant for emergency preparedness in the future. Other key issues include optimizing patient education, infection control, and access to transportation. Key themes in the response to the COVID-19 pandemic are flexibility of policy, clear strategies for emergency preparedness, and robust health systems that maximize accessibility and patient autonomy.

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